
DRAFT STATUTORY INSTRUMENTS

2019 No. 0000

EXITING THE EUROPEAN UNION

CONSUMER PROTECTION

**The Medical Devices (Amendment etc.) (EU Exit) Regulations
2019**

Made - - - - - ***

Coming into force in accordance with regulation 1

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 8(1) of, paragraph 7(2) of Schedule 4 and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018(a).

In accordance with paragraph 1(1) of Schedule 7 to the European Union (Withdrawal) Act 2018 a draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament.

The Treasury has consented to the making of these Regulations as required by paragraph 10 of Schedule 4 to the European Union (Withdrawal) Act 2018.

Citation and commencement

1.—(1) These Regulations may be cited as the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 and, subject to paragraphs (2) to (4), come into force on exit day.

(2) The following regulations come into force on the day that is 4 months after exit day—

- (a) regulation 4(4);
- (b) regulation 5(3);
- (c) regulation 6(3);
- (d) regulation 8(2);
- (e) regulation 9(2).

(3) Regulation 10, insofar as it inserts regulations 91 to 95, comes into force on 26th May 2020.

(4) Regulation 11, insofar as it inserts regulation 157 to 160, comes into force on 26th May 2022.

(a) 2018 c.16.

Interpretation

2. In these Regulations—

“the Act” means the European Union (Withdrawal) Act 2018;

“the 2002 Regulations” means the Medical Devices Regulations 2002(a).

PART 1

Amendment of the 2002 Regulations

Amendment of Part 1 of the 2002 Regulations

3.—(1) Part 1 of the 2002 Regulations is amended as follows.

(2) After regulation 1(citation and commencement) insert—

“Schedules

1A. Schedules 2 to 28 have effect.”;

(3) In regulation 2(b) (interpretation)—

- (a) at the start, before “In these Regulations” insert “Subject to Parts VIII and IX,”;
- (b) omit the definition of “Association Agreement”;
- (c) in the definition of “authorised representative” —
 - (i) for “established within the Community” substitute “established outside the United Kingdom but within the European Economic Area”,
 - (ii) for “authorities and bodies in the Community” substitute “authorities and bodies in the European Economic Area”;
- (d) after the definition of “clinical data” insert—
 - ““designated standard” has the meaning given in regulation 3A;”;
- (e) at the end of the definition of “Directive 90/385” insert “as it had effect immediately before exit day”;
- (f) at the end of the definition of “Directive 93/42” insert “as it had effect immediately before exit day”;
- (g) at the end of the definition of “Directive 98/79” insert “as it had effect immediately before exit day”;
- (h) omit the definition of “Directive 2001/83”;
- (i) omit the definition of “Directive 2006/42”;
- (j) in the definition of “EC CAB” omit “EC”;
- (k) omit the definition of “harmonised standard”;
- (l) in the definition of “intended for clinical investigation”, in paragraph (b), for “a Member State” substitute “the United Kingdom”;
- (m) in the definition of “machinery” for “Article 2(a) of Directive 2006/42” substitute “regulation 4 of the Supply of Machinery (Safety) Regulations 2008(c);”;

(a) S.I. 2002/618; these Regulations were made partly under section 2(2) of the European Communities Act 1972 c. 68 and were saved by virtue of s. 2(1) of the Act.

(b) Regulation 2 was amended by S.I. 2003/1697, 2005/2759, 2007/400, 2008/2936, 2011/1043, 2012/1426 and 2013/2327.

(c) S.I. 2008/1597; no relevant amendments.

- (n) in the definition of “medicinal product” for “article 1.2 of Directive 2001/83” substitute “regulation 2(1) of the Human Medicines Regulations 2012^(a)”;
 - (o) for the definition of “Mutual Recognition Agreements” substitute—
 - ““mutual recognition agreement” means an agreement that—
 - (a) is between the United Kingdom and a country listed in Schedule 2, and
 - (b) covers matters including the conditions under which the United Kingdom and the that country will accept or recognise the results of conformity assessment procedures undertaken by the each other’s designated bodies;”;
 - (p) omit the definition of “national standard”;
 - (q) in the definition of “notified body”
 - (i) omit “Part V or”;
 - (ii) for “the Mutual Recognition Agreements” substitute “a mutual recognition agreement”;
 - (iii) at the end insert “but, unless the context requires otherwise, does not include a UK notified body”;
 - (r) in the definition of “placing on the market”—
 - (i) for “Community” substitute “United Kingdom”;
 - (ii) at the end insert, “and related expressions must be construed accordingly”;
 - (s) in the definition of “putting into service” in paragraph (b) for “Community” substitute “United Kingdom”;
 - (t) in the definition of “stable derivatives device”, in sub-paragraph (a), for “article 1.10 of Directive 2001/83” substitute “regulation 2(2) of the Human Medicines Regulations 2012”;
 - (u) for the definition of “third party conformity assessment body” substitute—
 - ““third party conformity assessment body” means a body established in a country which is listed in Schedule 2 and designated in accordance with a relevant mutual recognition agreement to carry out conformity assessment procedures for the purposes of these Regulations;”
 - (v) in the definition of “UK notified body” for “regulation 45” substitute “and regulations 4F(8) and 4G(8)”;
 - (w) after the definition of “UK notified body” insert—
 - ““UK responsible person” means a person established in the United Kingdom who acts on behalf of a manufacturer established outside the United Kingdom in relation to specified tasks with regard to the manufacturer’s obligations under these regulations.”
- (4) In paragraph (1A), for the words “as amended from time to time” substitute “as they applied immediately before exit day and as modified by Schedule 2A.”.
- (5) In regulation 3^(b) (scope of these Regulations)—
- (a) for the heading substitute, “Scope of Parts II to VII”;
 - (b) in the opening words before paragraph (a), substitute “Parts II to VII of these Regulations do not apply to”;
 - (c) in paragraph (a)—
 - (i) for “Directive 2001/83” in the first place it occurs, substitute “the Human Medicines Regulations 2012”;
 - (ii) omit “governed by Title X of Directive 2001/83”;

^(a) S.I. 2012/1916; relevant amendments are S.I. 2013/1855, 2013/2593, 2014/324, 2014/1878, 2015/354, 2015/1503, 2016/407, 2016/186, 2017/241, 2017/715, 2018/64, 2018/199.

^(b) Regulation 3 was amended by S.I. 2007/400 and S.I. 2008/2936.

(d) in paragraph (f), for “Council Directive 76/768, as amended” substitute “Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30th November 2009 on cosmetic products;”.

(6) After regulation 3 insert—

“Designated standard

3A.—(1) In Parts II, III, IV, VIII and IX of these Regulations a “designated standard” means a technical specification which is—

- (a) adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory; and
- (b) designated by the Secretary of State by publishing a reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate.

(2) For the purposes of paragraph (1), a “technical specification” means a document which prescribes technical requirements to be fulfilled by a device, process, service or system (“the product”) and which lays down—

- (a) the characteristics required of a product, including levels of quality, performance, interoperability, environmental protection, health and safety and dimensions;
- (b) the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures; and
- (c) the production methods and processes relating to the product, where these have an effect on its characteristics.

(3) For the purposes of this regulation a “recognised standardisation body” means any one of the following organisations—

- (a) the European Committee for Standardisation (CEN);
- (b) the European Committee for Electrotechnical Standardisation (CENLAC);
- (c) the British Standards Institute (BSI).

(4) When considering whether the manner of publication of a reference is appropriate in accordance with paragraph (1)(b), the Secretary of State must have regard to whether the publication will draw the standard to the attention of any person who may have an interest in the standard.

(5) Before publishing the reference to a standard in relation to a technical specification which has been adopted by BSI, the Secretary of State must have regard to whether the technical specification is consistent with technical specifications adopted by the other recognised standardisation bodies.

(6) The Secretary of State may remove from publication the reference to a standard which has been published in accordance with paragraph (1)(b).

(7) Where the Secretary of State removes the reference to a standard from publication, that standard is no longer a designated standard.

(8) In this regulation, a reference to a “device” is a reference to a medical device or its accessory or an in vitro diagnostic medical device or its accessory to which these Regulations apply.

Confidentiality

3B.—(1) Subject to paragraph (2), and unless otherwise provided for in these Regulations, all parties involved in the application of these Regulations must respect the

confidentiality of information and data obtained in carrying out their tasks in order to protect the following—

- (a) personal data in accordance with the Data Protection Act 2018(a);
- (b) commercially confidential information, trade secrets of a person, including intellectual property rights (unless disclosure is in the public interest);
- (c) the effective operation of these Regulations, in particular for the purposes of inspections, investigations or audits.

(2) Paragraph (1) does not affect—

- (a) the rights and obligations of the Secretary of State, manufacturers, persons placing products on the market, UK responsible persons, importers, distributors and notified bodies (including UK notified bodies) with regard to the exchange of information and the dissemination of warnings;
- (b) obligations to disclose information under the criminal law.”.

(7) After regulation 4A(b) (transitional provisions for hip, knee and shoulder replacement) insert—

“Application of Part VIII to medical devices and their accessories, other than in vitro diagnostic medical devices and their accessories, before 26th May 2020

4B.—(1) Part VIII only applies before 26th May 2020 in respect of a device or accessory that is a relevant device for the purposes of Part II or III if the conformity assessment that the person placing it on the market or putting it into service relies on for doing so is the conformity assessment required by Part VIII (rather than by Part II or III).

(2) Accordingly, before 26th May 2020, unless paragraph (1) applies—

- (a) Part II continues to apply in respect of a device or accessory that is a relevant device for the purposes of that Part; and
- (b) Part III continues to apply in respect of a device or accessory that is a relevant device for the purposes of that Part.

(3) Where Part VIII applies —

- (a) Part II ceases to apply, apart from regulations 7A and 19 (to the extent that those regulations otherwise apply, for which see regulations 4D(1) to (5) and 4E(4)); and
- (b) Part III ceases to apply, apart from regulations 21A and 30(3) to (5) (to the extent that those regulations otherwise apply, for which see regulations 4D(6) and 4E(4)).

Application of Part IX to in vitro diagnostic medical devices and their accessories before 26th May 2022

4C.—(1) Part IX only applies before 26th May 2022 in respect of a device or accessory that is a relevant device for the purposes of Part IV if the conformity assessment that the person placing it on the market or putting it into service relies on for doing so is the conformity assessment required by Part IX (rather than by Part IV).

(2) Accordingly, before 26th March 2022, unless paragraph (1) applies, Part IV continues to apply in respect of a device or accessory that is a relevant device for the purposes of that Part.

(3) Where Part IX applies, Part IV ceases to apply, apart from regulations 33A and 44 (to the extent that those regulations otherwise apply, for which see regulations 4D(8) to (11) and 4E(8)).

(a) 2018 c. 12.

(b) Regulation 4A was inserted by S.I. 2007/400.

Revocations, transitional and saving provisions in respect of the new national registration requirements

4D.—(1) Regulation 19 is revoked on the day that is 4 months after exit day (which is the day on which regulation 7A comes into force).

(2) Regulation 7A does not apply until the day that is 8 months after exit day in respect of a device or accessory—

- (a) that—
 - (i) is a relevant device for the purposes of Part II, or
 - (ii) would be a relevant device for the purposes of Part II, but for the application of regulation 4B(1); and
- (b) that is classified (whether or not Part II applies in respect of the device) as belonging to—
 - (i) Class IIa, as referred to in regulation 7, or
 - (ii) Class IIb, as referred to in regulation 7, and is also a Group A device (within the meaning given in regulation 52(1)).

(3) Regulation 7A does not apply until the day that is 12 months after exit day in respect of a device or accessory—

- (a) that—
 - (i) is a relevant device for the purposes of Part II, or
 - (ii) would be a relevant device for the purposes of Part II, but for the application of regulation 4B(1); and
- (b) that is classified (whether or not Part II applies in respect of the device) as belonging to Class I, as referred to in regulation 7.

(4) Where regulation 7A does not apply in respect of a device or accessory by virtue of paragraph (2) or (3), regulation 19 continues to have effect after its revocation in respect of that device or accessory, with the modifications in paragraph (5)—

(5) On and after exit day and until its revocation, regulation 19 continues to have effect with the following modifications—

- (a) paragraph (3) applies as if for the words “the Community or in a State which is a Party to an Association Agreement” there were substituted “the United Kingdom”; and
- (b) as if paragraph (6) were omitted.

(6) Regulation 30(3) is revoked on the day that is 4 months after exit day (which is the day on which regulation 21A comes into force).

(7) On or after exit day and until its revocation, regulation 30(3) continues to have effect with the following modifications—

- (a) as if the words “Except as provided in paragraphs (4) and (5)” were omitted;
- (b) as if the words “under their own name” were omitted;
- (c) as if after Directive 90/385 the following words were inserted “or, if not the manufacturer, the person placing devices on the market under that Article,”.

(8) Regulation 44 is revoked on the day that is 4 months after exit day (which is the day on which regulation 33A comes into force).

(9) Regulation 33A does not apply until the day that is 8 months after exit day in respect of a device or accessory—

- (a) that—
 - (i) is a relevant device for the purposes of Part IV, or
 - (ii) would be a relevant device for the purposes of Part IV, but for the application of regulation 4C(1); and

- (b) that is—
 - (i) referred to in List B, mentioned in regulation 40(4), or
 - (ii) a device for self-testing (as defined in relation 32(1)).

(10) Regulation 33A does not apply until the day that is 12 months after exit day in respect of a device or accessory—

- (a) that —
 - (i) is a relevant device for the purposes of Part IV, or
 - (ii) would be a relevant device for the purposes of Part IV, but for the application of regulation 4C(1); and
- (b) that is classified (whether or not Part IX applies in respect of the device) as belonging to Class A, referred to in Schedule 23.

(11) Where regulation 33A does not apply in respect of a device or accessory by virtue of paragraph (9), regulation 44 continues to have effect after its revocation in respect of that device or accessory, with the following modifications—

- (a) paragraph (2)(b) applies as if for the words “the Community or a State which is a Party to an Association Agreement” there were substituted “the United Kingdom”; and
- (b) as if paragraph (3) were omitted.

(12) On and after exit day and until its revocation, regulation 44 continues to have effect with the following modifications—

- (a) paragraph (2)(b) applies as if for the words “the Community or a State which is a Party to an Association Agreement” there were substituted “the United Kingdom”; and
- (b) as if paragraph (3) were omitted.

Transitional provisions in respect of the European Commission’s UDI database

4E.—(1) Subject to paragraph (3), regulations 91 to 95 do not apply until the date which is 6 months after the date on which the UDI database managed by the European Commission becomes fully functional (a date that the European Commission is required to publish in the Official Journal of the European Union), unless that date (“the operational date”) is before 26th May 2020.

(2) Accordingly, until the operational date—

- (a) the following provisions do not apply—
 - (i) regulation 76(9) and (14)(c)(viii),
 - (ii) regulation 101(2),
 - (iii) paragraph 23(3)(h) of Schedule 3,
 - (iv) paragraph 1(c) of Schedule 6, and
 - (v) Schedule 8; and
- (b) the following provisions only apply with the following modifications—
 - (i) regulation 100(2), as if the words from “Except for” to “94 to 96,” were omitted; and
 - (ii) regulation 118(9)(a), as if the words “when the device is registered in accordance with regulation 94 and” were omitted.

(3) Regulation 91(4) only applies in respect of a device to which Part VIII applies, or in respect of an accessory to such a device—

- (a) on and after 26th May 2021 (or on and after the operational date if later), in the case of a device classified in accordance with Schedule 9 as—
 - (i) an implantable device, or an accessory to such a device, or

- (ii) a Class III device, or an accessory to such a device;
 - (b) on and after 26th May 2023 (or on and after the operational date if later), in the case of a device classified in accordance with Schedule 9 as—
 - (i) a Class IIa device, or an accessory to such a device, or
 - (ii) a Class IIb device, or an accessory to such a device;
 - (c) on and after 26th May 2025 (or on and after the operational date if later), in the case of a device classified in accordance with Schedule 9 as a Class 1 device, or an accessory to such a device;
 - (d) on and after the date which is 2 years after the operational date, in the case of a device considered to be a reusable device, or an accessory to such a device, in circumstances where it is required to bear the UDI carrier on the device or accessory itself.
- (4) If the operational date is before 26th May 2020, regulations 7A and 21A cease to apply on the operational date in respect of a device or accessory to which Part VIII applies because regulation 4B(1) applies.
- (5) Subject to paragraph (7), regulations 157 to 160 do not apply until the date which is 6 months after the operational date, unless the operational date is before 26th May 2022.
- (6) Accordingly, before the operational date—
- (a) the following provisions do not apply—
 - (i) regulation 145(8) and (13)(c)(viii), and
 - (iii) Schedule 22; and
 - (b) the following provisions only have effect with the following modifications—
 - (i) regulation 161(4)(a), as if the words “including the basic UDI-DI” were omitted; and
 - (ii) regulation 165(2), as if the words from “Except for” to “158 or 160,” were omitted.
- (7) Regulation 157(4) only applies in respect of a device to which Part VIII applies, or an accessory to such a device—
- (a) on and after 26th May 2023 (or on and after the operational date if later), in the case of a device classified in accordance with Schedule 23 as a Class D device, or an accessory to such a device;
 - (b) on and after 26th May 2025 (or on and after the operational date if later), in the case of a device classified in accordance with Schedule 23 as—
 - (i) a Class C device, or an accessory to such a device, or
 - (ii) a Class B device, or an accessory to such a device; or
 - (c) on and after 26th May 2027 (or on and after the operational date if later), in the case of a device classified in accordance with Schedule 23 as a Class A device, or an accessory to such a device.
- (8) If the operational date is before 26th May 2022, regulation 33A ceases to apply on the operational date in respect of a device or accessory to which Part IX applies because regulation 4C(1) applies.

Application of Parts II and III on and after 26th May 2020, the related transitional provisions and the revocation of Parts II and III on 26th May 2025

- 4F.**—(1) Parts II and Part III are revoked on 26th May 2025.
- (2) Pending their revocation, Parts II and III cease to apply on 26th May 2020, except as provided for in this regulation.
- (3) Subject to paragraph (4), regulations 7A and 21A continue to apply on and after 26th May 2020 unless by virtue of regulation 4E(4) they ceased to apply before that date in

respect of devices or accessories to which Part VIII applies (in which case regulations 7A and 21A cease to apply for all purposes on 26th May 2020).

(4) Unless, by virtue of paragraph (3), they ceased to apply for all purposes on 26th May 2020, regulations 7A and 21A cease to apply on the date which is 6 months after the date on which the UDI database managed by the European Commission becomes fully functional (a date that the European Commission is required to publish in the Official Journal of the European Union).

(5) Certificates issued in accordance with Directive 90/385 or Directive 93/42 before 26th May 2020 remain valid on and after 26th May 2020—

- (a) if issued before 26th May 2017 otherwise than in accordance with Annex 4 of Directive 90/385 or Annex IV of Directive 93/42, until the end of the period indicated on the certificate or, if sooner, 26th May 2025;
- (b) if issued before 26th May 2017 in accordance with Annex 4 of Directive 90/385 or Annex IV of Directive 93/42, until the end of the period indicated on the certificate or, if sooner, 26th May 2022;
- (c) if issued on or after 26th May 2017 but before 26th May 2020, until whichever of the following is the soonest—
 - (i) the end of the period indicated on the certificate,
 - (ii) the end of the period of 5 years from the date on which the certificate was issued, or
 - (iii) 26th May 2024.

(6) Subject to paragraph (7), Part II or III continues to apply on and after 26th May 2020 in respect of a device or an accessory that is a relevant device for the purposes of Part II or III, in circumstances where—

- (a) the conformity assessment that the person placing it on the market or it into service relies on for doing so is the conformity assessment required by Part II or III;
- (b) as a consequence, there is in respect of that relevant device a certificate of conformity, the validity of which is preserved by paragraph (5);
- (c) since the issuing of that certificate, there have been no significant changes to the design or intended purpose of the relevant device; and
- (d) the notified body responsible for that certificate continues to fulfil its obligations in respect of the continued supervision of the relevant device.

(7) The requirements of Part VIII in respect of post-market surveillance, market surveillance, vigilance and registration of economic operators and of devices apply in place of the corresponding requirements of Parts II and III (although regulations 7A and 21A may continue to apply, subject to paragraphs (3) and (4)).

(8) For the purposes of paragraph (6)(d)—

- (a) a body does not cease, as a consequence of the withdrawal of the United Kingdom from the European Union, to be the notified body responsible for a certificate if—
 - (i) it was a notified body designated as a UK notified body in accordance with regulation 45 (designation of notified bodies) as it applied immediately before exit day, and
 - (ii) before exit day, that designation had not been withdrawn under regulation 45(5);
- (b) a notified body fulfils its obligations if it carries out the activities required by the following provisions as they apply to the devices covered by the relevant certificate—
 - (i) for relevant devices to which Part II applies, the Annexes to Directive 93/42 and in particular sections 5 and 7.5 of Annex II, section 4 of Annex V and section 4 of Annex VI, and

- (ii) for relevant devices to which Part III applies, the Annexes to Directive 90/385 and in particular section 5 of Annex 2 and section 4 of Annex 5 to Directive 90/385.

Application of Part IV on and after 26th May 2022, the related transitional provisions and the revocation of Part IV on 26th May 2025

4G.—(1) Part IV is revoked on 26th May 2025.

(2) Pending its revocation, Part IV ceases to apply on 26th May 2022, except as provided for in this regulation.

(3) Subject to paragraph (4), regulation 33A continues to apply on and after 26th May 2022 unless by virtue of regulation 4E(8) it ceased to apply before that date in respect of devices or accessories to which Part IX applies (in which case regulation 33A ceases to apply for all purposes on 26th May 2022).

(4) Unless, by virtue of paragraph (3), it ceased to apply for all purposes on 26th May 2022, regulation 33A ceases to apply on the date which is 6 months after the date on which the UDI database managed by the European Commission becomes fully functional (a date that the European Commission is required to publish in the Official Journal of the European Union).

(5) Certificates issued in accordance with Directive 98/79 before 26th May 2022 remain valid on and after 26th May 2022—

- (a) if issued before 26th May 2017 otherwise than in accordance with Annex VI of Directive 98/79, until the end of the period indicated on the certificate or, if sooner, 26th May 2025;
- (b) if issued before 26th May 2017 in accordance with Annex VI of Directive 98/79, until the end of the period indicated on the certificate or, if sooner, 26th May 2024;
- (c) if issued on or after 26th May 2017 but before 26th May 2020, until the end of the period indicated on the certificate or, if sooner, 26th May 2024.

(6) Subject to paragraph (7), Part IV continues to apply on and after 26th May 2022 in respect of a device or an accessory that is a relevant device for the purposes of that Part, in circumstances where—

- (a) the conformity assessment that the person placing it on the market or it into service relies on for doing so is the conformity assessment required by Part IV;
- (b) as a consequence, there is in respect of that relevant device a certificate of conformity, the validity of which is preserved by paragraph (5);
- (c) since the issuing of that certificate, there have been no significant changes to the design or intended purpose of the relevant device; and
- (d) the notified body responsible for that certificate continues to fulfil its obligations in respect of the continued supervision of the relevant device.

(7) The requirements of Part IX in respect of post-market surveillance, market surveillance, vigilance and registration of economic operators and of devices apply in place of the corresponding requirements of Part IV (although regulation 33A may continue to apply, subject to paragraphs (3) and (4)).

(8) For the purposes of paragraph (6)(d)—

- (a) a body does not cease, as a consequence of the withdrawal of the United Kingdom from the European Union, to be the notified body responsible for a certificate if—
 - (i) it was a notified body designated as a UK notified body in accordance with regulation 45 (designation of notified bodies) as it applied immediately before exit day, and
 - (ii) before exit day, that designation had not been withdrawn under regulation 45(5); and

- (b) a notified body fulfils its obligations if it carries out the activities required by the Annexes to Directive 98/79 and in particular by section 5 of Annex IV and section 4 of Annex VII to Directive 98/79, as they apply to the devices covered by the relevant certificate.

Revocation of Commission Decision 2002/364 on 26th May 2025 and its effect before that date

4H.—(1) Commission Decision 2002/364/EC of 7 May 2002 on the common specifications for in vitro diagnostic medical devices^(a) (“the Decision”) (insofar as it is retained EU law) is revoked on 26th May 2025.

(2) Pending its revocation, the Decision has effect as it had effect immediately before exit day.

Revocation of Commission Decision 2010/227

4I. Commission Decision 2010/227/EU of 19 April 2010 on the European Databank on Medical Devices (Eudamed)^(b) is revoked.

Revocation of Regulation (EU) No 207/2012 on 26th May 2025 and its effect before that date

4J.—(1) Except as provided for in this regulation, pending its revocation by the European Commission^(c), Regulation (EU) No 207/2012 has effect as it had effect immediately before exit day.

(2) Before 26th May 2020, Regulation (EU) No. 207/2012 only applies as regards—

- (a) a device or accessory which is a relevant device for the purposes of Part II or III in respect of which Part II or III continue to apply by virtue of regulation 4B(2) or a device to which Part VIII applies by virtue of regulation 4B(1);

and

- (b) as if—

- (i) the reference to a notified body in Article 8 included reference to a UK notified body, where that UK notified body is responsible for the certificate of conformity that remains valid by virtue of regulation 4F(5), but
- (ii) Article 8 were otherwise omitted.

(3) On and after 26th May 2020 but before 26th May 2025, Regulation (EU) No 207/2012 only applies as regards—

- (a) a device or accessory that is a relevant device for the purposes of Part II or III in respect of which Part II or III continues to apply by virtue of regulation 4F(6) (subject to regulation 4F(7)) or a device to which Part VIII applies; and

- (b) as if—

- (i) the reference to a notified body in Article 8 included reference to a UK notified body, where that UK notified body is responsible for the certificate of conformity that remains valid by virtue of regulation 4F(5), but
- (ii) Article 8 were otherwise omitted.

^(a) OJ No. L 131, 16.5.2002, p. 17.

^(b) OJ No. L 102, 23.4.2010, p. 45.

^(c) see Article 122 of Regulation (EU) 2017/745 for reference to when the Regulation is to be revoked.

Revocation of Regulation (EU) No 722/2012 on 26th May 2025 and its effect before that date

4K.—(1) Except as provided for in this regulation, pending its revocation by the European Commission^(a), Regulation (EU) No 722/2012 has effect as it had effect immediately before exit day.

(2) Before 26th May 2020, Regulation (EU) No 722/2012 applies as regards—

- (a) a device or accessory that is a relevant device for the purposes of Part II or III in respect of which Part II or III continues to apply by virtue of regulation 4B(2);
- (b) a device to which Part VIII applies by virtue of regulation 4B(1);

(3) On and after 26th May 2020 but before 26th May 2025, Regulation (EU) No 722/2012 applies as regards a device or accessory that is a relevant device for the purposes of Part II or III in respect of which Part II or III continues to apply by virtue of regulation 4F(6) (subject to regulation 4F(7)) or to devices to which Part VIII applies.

(4) Before 26th May 2025, Regulation (EU) No 722/2012 only applies as regards a UK notified body—

- (a) where the UK notified body is responsible for a certificate of conformity issued for the relevant device in accordance with Directive 90/385 or Directive 93/42 that remains valid by virtue of regulation 4F(5); and
- (b) to the extent this is necessary for the fulfilment by the UK notified body of its obligations as regards the relevant device for the purposes of Part II or III.

Revocation of Regulation (EU) No 920/2013 on 26th May 2025 and its effect before that date

4L.—(1) Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices^(b) (“Regulation (EU) No 920/2013”) (insofar as it is retained EU law) is revoked on 26th May 2025.

(2) Except as provided for in this regulation, pending its revocation, Regulation (EU) No 920/2013 has effect as it had effect immediately before exit day.

(3) Before 26th May 2025, Regulation (EU) No 920/2013 only applies as regards a UK notified body—

- (a) where the UK notified body is responsible for a certificate of conformity issued for the device or accessory in accordance with Directive 90/385 or Directive 93/42 that remains valid by virtue of regulation 4F(5); and
- (b) to the extent this is necessary for the fulfilment by the UK notified body of its obligations as regards the device or accessory for the purposes of Part II or III.

(4) Before 26th May 2025, Regulation (EU) No 920/2013 only applies as regards the functions of the Secretary of State as a designating authority for the purpose of that Regulation, to the extent necessary for the fulfilment by the Secretary of State of the Secretary of State’s obligations as regards the supervision of UK notified bodies.

(5) Paragraph (4) only applies in respect of the functions of the Secretary of State—

- (a) which allow for or require the exchange of information with designating authorities in the European Union or with the European Commission; and
- (b) insofar as there are in place reciprocal arrangements with the EU, an EU entity, a member State or a public authority in a member State that allow for or require that exchange.

(a) see Article 122 of Regulation (EU) 2017/745 for reference to when the Regulation is to be revoked.

(b) OJ No. L 253, 25.9.2013, p. 8.

Revocation of Regulation (EU) No 2017/2185 and saving provision

4M.—(1) Insofar as it is retained EU law, Commission Implementing Regulation (EU) 2017/2185 of 23 November 2017 on the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices under Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices under Regulation (EU) 2017/746 of the European Parliament and of the Council^(a) (“Regulation (EU) No 2017/2185”) is revoked.

(2) Notwithstanding paragraph (1), where conformity assessment of medical devices under Part VIII or IX requires involvement of a notified body in the European Union and the use of one of the codes listed in Regulation (EU) No. 2017/2185, that that Regulation is saved to the extent necessary to give effect to that requirement.

The classification criteria in Directives 2003/12 and 2005/50

4N. Where regulation 7 applies either in accordance with regulation 4B(2)(a), or for the purposes of regulation 4D(2)(b) or (3)(b), or by virtue of regulation 4F(6), Directives 2003/12 and 2005/50 apply with the following modifications—

- (a) in the case of Directive 2013/12, as if Articles 2 to 4 were omitted; and
- (b) in the case of Directive 2005/50, as if Articles 3 to 6 were omitted.

Revocation of Regulation (EU) 2017/745

4O.—(1) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (“the Medical Devices Regulation”) (insofar as it is retained EU law) is revoked.

(2) Part VIII applies in respect of a device or accessory placed on the market or put into service before exit day in accordance with the conformity assessment required by the Medical Devices Regulation as it applies to a device or accessory placed on the market or put into service in accordance with Part VIII.

Revocation of Regulation (EU) 2017/746

4P.—(1) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (“the in vitro diagnostic medical devices Regulation”) (insofar as it is retained EU law) is revoked.

(2) Part IX applies in respect of a device or accessory placed on the market or put into service before exit day in accordance with the conformity assessment required by the Medical Devices Regulation as it applies to a device or accessory placed on the market or put into service in accordance with Part IX.

Modifications to deal with serious shortages

4Q.—(1) The Secretary of State may by regulations modify the application of any of the provisions of these Regulations in circumstances where, in the Secretary of State’s opinion, the United Kingdom or any part of the United Kingdom is experiencing or may experience a serious shortage, arising from the withdrawal of the United Kingdom from the European Union, of a device or accessory of a specified description that—

- (a) is a relevant device for the purposes of Part II, III or IV; or

(a) OJ No. L 309, 24.11.2017, p. 7.

(b) would be a relevant device for the purposes of Part II, III or IV but for the application of regulation 4B(1) or 4C(1).

(2) Regulations may only be made under paragraph (1) for the purposes of preventing, remedying or mitigating the serious shortage that in the opinion of the Secretary of State is being or may be experienced.

(3) The reference in paragraph (1) to a serious shortage arising from the withdrawal of the United Kingdom from the European Union includes reference to a serious shortage where the withdrawal of the United Kingdom from the European Union is one but not the only significant factor contributing to the shortage.

(4) No regulations under paragraph (1) may be made, or have effect after the end of the period of 2 years beginning with exit day.

(5) The power to make regulations under paragraph (1) is exercisable by statutory instrument.

(6) Regulations made under paragraph (1) are subject to annulment by resolution of either House of Parliament.

References in other legislation to expressions used in these Regulations

4R.—(1) In the following provisions, where reference is made, in whatever form, to the expression “medical device” having the meaning given in regulation 2, to the extent necessary for the practical application of that definition, the reference to regulation 2 is to be construed as a reference also or instead to regulation 69—

- (a) the definitions of “electronic cigarette” and “electronic cigarette refill container” in section 368R of the Communications Act 2003(a) (interpretation of Part 4A);
- (b) regulation 4(3)(b)(ii) of the National Health Service Commissioning Board (Additional Functions) Regulations 2017(b) (power to conclude and manage framework agreements);
- (c) the definition of “medical device” in regulation 2(1) of the Tobacco and Related Products Regulations 2016(c) (interpretation);
- (d) the definition of “medical device” in regulation 1(4) of the Nicotine Inhaling Products (Age of Sale and Proxy Purchasing) Regulations 2015(d) (citation, commencement and interpretation);
- (e) the definition of “equipment” in regulation 2(1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014(e) (interpretation);
- (f) the definition of “medical device” in regulation 2(1) of the Restriction on the Use of Certain Hazardous Substances in Electrical and Electrical Equipment Regulations 2012(f) (interpretation); and
- (g) the definition of “medical device” in article 3(1) of the Pharmacy Order 2010(g) (interpretation).

(2) In regulation 2(1) of the Restriction on the Use of Certain Hazardous Substances in Electrical and Electrical Equipment Regulations 2012, where reference is made to the expression “in vitro diagnostic medical device” having the meaning given in regulation 2, to the extent necessary for the practical application of that definition, “in vitro diagnostic medical device” is to be construed as also or instead having the meaning given to “in vitro diagnostic medical device” in regulation 137.

(a) 2003 c. 21. Section 368R was inserted by S.I. 2009/2979 and has been amended by S.I. 2010/831, 2012/1916 and 2016/507.
(b) S.I. 2017/212.
(c) S.I. 2016/507; amended by S.I. 2016/1127.
(d) S.I. 2015/895.
(e) S.I. 2014/2936; amended by S.I. 2015/64.
(f) S.I. 2012/3032; amended by S.I. 2018/942.
(g) S.I. 2010/231; amended by the Data Protection Act 2018 (c. 12), Schedule 19, paragraph 352, and by S.I. 2011/1043, 2015/806 and 968, and 2016/372 and 1030.

(3) In sub-paragraph (c) of the definition of “manufacturer” in regulation 1(3) of the Blood Safety and Quality Regulations 2005(a) (citation, commencement and interpretation), the reference made to the definition of “manufacturer” in relation 2(1) is to be construed, to the extent necessary for the practical application of that definition, as if it were defined also or instead by reference to regulation 69.

(4) In the following provisions, where reference is made to regulation 15, to the extent necessary for the practical application of the provision, that reference is to be construed as a reference also or instead to regulation 76(7)—

- (a) paragraph 32(3)(e) of Schedule 3 to the National Health Service (General Dental Services Contracts) (Wales) Regulations 2006(b) (other contractual terms – patient records);
- (b) paragraph 33(3)(e) of Schedule 3 to the National Health Service (Personal Dental Services Agreements) (Wales) Regulations 2006(c) (other contractual terms – patient records);
- (c) paragraph 33(3)(e) of Schedule 3 to the National Health Service (Personal Dental Services Agreements) Regulations 2005(d) (other contractual terms – patient records); and
- (d) paragraph 32(3)(e) of Schedule 3 to the National Health Service (General Dental Services Contracts) Regulations 2005(e) (other contractual terms – patient records).

Use in other legislation of a definition of “medical device” based on the definition in Directive 93/42

4S. In the following provisions, the definition of “medical device” is to be construed, to the extent necessary for the practical application of that definition, as if it were defined also or instead by reference to regulation 69—

- (a) regulation 1(3) of the National Health Service (Cross-Border Healthcare) Regulations 2013(f) (citation, commencement, extent and interpretation);
- (b) regulation 2 of the National Health Service (Cross-Border Health Care) (Scotland) Regulations 2013(g) (interpretation); and
- (c) regulation 2(1) of the Health Services (Cross-Border Health Care) Regulations (Northern Ireland) 2013(h) (interpretation).

References in other legislation to Directives 90/385, 93/42 and 98/79

4T.—(1) In section 1(12)(a) of the Human Tissue Act 2004(i) (authorisation of activities for scheduled purposes), the references to Directive 98/79 are to be construed, to the extent necessary for the practical application of that section, as references also or instead to Parts IV and IX.

(2) In regulation 10(5) of the Medicines (Products for Human Use) (Fees) Regulations 2016(j) (fee for advice for other purposes)—

- (a) the reference to the expression “medical device” having the meaning given in Article 1(2)(a) of Directive 93/42 is to be construed, to the extent necessary for the

(a) S.I. 2005/50; amended by S.I. 2005/2898, 2006/2013, 2010/1881, 2011/2581, 2013/235 and 2018/231.
(b) S.I. 2006/490.
(c) S.I. 2006/489.
(d) S.I. 2005/3373.
(e) S.I. 2005/3361.
(f) S.I. 2013/2269.
(g) SSI 2013/292; amended by SSI 2015/91.
(h) S.R. 2013 No. 299.
(i) 2004 c. 30. There have been no amendments to subsection (12) of section 1.
(j) S.I. 2016/190.

practical application of that definition, as a reference also or instead to having the meaning given in regulation 2 or 69; and

- (b) the reference to paragraph 5 of Annex III to Directive 93/42 is to be construed, to the extent necessary for the practical application of that definition, as a reference also or instead to Schedule 11.

(3) In Schedule 1 to the Pressure Equipment (Safety) Regulations 2016(a) (excluded pressure equipment and assemblies), the reference in paragraph 1(f)(iv) to not being covered by Directive 93/42 is to be construed, to the extent necessary for the practical application of that provision, as a reference also or instead to not being covered by Part II or VIII.

(4) In regulation 2 of the Waste Electrical and Electronic Equipment Regulations 2013(b) (interpretation)—

- (a) the reference to the expression “active implantable medical device” having the meaning given in Article 1(2)(c) of Directive 90/385 is to be construed, to the extent necessary for the practical application of that definition, as a reference also or instead to it having the meaning given in regulation 2 or in accordance with Schedule 9;
- (b) the reference to the expression “medical device” having the meaning given in Article 1(2)(a) of Directive 93/42 is to be construed, to the extent necessary for the practical application of that definition, as a reference to it also or instead having the meaning given to it in regulation 2 or 69;
- (c) the reference to the expression “accessory” having the meaning given in Article 1(2)(b) of Directive 93/42 is to be construed, to the extent necessary for the practical application of that definition, as also or instead having the meaning given to “accessory” in regulation 5 or to “accessory for a medical device” in regulation 69;
- (d) the reference to the expression “in vitro diagnostic medical device” having the meaning given in Article 1(2)(b) of Directive 98/79 is to be construed, to the extent necessary for the practical application of that definition, as—
 - (i) having the meaning given to it in regulation 2, or
 - (ii) also or instead having the meaning given to “in vitro medical device” in regulation 137.
- (e) the reference to the expression “accessory” having the meaning given in Article 1(2)(c) of Directive 98/79 is to be construed, to the extent necessary for the practical application of that definition, as also or instead having the meaning given to “accessory” in regulation 32 or to “accessory for an in vitro diagnostic medical device” in regulation 137.

(5) These Regulations are an enactment implementing a relevant Community Directive for the purposes of regulation 4 of the Personal Protective Equipment at Work Regulations (Northern Ireland) 1993(c) (provision of personal protective equipment).

(6) These Regulations are also an enactment implementing a relevant Community Directive for the purposes of regulation 4(5)(a) of the Personal Protective Equipment at Work Regulations 1992(d) (provision of personal protective equipment).”.

Amendment of Part II of the 2002 Regulations

4.—(1) Part II of the 2002 Regulations is amended as follows.

(2) In regulation 6 (Scope of Part II) after paragraph (c) insert—

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- (a) S.I. 2016/1105.
 - (b) S.I. 2013/3113; amended by S.I. 2015/1968, 2016/738 and 1154, and 2018/102 and 942.
 - (c) S.R. 1993 No. 20; amended by S.I. 2015/223, S.I. 2012/179, 2017/229.
 - (d) S.I. 1992/2966; amended by S.I. 1999/860, 2002/2174, 2015/1637 and 2018/390.

“(d) except for the requirement to register under regulation 7A or 19, medical devices or accessories to such devices placed on the market in accordance with Part VIII.”.

(3) In regulation 7 (Classification of general medical devices), omit paragraph (2).

(4) After regulation 7 insert—

“Registration of persons placing general medical devices on the market

7A.—(1) No person may place a relevant device on the market in accordance with this Part (or Part VIII insofar as it applies to relevant devices) unless that person—

- (a) is established in the United Kingdom; and
- (b) has complied with paragraph (2).

(2) A person complies with this paragraph if, before placing the relevant device on the market, the person—

- (a) informs the Secretary of State of the address of their registered place of business in the United Kingdom or, if the person does not have a registered place of business, an address in the United Kingdom at which service of any document relating in any way to the person’s placing of the relevant device on the market will be effective;
- (b) if they are not the manufacturer of the relevant device, provides the Secretary of State with written evidence that they have the manufacturer’s authority to place the relevant device on the market;
- (c) supplies the Secretary of State with a description of the relevant device; and
- (d) pays to the Secretary of State the relevant fee in accordance with regulation 53.

(3) Where a person provides the Secretary of State with the written evidence required by paragraph (2)(b), that person is to be regarded as the UK responsible person and that person must—

- (a) ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;
- (b) keep available for inspection by the Secretary of State a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements;
- (c) in response to a request from the Secretary of State, provide the Secretary of State with all the information and documentation necessary to demonstrate the conformity of a device;
- (d) forward to the manufacturer any request by the Secretary of State for samples, or access to a device and ensure that the Secretary of State receives the samples or has been given access to the device;
- (e) cooperate with the Secretary of State on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;
- (f) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;
- (g) terminate the legal relationship with the manufacturer if the manufacturer acts contrary to its obligations under these Regulations and inform the Secretary of State and, if applicable, the relevant notified body of that termination.

(4) In this regulation the references to “technical documentation” and “declaration of conformity” are to be construed in accordance with the following—

- (a) where this regulation applies and Part II applies —
 - (i) the reference to technical documentation is to be construed in accordance with Annex II, III or VII;

- (ii) the reference to the declaration of conformity is to be construed in accordance with Annexes II, IV, V, VI and VII as applied by regulation 13;
 - (b) where this regulation applies and Part VIII applies—
 - (i) the reference to technical documentation is to be construed in accordance with Schedules 4 and 5;
 - (ii) the reference to the declaration of conformity is to be construed in accordance with regulation 84.”.
- (5) In regulation 8 (essential requirements for general medical devices), in paragraph (3), for “Annex I to Directive 2006/42” insert “Part 1 of Schedule 2 to the Supply of Machinery (Safety) Regulations 2008”.
- (6) In regulation 9 (determining compliance of general medical devices with relevant essential requirements)—
 - (a) in paragraph (3)(b)—
 - (i) in sub-paragraph (i) omit “or another Community language, and”,
 - (ii) omit sub-paragraph (ii);
 - (b) in paragraph (9)—
 - (i) for the words from “Council Directive 89/686/EEC to “protective equipment” substitute “Regulation (EU) 2016/425 of the European Parliament and of the Council of 9th March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC”;
 - (ii) for “Directive 89/686” substitute “Regulation (EU) 2016/425”.
- (7) In regulation 12 (Exemptions from regulations 8 and 10) after paragraph (5) insert—

“(6) Regulations 8 and 10 do not apply where the Secretary of State directs that a relevant device, or a class of relevant devices, which meets other requirements or standards, or which is marked other than with a CE marking, which the Secretary of State determines is equivalent to the requirements and standards imposed by regulations 8 and 10, may be placed on the market.

(7) In paragraph (6), the Secretary of State, in determining whether another standard requirement, or marking (“the other standard”) is equivalent to a standard or requirement imposed by regulations 8 and 10, must be satisfied that the other standard imposes a degree of safety and quality equivalent to that imposed by those regulations.”.
- (8) In regulation 17(a) (Manufacturers etc. and conformity assessment procedures for general medical devices), omit paragraph (3).
- (9) Omit regulation 18(b) (UK notified bodies and the conformity assessment procedures for general medical devices).

Amendment of Part III of the 2002 Regulations

5.—(1) Part III of the 2002 Regulations is amended as follows.

(2) In regulation 21(c) (Scope of Part III)—

- (a) in paragraph (2), for “Annex I to that Directive” substitute “Part 1 of Schedule 2 to the Supply of Machinery (Safety) Regulations 2008”;
- (b) after paragraph (3) insert—

“(4) Except for the requirement to register in accordance with regulation 21A or 30(3) to (5), this Part does not apply to active implantable medical devices and accessories to such devices placed on the market in accordance with Part VIII.”.

(a) There are amendments to regulation 17 which are not relevant to these Regulations.
 (b) Regulation 18 was amended by S.I. 2003/1697, 2008/2936 and 2013/2327.
 (c) Regulation 21 was amended by S.I. 2008/2936.

(3) After regulation 21 insert—

“Registration of persons placing active implantable medical devices on the market

21A.—(1) No person may place a relevant device on the market in accordance with this Part or Part VIII insofar as it applies to relevant devices unless that person—

- (a) is established in the United Kingdom; and
- (b) has complied with paragraph (2).

(2) A person complies with this paragraph if, before placing the relevant device on the market, the person—

- (a) informs the Secretary of State of the address of their registered place of business in the United Kingdom or, if the person does not have a registered place of business, an address in the United Kingdom at which service of any document relating in any way to the person’s placing of the relevant device on the market will be effective;
- (b) if they are not the manufacturer of the relevant device, provides the Secretary of State with written evidence that they have the manufacturer’s authority to place the relevant device on the market;
- (c) supplies the Secretary of State with a description of each device concerned; and
- (d) pays to the Secretary of State the relevant fee in accordance with regulation 53.

(3) Where a person provides the Secretary of State with the written evidence required by paragraph (2)(b), that person is to be regarded as the UK responsible person and that person must—

- (a) ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;
- (b) keep available to the Secretary of State a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements;
- (c) in response to a request from the Secretary of State, provide the Secretary of State with all the information and documentation necessary to demonstrate the conformity of a device;
- (d) forward to the manufacturer any request by the Secretary of State for samples, or access to a device and verify that the Secretary of State receives the samples or is given access to the device;
- (e) cooperate with the Secretary of State on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;
- (f) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;
- (g) terminate the legal relationship with the manufacturer if the manufacturer acts contrary to its obligations under these Regulations and inform the Secretary of State and, if applicable, the relevant notified body of that termination.

(4) In this regulation the references to “technical documentation” and “declaration of conformity” are to be construed in accordance with the following—

- (a) where this regulation applies and Part III applies—
 - (i) the reference to technical documentation is to be construed in accordance with Annex 2, 3 or 5;
 - (ii) the reference to the declaration of conformity is to be construed in accordance with Annexes 2,3 and 5 as applied by regulation 27;
- (b) where this regulation applies and Part VIII applies—

- (i) the reference to technical documentation is to be construed in accordance with Schedules 4 and 5;
- (ii) the reference to the declaration of conformity is to be construed in accordance with regulation 84.”.

(4) In regulation 23 (Determining compliance of active implantable medical devices with relevant essential requirements), in paragraph 3(b)—

- (a) in sub-paragraph (i), omit “or another Community language, and”;
- (b) omit sub-paragraph (ii).

(5) In regulation 26 (Exemptions from regulations 22 and 24) after paragraph (3) insert—

“(4) Regulations 22 and 24 do not apply where the Secretary of State directs that a relevant device, or a class of relevant devices, which meets other requirements or standards or which is marked other than with a CE marking which the Secretary of State determines is equivalent to the requirements and standards imposed by regulations 22 and 24, may be placed on the market.

(5) In paragraph (4), the Secretary of State, in determining whether a standard or requirement or marking (“the other standard”) is equivalent to a standard or requirement imposed by regulations 22 and 24, must be satisfied that the other standard imposes a degree of safety and quality equivalent to that imposed by those regulations.”.

(6) In regulation 30(a) omit paragraphs (4) and (5).

(7) Omit regulation 31(b) (UK notified bodies and the conformity assessment procedures for active implantable medical devices).

Amendment of Part IV of the 2002 Regulations

6.—(1) Part IV of the 2002 Regulations is amended as follows.

(2) In regulation 33 (Scope of Part IV)—

(a) after paragraph 1(b) insert—

“(c) in vitro diagnostic medical devices and accessories to such devices placed on the market in accordance with Part IX except where the requirement to register in accordance with regulation 33A applies in respect of these devices.”;

(b) after paragraph 2(b) insert—

“(c) devices that are placed on the market in accordance with Part IX except where the requirement to register in accordance with regulation 33A applies in respect of these devices.”.

(3) After regulation 33 insert—

“Registration etc. of persons placing in vitro diagnostic medical devices on the market

33A.—(1) No person may place a relevant device on the market in accordance with this Part, or Part IX insofar as it applies to relevant devices, unless that person—

- (a) is established in the United Kingdom; and
- (b) has complied with paragraph (2).

(2) A person complies with this paragraph if, before placing a relevant device on the market, the person—

- (a) informs the Secretary of State of the address of their registered place of business in the United Kingdom or, if the person does not have a registered address, an

(a) Regulation 30 was amended by S.I. 2008/2396.
(b) Regulation 31 was amended by S.I. 2008/2936.

address in the United Kingdom at which service of any document relating in any way to the person's placing of a relevant device on the market will be effective;

- (b) if they are not the manufacturer of the relevant device, provides the Secretary of State with sufficient written evidence that they have the manufacturer's authority to place the relevant device on the market;
- (c) supplies the Secretary of State with relevant information in relation to each device concerned; and
- (d) pays to the Secretary of State the relevant fee in accordance with regulation 53.

(3) Where a person provides the Secretary of State with the evidence required by paragraph (2)(b), that person is to be regarded as the UK responsible person and that person must—

- (a) ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;
- (b) keep available for inspection by the Secretary of State a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements;
- (c) in response to a request from the Secretary of State, provide the Secretary of State with all the information and documentation necessary to demonstrate the conformity of a device;
- (d) forward to the manufacturer any request by the Secretary of State for samples, or access to a device and ensure that the Secretary of State receives the samples or has been given access to the device;
- (e) cooperate with the Secretary of State on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;
- (f) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;
- (g) terminate the legal relationship with the manufacturer if the manufacturer acts contrary to its obligations under these Regulations and inform the Secretary of State and, if applicable, the relevant notified body of that termination.

(4) In this regulation "relevant information" means—

- (a) in relation to a new relevant device, a statement indicating that the device is a new relevant device;
- (b) if the device consists wholly or partly of reagents, reagent products or calibration and control materials, appropriate information in terms of common technological characteristics and analytes;
- (c) if the device does not wholly or partly consist of reagents, reagent products or calibration and control materials, the appropriate indications;
- (d) in relation to devices in a list in Annex II and devices for self-testing—
 - (i) all data allowing for identification of such devices, the analytical and, where appropriate, diagnostic parameters as referred to in Section 3 of Part A of Annex I;
 - (ii) if requested by the Secretary of State, the labelling and instructions for use for when the device is placed on the market or put into service;
- (e) in relation to devices for performance evaluation which relate either to devices referred to in a list in Annex II or to devices for self-testing, all data allowing for identification of such devices, the analytical and where appropriate, diagnostic parameters as referred to in Section 3 of Part A of Annex I.

(5) Within two years of the placing of a new relevant device on the market, the Secretary of State may, where the Secretary of State considers it justified, request a report relating to the experience gained with the device subsequent to it being placed on the market.

(6) In this regulation a device is a “new relevant device” if—

- (a) there has been no such device continuously available on the United Kingdom or other market during the previous three years for the relevant analyte or other parameter; or
- (b) use of the device has involved analytical technology not continuously used in connection with a given analyte or other parameter on the United Kingdom or other market during the previous three years.

(7) In paragraph (3) the references to “technical documentation” and “declaration of conformity” are to be construed in accordance with the following—

- (a) where this regulation applies and Part IV applies—
 - (i) the reference to technical documentation is to be construed in accordance with Annexes III to VIII;
 - (ii) the reference to the declaration of conformity is to be construed in accordance with Annexes III, IV, V and VII as applied by regulation 40;
- (b) where this regulation applies and Part IX applies—
 - (i) the reference to technical documentation is to be construed in accordance with Schedules 18 and 19;
 - (ii) the reference to the declaration of conformity is to be construed in accordance with regulation 153.”.

(4) In regulation 35 (Determining compliance of in vitro diagnostic medical devices with relevant essential requirements), in paragraph (2), omit the words from “if the device may reach a final user” to the end.

(5) In regulation 39 (Exemptions from regulations 34, 36 and 38), after paragraph (2) insert—

“(3) Regulations 34 and 36 do not apply where the Secretary of State directs that a relevant device, or a class of relevant devices, which meets other requirements or standards or which is marked other than with a CE marking which the Secretary of State determines is equivalent to the requirements and standards imposed by regulations 34 and 36, may be placed on the market.

(4) In paragraph (3), the Secretary of State, in determining whether a standard or requirement or marking (“the other standard”) is equivalent to a standard or requirement imposed by regulations 34 and 36, must be satisfied that the other standard imposes a degree of safety and quality equivalent to that imposed by those regulations.”.

(6) In regulation 41 (Manufacturers etc. and conformity assessment procedures for in vitro diagnostic medical devices) in paragraph (5)—

- (a) omit from the beginning to “established”;
- (b) omit “in the United Kingdom”.

(7) Omit regulation 42 (UK notified bodies and the conformity assessment procedures for in vitro diagnostic medical devices).

Amendment of Part V of the 2002 Regulations

7.—(1) Part V of the 2002 Regulations is amended as follows.

(2) In regulation 45(a) (Designation etc. of UK notified bodies)—

- (a) in the heading, omit “Designation etc. of”;

(a) Regulation 45 was amended by S.I. 2003/1697 and S.I. 2013/2327.

- (b) for “the Mutual Recognition Agreements” in each place it occurs, substitute “a mutual recognition agreement”;
 - (c) omit paragraphs (1) to (3);
 - (d) in paragraph (5)—
 - (i) in the introductory wording, omit “under paragraph (1)”;
 - (ii) in sub-paragraph (c) omit “under paragraph (1)”.
- (3) In regulation 47(a)—
- (a) in paragraph (1)—
 - (i) for “an application has been made” substitute “, before exit day, an application was made”;
 - (ii) for “shall perform those functions”, substitute “shall perform the functions set out in regulation 67A(5)”;
 - (b) in paragraph (3)—
 - (i) for the first mention of “notified body” substitute “UK notified body”;
 - (ii) omit “, if the notified body is within the United Kingdom,”;
 - (iii) omit “or some other Community language acceptable to the notified body concerned”;
 - (c) in paragraph (5), for “notified body” in both places it occurs substitute “UK notified body”;
 - (d) in paragraphs (6) and (8), for “the Mutual Recognition Agreements” in each place it occurs, substitute “a mutual recognition agreement”.
- (4) In regulation 48 (Designation etc. of EC conformity assessment bodies)—
- (a) in the heading and in each other place it occurs omit “EC”;
 - (b) for “the Mutual Recognition Agreements” in each place it occurs, substitute “a mutual recognition agreement”;
 - (c) in paragraph (1) omit “European Community”.
- (5) In regulation 49 (Fees charged by UK notified bodies and EC conformity assessment bodies)—
- (a) in the heading and in each other place it occurs omit “EC”;
 - (b) for “the Mutual Recognition Agreements” in both places, substitute “a mutual recognition agreement”;
 - (c) in paragraph (1), for “under the Medical Devices Directives”, substitute “under these Regulations”.

Amendment of Part VI of the 2002 Regulations

8.—(1) Part VI of the 2002 Regulations is amended as follows.

(2) In regulation 53(b) (Fees in connection with the registration of devices and changes in registration details)—

- (a) for “regulation 19 or 44” substitute “regulations 7A, 19, 21A, 33A, 44, 93, 95, 158 or 160”;
- (b) after “registration of that person” insert “or, in the case of registration of a device, the device”.

(a) Regulation 47 was amended by S.I. 2008/2936 and S.I. 2013/2327.
 (b) Regulation 53 was amended by S.I. 2017/207.

- (c) In regulation 54(a) (Fees payable in connection with the designation of UK notified bodies)—
 - (d) in the heading omit “with the designation etc. of”;
 - (e) for “the Mutual Recognition Agreements” in both places, substitute “a mutual recognition agreement”;
 - (f) omit paragraph (1);
 - (g) omit paragraph (3C);
 - (h) in paragraph (4), omit sub-paragraph (a).
- (3) In regulation 55(b) (Fees payable in connection with the designation etc. of EC conformity assessment bodies —
- (a) in the heading and in every other place it occurs omit “EC”;
 - (b) in paragraph (3), for “the Mutual Recognition Agreements”, substitute “a mutual recognition agreement”.
- (4) In regulation 58 (Waivers, reductions and refunds) in paragraph (2)—
- (a) at the end of sub-paragraph (a) omit “or”;
 - (b) omit sub-paragraph (b);
 - (c) after sub-paragraph (b) in the full out words omit from “(other than” to “the Secretary of State”.

Amendment of Part VII of the 2002 Regulations

9.—(1) Part VII of the 2002 Regulations is amended as follows.

- (2) In regulation 59(c)(interpretation of Part VII)—
- (a) omit the definition of “registrable device”;
 - (b) in the definition of “relevant device” after “IV” insert “or a device for the purposes of Part VIII or IX.”.
- (3) In regulation 60(d) (designation etc. of authorised representatives)—
- (a) for the heading substitute “Status of UK responsible person”;
 - (b) omit paragraphs (1) and (2);
 - (c) for paragraph (3), substitute—
 - “A UK responsible person—
 - (a) may be proceeded against as a person placing the device on the market for the purposes of these regulations;
 - (b) in relation to the supply of the device to a person within the United Kingdom after it has been placed on the market, may be proceeded against as a person supplying the device after it has been placed on the market.”.
 - (d) in paragraph (4), for “an authorised representative” substitute “a UK responsible person”.
- (4) In regulation 61(e) (enforcement etc.)—
- (a) in paragraph (8) in sub-paragraph (a)—
 - (i) in paragraph (i), after “essential requirement” insert “, a general safety and performance requirement”;
 - (ii) in paragraph (ii), omit “set out in the Medical Devices Directives”;

(a) Regulation 54 was amended by S.I. 2003/1697, S.I. 2007/803, S.I. 2013/2327, S.I. 2017/207.

(b) Regulation 55 was amended by S.I. 2007/803, S.I. 2010/557 and S.I. 2017/207.

(c) Regulation 59 was amended by S.I. 2003/1697.

(d) Regulation 60 was amended by S.I. 2008/2936.

(e) Regulation 61 was amended by S.I. 2003/1400, S.I.2005/2009 and S.I. 2007/400.

- (b) in sub-paragraph (b), after “performance evaluation” insert “or study”.
- (5) In regulation 62 (compliance notices) in paragraph (1)—
 - (i) after “performance evaluation” insert “or study”;
 - (ii) for “the manufacturer or his authorised representative” substitute “any person”.
- (6) In regulation 63(a) (restriction notices) in paragraph (1)—
 - (i) in sub-paragraph (a), after “performance evaluation” insert “or study”;
 - (ii) in sub-paragraph (b), after “performance evaluation” insert “or study”.
- (7) Omit regulation 65(centralised system of records etc.).
- (8) In regulation 67(b) (review), for “2019” substitute “2025”.
- (9) Omit Schedule 1(c) (association agreements).
- (10) For Schedule 2(d) (mutual recognition agreements) substitute—

“SCHEDULE 2

Regulation 1A

Mutual Recognition Agreement countries

- Australia
- New Zealand
- Canada
- The United States of America
- The Swiss Confederation”.

PART 2

New Part VIII of the Medical Devices Regulations

- 10.** After regulation 67 of the 2002 Regulations insert—

“PART VIII

Restatement of the Rights, powers, liabilities, obligations, restrictions, remedies
and procedures recognised under the Medical Devices Regulation (see
regulation 4O)

Scope and Definitions

Subject matter and Scope

68.—(1) This Part lays down the rules for and applies to the placing on the market, the making available on the market and the putting into service of—

- (a) medical devices for human use; and
- (b) accessories to such medical devices.

(2) This Part also applies to—

(a) Regulation 63 was amended by S.I. 2008/2936.
 (b) Regulation 67 was inserted by S.I. 2013/2327.
 (c) Schedule 1 was amended by 2013/2327.
 (d) Schedule 2 was amended by S.I. 2013/2327.

- (a) clinical investigations concerning medical devices for human use and accessories to such devices; and
 - (b) the groups of products without an intended medical purpose listed in Schedule 16.
- (3) Devices with both an intended medical and non-medical purpose must fulfil the requirements applicable to devices with an intended medical purpose and those applicable to devices without an intended medical purpose.
- (4) For the purposes of this Part and Schedules 3 to 16 medical devices, accessories to medical devices and products listed in Schedule 16 are referred to as ‘devices’.
- (5) The Secretary of State may by Regulations amend the list in Schedule 16.
- (6) This Part does not apply to—
- (a) relevant devices placed on the market in accordance with Part II or Part III;
 - (b) subject to paragraph (7), in vitro diagnostic medical devices placed on the market under Part IX;
 - (c) medicinal products as defined by regulation 2 of the Human Medicines Regulations 2012;
 - (d) advanced therapy medicinal products covered by regulation 2A of the Human Medicines Regulations 2012;
 - (e) human blood, human blood products, plasma or blood cells of human origin or devices which incorporate, when placed on the market or put into service, such blood products, plasma or cells except for devices referred to in paragraph (8);
 - (f) cosmetic products covered by Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products;
 - (g) transplants, tissues or cells of animal origin or their derivatives, or products containing or consisting of them; but this Part does apply to devices which utilise tissues or cells of animal origin (or their derivatives) which are non-viable or rendered non-viable;
 - (h) transplants, tissues or cells of human origin, or their derivatives, covered by the Human Tissue (Quality and Safety for Human Application) Regulations 2007^(a) or by the Human Fertilisation and Embryology Act 1990^(b) or products containing or consisting of them but this Part does apply to devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable;
 - (i) products, other than those in paragraphs (e), (g) and (h), that contain or consist of viable biological material or viable organisms, including living micro-organisms, bacteria fungi or viruses in order to achieve or support the intended purposes of the product;
 - (j) food covered by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the principles and requirements of food law, establishing the European Food Safety Agency and laying down procedures in matters of food safety.
- (7) Any device which, when placed on the market or put into service, incorporates as an integral part an in vitro diagnostic medical device covered by Part IX, is governed by this Part but the requirements of Part IX also apply to the in vitro diagnostic medical device part of the device.
- (8) Subject to sub-paragraph (9), any device which, when placed on the market or put into service, incorporates, as an integral part, a substance which, if used separately, would be considered a medicinal product (including a product derived from human blood or blood plasma) and that has an action ancillary to that of the device, must be assessed and authorised in accordance with this Part.

(a) S.I. 2007/1523.

(b) 1990 c. 37.

(9) If the action of the device is ancillary to that of the medicinal product, the product must be governed by the Human Medicines Regulations 2012.

(10) Where paragraph (9) applies, the general safety and performance requirements set out in Schedule 3 must also apply to the device part of the product.

(11) Subject to paragraph (12), any device which is intended to administer a medicinal product is governed by this Part without prejudice to the provisions of the Human Medicines Regulations 2012 .

(12) If the device intended to administer a medicinal product and the medicinal product are placed on the market in such a way that they form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single integral product must be governed by the Human Medicines Regulations 2012.

(13) Where paragraph (12) applies, the relevant general safety and performance requirements set out in Schedule 3 apply to the device part of the single integral product.

(14) A device which, when placed on the market, or put into service, incorporates, as an integral part, non-viable cells of human origin or their derivatives that have an action ancillary to that of the device must be assessed and authorised in accordance with this Part but the provisions for donation, procurement and testing laid down in the Human Tissue (Quality and Safety for Human Application) Regulations 2007 also apply.

(15) If a device which, when placed on the market, or put into service, incorporates, as an integral part, non-viable cells of human origin or their derivatives that have an action which is principal and not ancillary to that of the device and that product is not governed by the Human Medicines Regulations 2012, the product must be governed by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 but the general safety and performance requirements set out in Schedule 3 also apply to the device.

(16) Where a device is also machinery within the meaning of the Supply of Machinery (Safety) Regulations 2008(a) and where—

- (a) a hazard under that legislation exists; and
- (b) the provisions of that legislation are more specific than the general safety and performance requirements set out in Schedule 3,

the device must also meet the essential health and safety requirements set out in Part 1 of Schedule 2 to the Supply of Machinery (Safety) Regulations 2008.

(17) This Part does not affect the application of the Ionising Radiation (Basic Safety Standards) (Miscellaneous Provisions) Regulations 2018(b) or any of the other measures which immediately before exit day transposed Council Directive 2013/59/Euratom(c) and which are retained EU law.

(18) This Part does not affect the power of the Secretary of State to restrict the use of any specific type of device in relation to aspects not covered by this Part.

(19) This Part does not affect the organisation, delivery or financing of health services and medical care including—

- (a) the rules relating to the supply of medical devices on a medical prescription;
- (b) requirements relating to—
 - (i) the dispensing of medical devices by healthcare institutions or healthcare professionals;
 - (ii) the use of certain medical devices being accompanied by specific professional counselling.

(20) This Part does not restrict the freedom of the press or freedom of expression in so far as those freedoms are guaranteed under the law.

(a) S.I. 2008/1597.

(b) S.I. 2018/482.

(c) OJ No. L 13, 17.1.2014, p. 1.

Definitions

69. In this Part and in Schedules 3 to 16—

“accessory for a medical device” means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical devices to specifically enable the medical device to be used in accordance with its intended purpose or to specifically and directly assist the medical functionality of the medical device in terms of its intended purpose;

“active device” means—

- (a) any device, which depends for its operation on a source of energy (other than that generated by the human body for that purpose, or by gravity) and which acts by changing the density of or converting that energy;
- (b) software;

but a device is not an active device if it is intended to transmit energy, substances or other elements between an active device and the patient without any significant change;

“adverse event” means any untoward occurrence, unintended disease or injury or any untoward clinical sign, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a clinical investigation, whether or not related to the investigational device;

“agglomerate”, in the definition of “nanomaterial”, means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the surface areas of the external components;

“aggregate”, in the definition of “nanomaterial”, means a particle comprised of strongly bound or fused particles;

“authorised health professional” has the same meaning as in regulation 2 of the Medicines for Human Use (Clinical Trials) Regulations 2004(a);

“authorised representative” means any person established outside the United Kingdom but within the European Economic Area who has received and accepted a written mandate from a manufacturer located outside the European Economic Area, to act on the manufacturer’s behalf in carrying out certain obligations under Regulation (EU) 2017/745;

“benefit-risk determination” means the analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer;

“CE marking of conformity” or “CE marking” means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Part and with any other applicable legislation;

“clinical benefit” means the positive impact of the device on the health of an individual, expressed in terms of a measurable, meaningful and relevant clinical outcome, including outcomes related to diagnosis, or positive impact on patient management or public health;

“clinical data” means information concerning safety or performance that is generated from the use of a device and is sourced from the following—

- (a) clinical investigations of the device concerned;
- (b) clinical investigations or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated;
- (c) reports published in peer reviewed scientific literature on other clinical experience of either the device or a device for which equivalence to the device in question can be demonstrated;

(a) S.I. 2004/1031, no relevant amendments.

(d) clinically relevant information coming from post market surveillance, in particular the post-market clinical follow up;

“clinical evaluation” means a systematic investigation and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance including clinical benefits, of the device when used as intended by the manufacturer;

“clinical evidence” means clinical data and clinical evaluation results pertaining to a device of a sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefits, when used as intended by the manufacturer;

“clinical investigation” mean a systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device;

“clinical investigation plan” means a document that describes the rationale, objectives, design, methodology, monitoring, statistical considerations, organisation and conduct of a clinical investigation;

“clinical performance” means the ability of a device, resulting from any direct or indirect medical effects which stem from its technical or functional characteristics, including diagnostic characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients, when used as intended by the manufacturer;

“common specifications” or “CS” must be construed in accordance with regulation 75;

“compatibility” means the ability of a device, including software, when used together with one or more other devices in accordance with its intended purpose to do any or all of the following—

- (a) perform without losing or compromising the ability to perform as intended,
- (b) integrate or operate without the need for modification or adaptation of any part of the combined devices,
- (c) be used together without conflict, interference or adverse reaction;

“conformity assessment” means the process demonstrating whether the requirements of this Part have been fulfilled;

“conformity assessment body” means a body that performs third-party conformity assessment activities including calibration, testing, certification and inspection;

“corrective action” means action taken to eliminate the cause of a potential or actual non-conformity or other undesirable situation;

“custom-made device” means any device specifically made in accordance with a written prescription of a registered medical practitioner, or any other person authorised to write a prescription by virtue of their professional qualification which gives, under that person’s responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual condition or need but the following devices are not custom-made devices—

- (a) mass-produced devices which need to be adapted to meet the specific requirements of a professional user, and
- (b) devices which are mass produced by means of an industrial manufacturing process in accordance with the written prescriptions of any authorised person;

“derivative” means a non-cellular substance which has been extracted from human or animal tissue or cells through a manufacturing process but where the final substance used for manufacturing of the device does not itself contain any cells or tissues;

“designated standard” has the same meaning as in regulation 3A;

“device deficiency” in relation to an investigational device means any inadequacy in its identity, quality, durability, reliability, safety or performance, including malfunction, use errors or inadequacy in information supplied by the manufacturer;

“Directive 2001/83/EC” means Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use^(a) as it applies in European Union law;

“distributor” means any person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting it into service;

“economic operator” means a manufacturer, an authorised representative, a UK responsible person, an importer, a distributor or a person referred to in regulation 87(1) and 87(4);

“ethics committee” means an independent body established or recognised under the Care Act 2014^(b) and empowered to give opinions for the purposes of this Part;

“falsified device” means any device with a false presentation of its identity, of its source or its CE marking certificates or documents relating to CE marking procedures, but a device is not a falsified device where the false presentation is unintentional;

“field safety notice” means a communication sent by the manufacturer to users or customers in relation to field safety corrective action;

“field safety corrective action” means corrective action taken by the manufacturer for technical or medical reasons to prevent or reduce the risk of serious incident in relation to a device made available on the market;

“fully refurbishing” (in the definition of “manufacturer”) means—

- (a) complete rebuilding of a device already placed on the market or put into service; or
- (b) the making of a new device from used devices, to bring it into conformity with this Part,

combined with the assignment of a new lifetime to the refurbished device;

“generic device group” means a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

“health institution” means an organisation (based in the United Kingdom) the primary purpose of which is the care or treatment of patients or the promotion of public health;

“implantable device” means any device (including those which are wholly or partly absorbed) which is intended through clinical intervention—

- (a) to be totally introduced into the human body and to remain in place after the procedure;
- (b) to replace an epithelial surface or the surface of the eye and to remain in place after the procedure; or
- (c) to be partially introduced into the human body and to remain in place for at least 30 days after the procedure;

“importer” means any person established within the United Kingdom that places on the market a device from a country outside the United Kingdom;

“incident” in relation to a device made available on the market means any malfunction or deterioration in its characteristics or performance of a device, including use-error due to its ergonomic features, any inadequacy in the information supplied by the manufacturer and any undesirable side effects;

“informed consent” means a subject’s free and voluntary expression of his or her willingness to participate in a particular clinical investigation, after having been informed of all aspects of the clinical investigation that are relevant to the subject’s

(a) OJ No. L 311, 28.11.2001, p. 67 (last amended by Directive 2012/26/EU of the European Parliament and of the Council of 25th October 2012 OJ No. L 299, 27.10.2012, p. 1).

(b) 2014 c. 23.

decision to participate or, in the case of minors or incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical investigation;

“instructions for use” means the information provided by the manufacturer to inform the user of the device’s intended purpose, proper use and of any precautions to be taken;

“intended purpose” means the use for which the device is intended as set out in—

- (a) the data supplied by the manufacturer on the label;
- (b) the instructions for use;
- (c) the promotional or sales material; or
- (d) promotional statements;

and as specified by the manufacturer in the clinical evaluation;

“interoperability” is the ability of two or more devices, including software from the same manufacturer or from different manufacturers, to do any or all of the following—

- (a) exchange information and use the information that has been exchanged for the correct execution of a specified function without changing the content of the data;
- (b) communicate with each other;
- (c) work together as intended;

“invasive device” means any device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body;

“investigational device” means a device that has been assessed in a clinical trial;

“investigator” means the individual responsible for the conduct of a clinical investigation at a clinical investigation site;

“label” means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices;

“lay person” means an individual who does not have formal education in the relevant field of healthcare or medical practice;

“legally designated representative”, has the meaning given to the term “legal representative” in Part 1 of Schedule 1(a) to the Medicines for Human Use (Clinical Trials) Regulations 2004;

“making available on the market” means any supply of a device, other than an investigational device, for distribution, consumption or use on the United Kingdom market in the course of a commercial activity, whether in return for payment or free of charge and related expressions must be construed accordingly;

“manufacturer” means a person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark;

“market surveillance” means the activities carried out and measures taken by the Secretary of State to check and ensure that devices comply with the requirements set out in this Part and do not endanger health safety or any other aspect of public interest protection;

“medical device” means—

- (a) any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes—

(a) the definition of “legal representative” in Part I of Schedule 1 to S.I. 2004/1031 was amended by S.I. 2006/1928 r. 27(1)(i)(aa) and (bb).

- (i) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- (ii) diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- (iii) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- (iv) providing information by means of in vitro examination of specimens derived from the human body, including organ, blood, and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means;

- (b) any device for the control or support of conception;
- (c) products specifically intended for the cleaning, disinfection or sterilisation of—
 - (i) medical devices referred to in sub-paragraphs (a) and (b);
 - (ii) accessories to medical devices; or
 - (iii) products listed in Schedule 16;

“minor” means a person under the age of 16 years;

“nanomaterial” means—

- (a) natural, incidental or manufactured material containing particles in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100nm; or
- (b) fullerenes, graphene flakes and single wall carbon nanotubes with one of more external dimensions below 1nm;

“non-viable” means having no potential for metabolism or multiplication;

“notified body” means a conformity assessment body designated in accordance with Regulation (EU) 2017/745;

“particle”, in the definition of “nanomaterial”, means a minute piece of matter with defined physical boundaries;

“performance” means the ability of a device to achieve its intended purpose as stated by the manufacturer;

“placing on the market” means the first making available of a device, other than an investigational device, on the United Kingdom market and related expressions must be construed accordingly;

“post-market surveillance” means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purposes of identifying any need to immediately apply any necessary corrective or preventative actions;

“post market clinical follow-up” (PMCF) means a continuous process of updating the clinical evaluation;

“procedure pack” means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose;

“putting into service” means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the United

Kingdom market for the first time for its intended purpose, and related expressions must be construed accordingly;

“recall” means any measure aimed at achieving the return of a device that has already been made available to the end user;

“Regulation (EU) 2017/745” means Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC^(a) as it has effect in European Union law;

“reprocessing” in relation to a used device means the process, including the cleaning, disinfection, sterilisation and related procedures, and the testing and restoration of the technical and functional safety of the device, carried out in order to allow its safe reuse;

“risk” means the combination of the probability of occurrence of harm and the severity of that harm;

“serious adverse event” means any adverse event that led to any of the following—

- (a) death;
- (b) serious deterioration in the health of the subject, that resulted in any of the following—
 - (i) life-threatening illness or injury,
 - (ii) permanent impairment of a body structure or body function,
 - (iii) hospitalisation or prolongation of hospitalisation,
 - (iv) medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or body function,
 - (v) chronic disease;
- (c) foetal distress, foetal death or congenital physical or mental impairment or birth defect;

“serious incident” means an incident that directly or indirectly led, might have led or might lead to any of the following—

- (a) the death of a patient, user or other person;
- (b) the temporary or permanent deterioration of a patient’s, user’s or other person’s state of health;
- (c) a serious public health threat;

“serious public health threat” means an event which could result in imminent risk of death, serious deterioration in the person’s state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place or time;

“single-use device” means a device that is intended to be used on one individual during a single procedure;

“sponsor” means any person who takes responsibility for the initiation of the clinical investigation, the management of the clinical investigation and the setting up of the financing of the clinical investigation;

“subject” means the individual who participates in the clinical investigation;

“system” means a combination of products, whether or not they are packaged together, which are intended to be interconnected or combined to achieve a specific medical purpose;

“Unique Device Identifier” (‘UDI’) means a series of numeric or alphanumeric characters that is created through internationally recognised and accepted device

(a) OJ No. L117, 5.5.2017, p. 1.

identification and coding standards and that allows unambiguous identification of specific devices on the market;

“UDI system”, “UDI database” and related expressions have the meaning given in, or are to be construed in accordance with, in Part C of Schedule 8;

“UK responsible person” has the same meaning as in regulation 2;

“user” means a healthcare professional or lay person who uses a device;

“withdrawal” means any measure aimed at preventing a device in the supply chain from being made available on the market.

Regulatory status of products and amendment of definitions

70.—(1) Subject to paragraph (3), the Secretary of State may by regulations determine whether or not a specific product, or category or group of products, falls within the definition of a medical device or an accessory to a medical device.

(2) The Secretary of State may by regulations amend the definition of “nanomaterial” and associated definitions in regulation 69—

- (a) in the light of technical and scientific progress; and
- (b) taking into account definitions agreed at international level.

(3) Before making regulations under paragraph (1), the Secretary of State must consult such persons, agencies or bodies as the Secretary of State considers it appropriate to consult.

Making available on the market and putting into service of devices, obligations of economic operators. Reprocessing, CE marking, Free Movement

Placing on the market and putting into service

71.—(1) A device to which this Part applies may be placed on the market or put into service only if it complies with this Part when duly supplied and properly installed, maintained and used in accordance with its intended purpose.

(2) A device to which this Part applies must meet the general safety and performance requirements set out in Schedule 3 which apply to it, taking into account its intended purpose.

(3) Demonstration of the general safety and performance requirements must include a clinical evaluation in accordance with regulation 102.

(4) Devices that are manufactured and used within health institutions must be considered as having been put into service.

(5) With the exception of the relevant safety and performance requirements set out in Schedule 3, the requirements of this Part do not apply to a device which is manufactured and used only within health institutions provided that—

- (a) the device is not transferred to another legal entity;
- (b) manufacture and use of the device occurs under appropriate quality management systems;
- (c) the health institution justifies in its documentation that the target patient group’s specific needs cannot be met, or cannot be met at the appropriate level of performance, by an equivalent device available on the market;
- (d) on request from the Secretary of State, the health institution provides the Secretary of State with information (which must include justification for its manufacturing, modification and use of such devices) on the use of the devices;
- (e) the health institution draws up and makes publically available a statement setting out—

- (i) the name and address of the manufacturing health institution,
 - (ii) the details necessary to identify the devices,
 - (iii) a declaration that the devices meet the general safety and performance requirements set out in Schedule 3 or, where applicable, information on which requirements are not fully met and a reasoned justification for not meeting those requirements;
- (f) the health institution draws up a document which makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices and the intended purpose, and which is sufficiently detailed to enable the Secretary of State to ascertain whether the general safety and performance requirements set out in Schedule 3 are met;
 - (g) the health institution takes all necessary measures to ensure that the device is manufactured in accordance with the documentation referred to in sub-paragraph (f);
 - (h) the health institution reviews experience gained from the clinical use of the devices and takes all necessary corrective actions.

(6) The Secretary of State may require a health institution which has complied with paragraph (5) to provide the Secretary of State with any further information about the devices which it has manufactured or used.

(7) The Secretary of State may restrict the manufacture and the use of a specified type of device manufactured in accordance with paragraph (5) and, for the purpose of considering such a restriction, must be permitted access to inspect the activities of health institutions.

(8) Paragraph (5) does not apply to devices that are manufactured on an industrial scale.

Distance Sales

72.—(1) A device offered by means of information society services to a person established in the United Kingdom must comply with this Part.

(2) A device which is—

- (a) not placed on the market;
- (b) used for the provision of a diagnostic or therapeutic service used in the context of a commercial activity, whether in return for payment or free of charge; and
- (c) offered by means of information society services or by other means of communication (whether directly or through intermediaries) to a person in the United Kingdom,

must comply with this Part.

(3) The Secretary of State may require a person offering a device, as described in paragraph (1) or providing a service described in paragraph (2), to provide the Secretary of State with a copy of the declaration of conformity relating to the device.

(4) In this regulation “information society service” means a “service” within the meaning of Article 1(1)(b) of Directive 2015/1535/EU of the European Parliament and of the Council of 9 September 2015^(a) (as it has effect in European Union law).

Claims

73. In the labelling, instructions for use, making available, putting into service or advertising of a device a person must not use text, names, trademarks, pictures, figurative or other signs that may mislead the user or the patient with regard to the device’s intended purpose, safety or performance by—

(a) OJ No. L 241, 17.9.2015, p. 1.

- (a) ascribing functions and properties to a device which the device does not have;
- (b) creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have;
- (c) failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose; or
- (d) suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out.

Use of designated standards

74.—(1) Devices that are in conformity with the designated standards, or the relevant parts of those standards, are presumed to be in conformity with the requirements of this Part covered by those standards or relevant parts of those standards.

(2) Paragraph (1) also applies to system or process requirements to be fulfilled in accordance with this Part by economic operators or sponsors, including those relating to quality management systems, risk management, post market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow up ('PMCF').

Common Specifications

75.—(1) Subject to paragraphs (5) and (6), in this Part “common specifications” (CS) means common specifications which are—

- (a) adopted by the European Commission in accordance with the procedure set down in Article 9(1) of Regulation (EU) 2017/745; and
- (b) designated by the Secretary of State by publishing a reference to the CS and maintaining that publication in a manner in which the Secretary of State considers appropriate.

(2) Devices that comply with CS adopted in accordance with paragraph (1) or specified in regulations made under paragraph (6), are presumed to be in conformity with the requirements of this Part covered by CS or the relevant parts of the CS.

(3) Manufacturers must comply with CS adopted in accordance with paragraph (1), or specified in regulations made under paragraph (6), unless they can justify that they have adopted solutions that ensure a level of safety and performance that is at least equivalent to the CS.

(4) When considering whether the manner of publication of a reference is appropriate in accordance with paragraph (1)(b), the Secretary of State must have regard to whether the publication will draw CS to the attention of any person who may have an interest in the CS.

(5) The Secretary of State may cancel the designation of CS by removing from publication the reference to the CS published in accordance with paragraph (1)(b) and, where the Secretary of State has done so, that CS is no longer a CS.

(6) Where the European Commission have not adopted a common specification but the Secretary of State is of the opinion that a common specification is necessary to address urgent public health concerns, the Secretary of State may by regulations specify a CS and publish the CS and designate it in accordance with paragraph (1)(b).

General obligations of manufacturers

76.—(1) When placing devices on the market or putting them into service, manufacturers must ensure that they have been designed and manufactured in accordance with the requirements of this Part.

(2) Manufacturers must establish, document, implement and maintain a system for risk management as described in paragraph 3 of Schedule 3.

(3) Manufacturers must conduct a clinical evaluation in accordance with the requirements set out in regulation 102 and Schedule 14 including PMCF.

(4) Manufacturers of devices other than custom-made devices must draw up and keep up to date technical documentation for those devices.

(5) The technical documentation in paragraph (4) must—

- (a) be such as to allow the conformity of the device with the requirements of this Part to be assessed;
- (b) include the elements set out in Schedules 4 and 5.

(6) Where the Secretary of State considers it necessary in the light of technical progress, the Secretary of State may by regulations amend Schedules 4 and 5.

(7) Manufacturers of custom-made devices must draw up, keep up to date and keep available for the Secretary of State documentation in accordance with paragraph 12(2) of Schedule 13.

(8) Where compliance with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than custom-made or investigational devices, must draw up a declaration of conformity in accordance with regulation 84, and affix the CE marking of conformity in accordance with regulation 85.

(9) Manufacturers must comply with the obligations relating to the UDI system referred to in regulation 91 and with the registration obligations referred to in regulations 93 and 95.

(10) Manufacturers must keep the technical documentation, the declaration of conformity and, if applicable, a copy of any relevant certificate (including amendments and supplements), available for the Secretary of State—

- (a) in the case of implantable devices for a period of at least 15 years after the last device covered by the declaration of conformity has been placed on the market;
- (b) in the case of all other devices, for a period of at least 10 years after the last device covered by the declaration of conformity has been placed on the market.

(11) The Secretary of State may require a manufacturer to provide the technical documentation and such a request may be for the entirety of the documentation or for a summary.

(12) A manufacturer with a registered place of business outside the United Kingdom must ensure that the person responsible for placing the device on the United Kingdom market has the necessary documentation permanently available.

(13) Manufacturers must ensure that procedures are in place to keep series production in conformity with the requirements of this Part including—

- (a) ensuring that changes in device design or characteristics and changes in the designated standards or CS by reference to which the conformity of the device is declared are adequately, and in a timely manner, taken into account;
- (b) ensuring that for devices (other than investigational devices) a quality management system, which is proportionate to the risk class and type of device is established, documented, implemented, maintained, kept up to date and continually improved.

(14) The quality management system required by paragraph (13) must—

- (a) cover all parts and elements of the manufacturer's organisation dealing with the quality of processes, procedures and devices;
- (b) govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of this Part;
- (c) provide details of at least the following—

- (i) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system;
 - (ii) the identification of applicable general safety and performance requirements and exploration of options to address those requirements;
 - (iii) the responsibility of the management;
 - (iv) resource management, including selection and control of suppliers and sub-contractors;
 - (v) risk management as set out in paragraph 3 of Schedule 3;
 - (vi) clinical evaluation in accordance with regulation 102 and Schedule 14, including PMCF;
 - (vii) product realisation, including planning, design, development, production and service provision;
 - (viii) verification of the UDI assignments made in accordance with regulation 91 to all relevant devices and ensuring consistency and validity of information provided in accordance with regulation 93;
 - (ix) setting-up, implementation and maintenance of a post-market surveillance system, in accordance with regulation 121;
 - (x) processes for handling communication with the Secretary of State (and authorities in other relevant states), notified bodies, other economic operators, customers and any other stakeholders;
 - (xi) processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;
 - (xii) management of corrective and preventive actions and verification of their effectiveness;
 - (xiii) processes for monitoring and measurement of output, data analysis and product improvement.
- (15) Manufacturers must implement and keep up to date the post market surveillance system in accordance with regulation 121.
- (16) Manufacturers must ensure that—
- (a) the device is accompanied by the information set out in paragraph 23 of Schedule 3;
 - (b) the particulars on the label are indelible, easily legible and clearly comprehensible to the intended user or patient.
- (17) Manufacturers who consider or have reason to believe that a device which they have placed on the market or put into service is not in conformity with this Part must—
- (a) immediately take the necessary corrective action to bring that device into conformity, to withdraw it or to recall it, as appropriate;
 - (b) inform the distributors of the device in question and, where applicable, the authorised representative, the UK responsible person and importers accordingly;
 - (c) where the device presents a serious risk, immediately inform the Secretary of State and, where applicable, the notified body that issued a certificate for the device, in particular, of the non-compliance and of any corrective action taken.
- (18) Manufacturers must have a system for recording and reporting incidents and field safety corrective actions as described in regulation 125 and regulation 126.
- (19) Manufacturers must, when they are required to do so by the Secretary of State in relation to a device—
- (a) provide the Secretary of State with all the information and documentation necessary to demonstrate the conformity of the device;

- (b) cooperate with the Secretary of State on any corrective action to be taken to eliminate or, if that is not possible, mitigate the risks posed by the device which they have placed on the market or put into service;
- (c) provide samples of the device free of charge or, where that is impracticable, grant access to the device.

(20) A manufacturer who fails to cooperate with a requirement made under paragraph (19) may be subject to enforcement action under Part VII or to any other enforcement measures available to the Secretary of State under consumer protection legislation.

(21) Subject to the Data Protection Act 2018^(a) and to the protection of any intellectual property rights, the Secretary of State must, where there is reason to believe that a device has caused damage and where a request is made in writing by a person in sub-paragraph (a), (b) or (c) facilitate the provision of the information and documentation mentioned in paragraph (19) to—

- (a) any person who has been or could have been injured by the device;
- (b) any person entitled to bring an action on behalf of the person in sub-paragraph (a); or
- (c) any other person reasonably believed to have been affected by the damage caused by the device.

(22) The Secretary of State need not comply with paragraph (21) where disclosure of the information and documentation is to be dealt with in legal proceedings.

(23) Where a manufacturer has entered into an arrangement with another person to design or manufacture a device, the identity of that other person must form part of the information submitted in accordance with regulation 95.

(24) Manufacturers must, taking account of the risk class of a device and the type of device which they produce and the size of their enterprise, hold sufficient insurance (or equivalent financial resources) to meet any potential financial liability arising from damage caused by each such device.

UK responsible person

77. A person regarded as the UK responsible person must—

- (a) ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;
- (b) keep available for inspection by the Secretary of State a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements;
- (c) in response to a request from the Secretary of State, provide the Secretary of State with all the information and documentation necessary to demonstrate the conformity of a device;
- (d) forward to the manufacturer any request by the Secretary of State for samples, or access to a device and ensure that the Secretary of State receives the samples or has been given access to the device;
- (e) cooperate with the Secretary of State on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;
- (f) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;

^(a) 2018 c. 12.

- (g) terminate the legal relationship with the manufacturer if the manufacturer acts contrary to its obligations under these Regulations and inform the Secretary of State and, if applicable, the relevant notified body of that termination.

General obligations of importers

78.—(1) Importers must only place devices on the market which are in conformity with this Part.

(2) In order to place a device on the market, importers must ensure that—

- (a) the device has been CE marked and that the declaration of conformity of the device has been drawn up;
- (b) its manufacturer or, if applicable its authorised representative, is identified;
- (c) the device is labelled in accordance with this Part and accompanied by the required instructions for use;
- (d) where applicable, a UDI has been assigned by the manufacturer in accordance with regulation 91.

(3) Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Part, the importer—

- (a) must not place the device on the market until it has been brought into conformity; and
- (b) must inform the manufacturer.

(4) Where an importer considers or has reason to believe that a device presents a serious risk or is a falsified device, the importer must also inform the Secretary of State.

(5) Importers must indicate on the device or on its packaging or in a document accompanying the device—

- (a) their name,
- (b) if applicable, their registered trade name or registered trade mark,
- (c) if applicable, their registered place of business or the address at which they can be contacted.

(6) Importers must ensure that any additional label does not obscure information on the label provided by the manufacturer.

(7) Importers must verify that the device has been registered with the Secretary of State and must add their name to the registration.

(8) Importers must—

- (a) ensure that while a device is under their responsibility, storage or transport conditions do not jeopardise a device's compliance with the general safety and performance requirements set out in Schedule 3;
- (b) comply with any conditions set by the manufacturer.

(9) Importers must keep a register of—

- (a) complaints about devices;
- (b) non-conforming devices;
- (c) recalls of devices;
- (d) withdrawals of devices;

and must provide the manufacturer or distributor with any information reasonably requested by them in order to allow them to investigate complaints.

(10) Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Part must—

- (a) inform the manufacturer and, if applicable, the authorised representative and the UK responsible person;

- (b) cooperate with the manufacturer and the Secretary of State to ensure the necessary corrective action to bring the device into conformity, to withdraw or recall it, is taken.

(11) Where a device presents a serious risk, importers must immediately inform the Secretary of State and, if applicable, the notified body that issued the certificate and must give details of the non-compliance giving rise to the risk and of any corrective action.

(12) Importers who receive complaints from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market must immediately inform the manufacturer and if applicable the authorised representative and the UK responsible person.

(13) Importers must keep the declaration of conformity and any relevant certificate for the period referred to in regulation 76(10).

(14) Importers must, if required by the Secretary of State to do so—

- (a) cooperate with the Secretary of State on any action to eliminate or, if that is not possible, mitigate the risks posed, by devices which they have placed on the market;
- (b) provide samples of a device or, if that is impractical, grant the Secretary of State access to the device.

General obligations of distributors

79.—(1) When making a device available on the market, distributors must, in the context of their activities, comply with the requirements of this Part.

(2) Before making a device available on the market, distributors must ensure that all the following requirements are met—

- (a) the device has been CE marked and the declaration of conformity of the device has been drawn up;
- (b) the device is accompanied by the information supplied by the manufacturer in accordance with regulation 76(16);
- (c) for imported devices, the importer has complied with the requirements set out in regulation 78(5);
- (d) that, where applicable, a UDI has been assigned by the manufacturer.

(3) In order to meet the requirements of sub-paragraphs (a), (b) and (d) of paragraph (2) the distributor may apply a sampling method that is representative of the devices supplied by the distributor.

(4) Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Part, the distributor must—

- (a) not make the device available on the market until it has been brought into conformity;
- (b) inform the manufacturer;
- (c) where applicable, inform the importer, the authorised representative and the UK responsible person.

(5) Where a distributor considers or has reason to believe that the device presents a serious risk or is a falsified device, the distributor must, in addition to complying with paragraph (4) also inform the Secretary of State.

(6) Distributors must ensure that, while the device is under their responsibility, storage and transport conditions comply with the conditions set by the manufacturer.

(7) Where a distributor considers or has reason to believe that a device which that distributor has made available on the market is not in conformity with this Part, the distributor must—

- (a) inform the manufacturer and where applicable, the manufacturer's authorised representative, the UK responsible person and the importer;
- (b) cooperate with the manufacturer and with the Secretary of State and, where applicable, the manufacturer's authorised representative, UK responsible person and the importer to ensure the necessary corrective action to bring the device into conformity, to withdraw or to recall the device, is taken.

(8) Where the distributor considers or has reason to believe that a device which it has made available on the market presents a serious risk it must immediately inform the Secretary of State.

(9) Distributors must, unless the relevant information will be provided by another economic operator, upon request by the Secretary of State, provide the Secretary of State with all the information at their disposal and necessary to demonstrate the conformity of the device.

(10) Distributors must, at the Secretary of State's request—

- (a) cooperate with the Secretary of State on any action taken to eliminate the risks posed by devices which they have made available on the market;
- (b) provide free samples of the device or, if that is impractical, grant the Secretary of State access to the device.

Person responsible for regulatory compliance

80.—(1) Subject to paragraph (4), manufacturers must have available within their organisation at least one person who is responsible for regulatory compliance and who possesses the requisite expertise in the field of medical devices.

(2) Subject to paragraph (3), the requisite expertise in paragraph (1) may be demonstrated by either of the following—

- (a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised by the Secretary of State as equivalent in—
 - (i) law,
 - (ii) medicine,
 - (iii) pharmacy,
 - (iv) engineering, or
 - (v) another relevant scientific discipline,and at least one year of professional experience in regulatory affairs management relating to medical devices;
- (b) 4 years of professional experience in—
 - (i) regulatory affairs, or
 - (ii) in quality management systems relating to medical devices.

(3) Where a manufacturer manufactures custom-made devices the requisite experience may be demonstrated by having at least 2 years of professional expertise within a relevant field of manufacturing.

(4) Micro and small businesses, within the meaning of Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises^(a) (as it has effect in European Union law), are not required to have a person responsible for regulatory compliance within their organisation but must have such a person permanently and continuously at their disposal.

(a) OJ No. L 124, 20.5.2003, p. 36.

(5) The person responsible for regulatory compliance must at least be responsible for ensuring that—

- (a) the conformity of devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before the device is released;
- (b) the technical documentation and declaration of conformity are drawn up and kept up-to date;
- (c) the post market surveillance obligations are complied with in accordance with regulation 76(15);
- (d) the reporting obligations referred to in regulations 125 to 128 are fulfilled;
- (e) in the case of investigational devices, the statement referred to in paragraph 4(1) of Chapter II of Schedule 15 is issued.

(6) If a number of persons are jointly responsible for regulatory compliance their respective areas of responsibility must be stipulated in writing.

(7) The person responsible for regulatory compliance must not suffer any disadvantage within the manufacturer's organisation in relation to the person's proper fulfilment of their duties, regardless of whether or not they are employees of the organisation.

Cases in which obligations of manufacturers apply to importers, distributors or other persons

81.—(1) A distributor, importer or other person has the obligations of a manufacturer if that person does any of the following—

- (a) makes available on the market a device under its name, registered trade name or registered mark, except in cases where a distributor or importer enters into an agreement with manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Part;
- (b) changes the intended purpose of a device already placed on the market or put into service;
- (c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

(2) Paragraph (1) does not apply to a person who, without changing its intended purpose, assembles or adapts for an individual patient a device which is already on the market.

(3) For the purposes of paragraph (1)(c) the following are not to be considered to be a modification of a device that could affect its compliance with the applicable requirements—

- (a) provision of information supplied by the manufacturer, in accordance with paragraph 23 of Schedule 3, relating to a device already on the market and of further information which is necessary in order to market the device;
- (b) changes to the outer packaging of a device already placed on the market, including a change of the pack size, if the repackaging is carried out in such conditions that the original condition of the device cannot be affected but, for devices placed on the market in a sterile condition, the original condition of the device must be presumed to be adversely affected if the packaging necessary for maintaining the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.

(4) A distributor or importer that carries out any of the activities mentioned in paragraph (3) must indicate on the device or, where that is impractical, on the packaging or in a document accompanying the device—

- (a) the activity carried out;
- (b) the name of the importer or distributor;

- (c) any registered trade name or trade mark of the importer or distributor;
 - (d) the registered place of business and the address at which the importer or distributor can be contacted.
- (5) Distributors and importers who carry out the activities in paragraph (3) must have a quality management system in place which—
- (a) ensures that the activities in paragraph (3) are performed by a means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy;
 - (b) contains procedures which ensure that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in order to respond to safety issues or to bring the device into conformity with this Part.
- (6) At least 28 days prior to making the relabelled or repackaged device available on the market, distributors or importers carrying out any of the activities in paragraph (3) must—
- (a) inform the manufacturer and the Secretary of State of the intention to make a relabelled or repackaged device available;
 - (b) upon request, provide the manufacturer and the Secretary of State with a sample or mock-up of the relabelled or repackaged device (including any translated label and instructions for use);
 - (c) submit to the Secretary of State a certificate, issued by a notified body designated for the type of devices that are subject to activities mentioned in paragraph (3), attesting that the quality management system of the distributor or importer complies with the requirements laid down in paragraph (4).

Single-use devices and their reprocessing

82.—(1) Reprocessing and further use of single-use devices may only take place in accordance with this Part.

(2) Subject to paragraph (4), any person who reprocesses a single-use device to make it suitable for further use must be considered a manufacturer of the reprocessed device and must assume the obligations of a manufacturer in this Part.

(3) A person who reprocesses a device must be considered to be the producer for the purposes of Part I of the 1987 Act.

(4) Where single-use devices are reprocessed and used within a health institution, the Secretary of State may direct that not all the rules relating to manufacturers obligations laid down in this Part apply provided that the following conditions are met—

- (a) the safety and performance of the reprocessed device is equivalent to that of the original device and the requirements of regulation 71(5) are complied with;
- (b) the reprocessing is performed in accordance with the CS detailing requirements concerning—
 - (i) risk management, including the analysis of the construction and material, related properties of the device (reverse engineering) and procedures to detect changes in the design of the original device as well as of its planned application after reprocessing;
 - (ii) the validation of procedures for the entire process, including cleaning steps;
 - (iii) the product release and performance testing;
 - (iv) the quality management system;
 - (v) the reporting of incidents involving devices that have been reprocessed; and
 - (vi) the traceability of reprocessed devices.

(5) The Secretary of State must encourage and may require health institutions to provide information to patients on the use of reprocessed devices within the health institution and,

where appropriate, any other information on the reprocessed devices that patients are treated with.

(6) The Secretary of State may also direct that the provisions of paragraph (4) apply where single-use devices are processed by an external reprocessor at the request of a health institution, provided that the reprocessed device in its entirety is returned to the health institution and the external reprocessor complies with the requirements of paragraph (4).

(7) Reprocessing of devices may only be performed in accordance with any designated standards that cover the matters outlined in paragraph (4)(b) and may not be performed unless such designated standards have been adopted.

(8) Only single-use devices that have been placed on the market in accordance with Part II or this Part of these Regulations may be reprocessed.

(9) Only reprocessing of single-use devices that are considered safe according to the latest scientific evidence may be carried out.

(10) The name and address of the person referred to in paragraph (2) and the other relevant information referred to in paragraph 23 of Schedule 3 must be indicated on the label and, where applicable, in the instructions for use of the reprocessed device.

(11) The name and address of the manufacturer of the original single-use device must no longer appear on the label, but must be mentioned in the instructions for use of the reprocessed device.

Implant card and information to be supplied to the patient with an implanted device

83.—(1) The manufacturer of an implantable device must provide, together with the device, the following—

- (a) information allowing the identification of the device, including the device name, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer;
- (b) any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference with reasonably foreseeable external influences, medical examinations or environmental conditions;
- (c) any information about the expected lifetime of the device and any necessary follow-up;
- (d) any other information to ensure safe use of the device by the patient, including the information in paragraph (u) of sub-paragraph (6) of paragraph 23 of Schedule 3.

(2) The information referred to in paragraph (1)—

- (a) must be provided, for the purpose of making it available to the particular patient who has been implanted with the device, by means that allow rapid access to the information;
- (b) must be written in a way that is readily understood by a lay person and must be updated where appropriate, such updates being made available to the patient on the manufacturer's website;
- (c) for the information referred to in paragraph (1)(a), must be on an implant card delivered with the device.

(3) Health institutions must—

- (a) make the information referred to in paragraph (1) available by means which allow rapid access to that information, to any patients who have been implanted with the device,
- (b) provide those patients with the implant card.

(4) The requirements of this regulation do not apply to the following implants—

- (a) Sutures;
- (b) Staples;

- (c) dental fillings;
- (d) dental braces;
- (e) tooth crowns;
- (f) screws;
- (g) wedges;
- (h) plates;
- (i) wires;
- (j) pins;
- (k) clips;
- (l) connectors.

(5) The Secretary of State may, by regulations, amend the list in paragraph (4) by adding other types of implants to it or by removing implants from the list.

Declaration of conformity

84.—(1) The declaration of conformity must state that the requirements specified in this Part or, where relevant, in Regulation (EU) 2017/745 or both sets of requirements, have been fulfilled in relation to the device that is covered.

(2) The manufacturer must continuously update the declaration of conformity and the declaration of conformity must—

- (a) contain the information set out in Schedule 6;
- (b) be in English.

(3) Where a device is subject to other legislation which requires a declaration of conformity by the manufacturer, a single declaration of conformity must be drawn up in respect of all the legislation applicable to the device and must contain the information required for identification of the legislation to which the declaration relates.

(4) By drawing up the declaration of conformity, the manufacturer assumes responsibility for compliance with the requirements of this Part and all other legislation applicable to the device.

CE marking of conformity

85.—(1) Devices, other than custom-made or investigational devices, considered to be in conformity with the requirements of this Part must bear the CE marking of conformity set out in Schedule 7.

(2) The CE marking—

- (a) must be affixed visibly, legibly and indelibly to the device or its sterile packaging;
- (b) where such affixing is not possible or not warranted on account of the nature of the device, must be affixed to the packaging;
- (c) must also appear in any instructions for use and on any sales packaging.

(3) The CE marking must be affixed before the device is placed on the market and may be followed by a pictogram or any other mark indicating a special risk or use.

(4) Where applicable, the CE marking must be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in regulation 98 and the identification number must also be indicated in any promotional material which mentions that a device fulfils the requirements for CE marking.

(5) Where devices are subject to other legislation which also provides for the affixing of the CE marking, the CE marking must indicate that the devices also fulfil the requirements of that other legislation.

Devices for special purposes

86.—(1) The Secretary of State must not create obstacles to—

- (a) investigational devices being supplied to an investigator for the purpose of a clinical investigation if they meet the requirements of this Part;
- (b) custom made devices which meet the requirements of this Part.

(2) Other than investigational devices which already bear a CE marking, the devices to which paragraph (1) relates must not bear a CE marking.

(3) Custom-made devices must be accompanied by the statement referred to in paragraph 1 of Schedule 13 which must be identified by name, an acronym or a numerical code.

(4) The Secretary of State may require a manufacturer of a custom-made device to send to the Secretary of State a list of such devices.

(5) The Secretary of State must not create obstacles to the showing of devices, which do not comply with this Part, at trade fairs, exhibitions, demonstrations or similar events provided that the following conditions are met—

- (a) a visible sign clearly indicates that such a device is intended for presentation or demonstration purposes;
- (b) that such a device cannot be made available until it has been brought into compliance with this Part.

System and procedure packs

87.—(1) A person who combines devices bearing a CE mark with other devices or products listed in paragraph (2), in a manner that is compatible with the intended purpose of the devices or other products and within the limits specified by their manufacturer, for the purpose of placing them on the market as a system or procedure pack, must draw up a statement.

(2) The devices or other products mentioned in paragraph (1) are—

- (a) other devices bearing the CE marking;
- (b) in vitro diagnostic medical devices bearing the CE marking in conformity with Part IX;
- (c) other products which conform with legislation that applies to them only where they are used within a medical procedure or their presence in the system or procedure pack is otherwise justified.

(3) In the statement required by paragraph (1), the person must declare that—

- (a) they have verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturer's instructions and have carried out their activities in accordance with those instructions;
- (b) they packaged the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together;
- (c) the activity of combining devices and, if applicable, other products as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.

(4) Any person who sterilises system or procedure packs referred to in paragraph (1) for the purpose of placing them on the market, may apply either the procedure set out in Schedule 10 or the procedure set out in Part A of Schedule 12 and must draw up a statement declaring that the sterilisation has been carried out in accordance with the manufacturer's instructions.

(5) Where —

- (a) a system or procedure pack consists of devices or products which do not bear the CE marking;
 - (b) the chosen combination of devices is not compatible (having regard to their original intended purpose); or
 - (c) sterilisation has not been carried out in accordance with the manufacturer's instructions the system or procedure pack must be treated as a device in its own right, must be subject to the relevant conformity assessment procedure in regulation 98 and the person who creates the system or procedure pack must assume the obligations of a manufacturer.
- (6) The system or procedure packs referred to in paragraph (1)—
- (a) must not themselves bear an additional CE marking;
 - (b) must bear the name, registered trade name or registered trade mark and the address of the person intending to place a system or procedure pack on the market in accordance with paragraphs (1) or (3);
 - (c) must be accompanied by the information referred to in paragraph 23 of Schedule 3.
- (7) The statement referred to in paragraph (2) must be kept, in respect of the devices which have been combined, at the disposal of the Secretary of State for the period specified in regulation 76(10) and, where different periods would apply to different devices within the system or procedure pack, the longest period must apply.

Parts and components

88.—(1) Any person who makes available on the market an item specifically intended to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or restore the function of the device without changing its performance or safety characteristics or its intended purpose, must—

- (a) ensure that the item does not adversely affect the safety and performance of the device; and
- (b) keep available supporting evidence of that for the Secretary of State.

(2) An item that is intended specifically to replace a part or component of a device and that significantly changes the performance or safety characteristics or the intended purpose of the device is considered to be a device and must meet the requirements laid down in this Part.

Identification and traceability of devices, registration of devices and of economic operators, summary of safety and performance and clinical performance

Identification within the supply chain

89.—(1) Distributors and importers must cooperate with manufacturers (or, if applicable, the manufacturer's authorised representative and UK responsible person) to achieve an appropriate level of traceability of devices.

(2) Economic operators must, where applicable, be able to identify the following to the Secretary of State, for the period referred to in regulation 76(10)—

- (a) any economic operator to whom they have directly supplied a device;
- (b) any economic operator who has directly supplied them with a device;
- (c) any health institution or healthcare professional to which they have directly supplied a device.

Medical devices nomenclature

90.—(1) The Secretary of State must ensure that an internationally recognised medical devices nomenclature is available free of charge to manufacturers and other persons required by this Part to use that nomenclature.

(2) The Secretary of State must also endeavour to ensure that nomenclature is available to other stakeholders free of charge, where reasonably practicable.

Unique device identification system

91.—(1) ‘UDI system’ must consist of –

- (a) production of a UDI that comprises—
 - (i) a UDI device identifier (‘UDI-DI’) specific to a manufacturer and a device, providing access to the information laid down in Part B of Schedule 8;
 - (ii) a UDI production identifier (‘UDI-PI’) that identifies the unit of device production and if applicable the packaged devices, as specified in Part C of Schedule 8;
- (b) placing of the UDI on the label of the device or on its packaging;
- (c) storage of the UDI by economic operators, health institutions and healthcare professionals, in accordance with the conditions laid down in paragraphs (8) and (9) of this regulation respectively;
- (d) establishment of an electronic system for Unique Device Identification (‘UDI database’) in accordance with regulation 94.

(2) Before placing a device, other than a custom-made device, on the market, the manufacturer must assign to the device and, if applicable, to all higher levels of packaging, a UDI created in compliance with the rules of an issuing entity.

(3) Before a device, other than a custom-made or investigational device, is placed on the market the manufacturer must ensure that the information referred to in Part B of Schedule 8 about the device is correctly submitted and transferred to the UDI database referred to in regulation 94.

(4) UDI carriers must be placed on the label of the device and on all higher levels of packaging but “higher levels of packaging” does not include shipping containers.

(5) The UDI must be used for reporting serious incidents and field safety corrective actions in accordance with regulation 125.

(6) The Basic UDI-DI of the device must appear on the declaration of conformity referred to in regulation 84.

(7) As part of the technical documentation referred to in Schedule 4 the manufacturer must keep up-to-date a list of the UDIs that it has assigned.

(8) Economic operators must store and keep, preferably by electronic means, the UDI of the devices which they have supplied or with which they have been supplied, if those devices belong to—

- (a) Class III implantable devices;
- (b) the devices, categories or groups of devices determined by regulations made under paragraph (12)(a).

(9) Health institutions must store and keep, preferably by electronic means, the UDI of the devices which they have supplied or with which they have been supplied, if those devices are Class III implantable devices.

(10) For devices other than Class III implantable devices, the Secretary of State may require, health institutions to store and keep, preferably by electronic means, the UDI of the devices with which they have been supplied.

(11) The Secretary of State may require healthcare professionals to store and keep, preferably by electronic means, the UDI of the devices with which they have been supplied.

(12) The Secretary of State may by regulations—

- (a) determine the devices, categories or groups of devices mentioned in paragraph (8);
- (b) amend the list of information set out in Part B of Schedule 8 in the light of technical progress;
- (c) amend Schedule 8 in the light of international developments and technical progress.

(13) In this regulation, regulation 93 and Schedule 8 “issuing entity” means an organisation designated by the European Commission for the purpose of issuing UDIs pursuant to Regulation (EU) 2017/745.

UDI database

92.—(1) The Secretary of State must set up and manage a UDI database to validate, collate, process and make available to the public the information mentioned in Part B of Schedule 8.

(2) The UDI database may be a separate database or form part of a larger database which may include the system required by regulation 94.

(3) In designing the UDI database, the Secretary of State must—

- (a) take into account the general principles set out in paragraph 5 of Part C Schedule 8;
- (b) ensure that UDI-PIs and commercially confidential product information cannot be included in the database.

(4) The core data elements to be provided to the UDI database, referred to in Part B of Schedule 8 must be accessible to the public free of charge.

(5) The technical design of the UDI database must ensure maximum accessibility to information, including multi-user access and automatic uploads and downloads of that information.

(6) The Secretary of State must provide for technical and administrative support to manufacturers and other users of the UDI database.

(7) The UDI database must also be set up to manage the information and core data elements in respect of devices falling under Part IX.

Registration of devices

93.—(1) Before placing a device, other than a custom-made device, on the market, the manufacturer must, in accordance with the rules of the issuing entity referred to in regulation 91(13), assign a Basic UDI-DI, as defined in Part C of Schedule 8, to the device and must provide it to the Secretary of State together with the other core data elements referred to in—

- (a) Part B of Schedule 8 related to that device;
- (b) Paragraph 2 in Part A of Schedule 8.

(2) Before placing on the market a system or procedure pack pursuant to regulation 87(1) and (4), that is not a custom-made device, the person responsible must assign to the system or procedure pack, in compliance with the rules of the issuing entity, a Basic UDI-DI and must provide it to the UDI database together with the other core data elements referred to in Part B of Schedule 8 related to that system or procedure pack.

(3) Where a manufacturer is not established in the United Kingdom, the UK responsible person must ensure that the manufacturer has complied with paragraphs (1) or (2).

Electronic system for registration of devices and economic operators

94. The Secretary of State must set up and manage an electronic system to—

- (a) create a registration number for the purpose of identifying the manufacturer and, where applicable, the importer, authorised representative, the UK responsible person and distributor; and
- (b) register the information provided for in paragraph 1 and paragraph 2 (with the exception of paragraph 2(b)) of Part A of Schedule 8.

Registration of economic operators

95.—(1) No person may place a device, other than a custom made device, on the market, unless that person is—

- (a) established in the United Kingdom;
- (b) has complied with paragraph (2).

(2) Before placing a device, other than a custom made device, on the market—

- (a) a manufacturer, falling within paragraph (1)(a), must register with the electronic system referred to in regulation 94 and provide the information set out in paragraph 1 of Part A of Schedule 8;
- (b) where there is no manufacturer established in the United Kingdom, the person placing the product on the market is to be regarded as the UK responsible person and that person must register with the electronic system referred to in regulation 94 and provide the information set out in paragraph 1 of Part A of Schedule 8.

(3) Unless they have already registered as a person within paragraph (2)(b), importers must also provide the relevant information in paragraph 1 of Part A of Schedule 8.

(4) Within one week of a change occurring in the information referred to in paragraph (2), the person providing the relevant information in accordance with paragraphs (2) or (3) must update the information in the electronic system referred to in regulation 94.

(5) Not later than one year after the submission of the information referred to in paragraph (2), and every second year after that, the person must confirm the accuracy of the information.

(6) Notwithstanding the person's responsibility for the accuracy of the information, the Secretary of State must verify the information provided under paragraph (2).

(7) The information entered in the electronic system must be accessible to the public.

(8) The Secretary of State may use the information provided under paragraph (2) for the purpose of charging a fee in connection with carrying out the activities set out in this Part.

Summary of safety and clinical performance

96.—(1) For implantable devices and for Class III devices, other than custom-made or investigational devices, a manufacturer must draw up a summary of safety and clinical performance.

(2) The summary of safety and clinical performance must be written in a way that is clear to the intended user and, if applicable, to the patient and must be made available to the public.

(3) The manufacturer must state on the label or the instructions for use where the summary of safety and clinical performance can be found.

(4) The summary of safety and clinical performance must include at least the following—

- (a) identification of the device and the manufacturer including the Basic UDI-DI;
- (b) the intended purpose of the device, any indications or contraindications and the target populations;

- (c) a description of the device, including a reference to any previous generations or variants and a description of the differences;
- (d) where relevant, a description of any accessories, other devices and products which are intended to be used in combination with the device;
- (e) possible diagnostic therapeutic alternatives;
- (f) the summary of clinical evaluation as referred to in Schedule 14, and relevant information on post-market clinical follow-up;
- (g) suggested profile and training for users;
- (h) information on any residual risks and any undesirable side effects, warnings and precautions.

(5) The Secretary of State may by regulations set out the form and presentation of the data elements to be included in the summary of safety and clinical performance.

Classification and conformity assessment

Classification of devices

97. Devices must be divided into Classes I, IIa, IIb and III according to the classification rules in Schedule 9.

Conformity assessment procedures

98.—(1) Subject to regulation 100, before placing a device on the market, putting a device into service or making a device available on the market, a person must ensure that the manufacturer has undertaken an assessment of the conformity of the device in accordance with the applicable conformity assessment procedures outlined in paragraphs (2) to (10) and set out in Schedules 10 to 12.

(2) Class III devices, other than custom-made or investigational devices, must be subject to—

- (a) a conformity assessment as specified in Chapters I and III of Schedule 10; or
- (b) a conformity assessment as specified in Schedule 11 coupled with a conformity assessment as specified in Schedule 12.

(3) Subject to paragraph (4), Class IIb devices, other than customer-made or investigational devices, must be subject to a conformity assessment—

- (a) as specified in Chapters I and III of Schedule 10, including an assessment of the technical documentation as specified in paragraph 2 of that Schedule of at least one representative device per generic device group; or
- (b) a conformity assessment based on type examination as specified in Schedule 11 coupled with a conformity assessment based on product conformity verification as specified in Schedule 12.

(4) For Class IIb implantable devices, except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors, the assessment of the technical documentation as specified in paragraph 2 of Schedule 10 must apply for every device.

(5) The Secretary of State may, by regulations, add to, or remove items from, the list of exempted Class IIb devices in paragraph (4), but the Secretary of State may only add to that list where the technology is well established and where the technology is similar to the devices listed.

(6) Class IIa devices, other than custom made or investigational devices, must be subject to—

- (a) a conformity assessment as specified in Chapters I and III of Schedule 10, including an assessment of the technical documentation as specified in paragraph 2

of that Schedule of at least one representative device for each category of devices;
or

- (b) a conformity assessment specified in paragraph 8 or paragraph 12 of Schedule 12 along with the technical documentation (as set out in Schedules 4 and 5 for at least one representative device for each category of device.

(7) Subject to paragraph (8), Class I devices, other than custom-made or investigational devices, must be subject to a conformity assessment procedure which consists of the manufacturer issuing the declaration of conformity referred to in regulation 84 after drawing up the technical documentation set out in Schedules 4 and 5.

(8) If Class I devices are placed on the market in sterile condition, have a measuring function or are reusable surgical instruments, the manufacturer must apply the procedures set out in—

- (a) Chapters I and III of Schedule 10; or
- (b) Part A of Schedule 12.

(9) Subject to paragraph (10), custom-made devices must be subject to the conformity assessment procedure set out in Schedule 13 and draw up the statement set out in paragraph 1(g) of that Schedule.

(10) Class III custom made implantable devices must, in addition to the procedure in paragraph (9), be subject to—

- (a) the conformity assessment specified in Chapter I of Schedule 10; or
- (b) the conformity assessment specified in Part A of Schedule 12.

(11) Devices which incorporate a medicinal product the action of which is ancillary to that of the device as set out in regulation 68(8), must, in addition to the procedures set out in paragraphs (2), (3), (6) or (7), also be subject to the procedure specified in Section 5.2 of Annex IX or, if applicable, Section 6 of Annex X to Regulation (EU) 2017/45.

(12) Devices which are manufactured utilising animal or human tissues and which fall within this Part in accordance with regulation 68(6)(g) and 68(6)(h), must, in addition to the procedures set out in paragraphs (2), (3), (6) or (7), also be subject to the procedure specified in Section 5.3 of Annex IX or that Section read with Section 6 of Annex X to Regulation (EU) 2017/45.

(13) Investigational devices must be subject to the requirements set out in regulations 103 to 119.

Involvement of notified bodies in conformity assessment procedures

99.—(1) Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of its choice, provided that the chosen notified body is designated for conformity assessment activities related to the types of devices concerned.

(2) The manufacturer may not lodge an application in parallel with another notified body for the same conformity assessment procedure.

Exceptions to the conformity assessment procedures

100.—(1) The requirements of regulation 98 do not apply where, on request, the Secretary of State has authorised the placing on the market, making available on the market or putting into service within the United Kingdom of a specific device and where that authorisation is granted for the purpose of protecting public health or patient safety or health.

(2) Except for the requirement to register in accordance with regulations 93 or 95, the requirements of this Part do not apply where the Secretary of State directs that a relevant device (or a class of relevant devices), which meets other requirements or standards (or which is marked other than with a CE marking) which the Secretary of State considers to be

equivalent to the requirements and standards imposed by this Part, may be placed on the market.

(3) In paragraph (2), a standard or requirement is equivalent to a standard or requirement imposed by this Part if, in respect of the relevant device (or class of relevant devices), the standard or requirement provides for an equivalent level of safety and quality to that imposed by this Part.

Certificate of free sale

101.—(1) For the purpose of export and upon request by a manufacturer, the Secretary of State must issue a certificate of free sale declaring that the manufacturer has its registered place of business in the United Kingdom and that the device in question, bearing the CE marking in accordance with this Part, may be marketed in the United Kingdom.

(2) The certificate of free sale must set out the Basic UDI-DI of the device as provided to the UDI database under regulation 92 and, where a notified body has issued a certificate, the certificate of free sale must set out the unique number identifying the certificate issued by the notified body.

Clinical evaluation and clinical investigations

Clinical evaluation

102.—(1) Conformity with the relevant general safety and performance requirements set out in Schedule 3, the evaluation of undesirable side-effects and the acceptability of the benefit-risk-ratio referred to in paragraphs 1 and 8 of Schedule 3, must be based on clinical data which provides sufficient clinical evidence and, where applicable, the relevant data referred to in Schedule 5.

(2) The manufacturer must specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements and that level of clinical evidence must be appropriate in view of the characteristics of the device and its intended purpose.

(3) Manufacturers must plan, conduct and document a clinical evaluation in accordance with this Part and with Part A of Schedule 14.

(4) A clinical evaluation must be based on the following—

(a) a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where the following conditions are satisfied—

(i) it is demonstrated that the device subject to clinical evaluation for the intended purpose is equivalent to the device to which the data relate, in accordance with paragraph 3 of Schedule 14,

(ii) the data adequately demonstrate compliance with the relevant general safety and performance requirements;

(b) a critical evaluation of the results of all available clinical investigations, taking duly into consideration whether the investigations were performed under regulations 103 to 119 and Schedule 15;

(c) a consideration of currently available alternative treatment options for that purpose, if any.

(5) Subject to paragraphs (6), (8) and (9), clinical investigations must be performed for implantable devices and Class III devices.

(6) A clinical investigation need not be performed on an implantable device or a Class III device if the following conditions are met—

(a) the device has been designed by modifying a device already marketed by the same manufacturer;

- (b) the modified device has been demonstrated by the manufacturer to be equivalent to the marketed device, in accordance with paragraph 3 of Schedule 14 and this demonstration has been endorsed by the notified body;
- (c) the clinical evaluation of the marketed device is sufficient to demonstrate conformity of the modified device with the relevant safety and performance requirements.

(7) For the purposes of paragraph (6)(c), the Secretary of State may request the PMCF plan for the purposes of checking that the plan is appropriate and includes post market studies to demonstrate the safety and performance of the device.

(8) A clinical investigation need not be performed on an implantable device or a Class III device if, in addition to the conditions set out in paragraph (6), the following conditions are also met—

- (a) the device (the second device) has been demonstrated by its manufacturer to be equivalent to a device (the first device) which has already been marketed by a manufacturer other than manufacturer of the second device;
- (b) the two manufacturers have a contract in place which explicitly allows the manufacturer of the second device full access, on an ongoing basis, to the technical documentation of the relating to the first device;
- (c) the clinical evaluation of the first device was performed in compliance with this Part or Regulation (EU) 2017/745 and the manufacturer of the second device provides clear evidence of that to the Secretary of State.

(9) A clinical investigation need not be performed on any of the following list of implantable devices or Class III devices provided the clinical evaluation is based on sufficient clinical data and the device is in compliance with a designated standard—

- (a) devices which have been lawfully placed on the market or put into service in accordance with Parts II or III of these Regulations and for which the clinical evaluation—
 - (i) is based on sufficient clinical data, and
 - (ii) is in compliance with the relevant product-specific CS for clinical evaluation of that kind of device, where such CS is available; or
- (b) devices that are—
 - (i) staples,
 - (ii) sutures,
 - (iii) dental fillings,
 - (iv) dental braces,
 - (v) tooth crowns,
 - (vi) screws,
 - (vii) wedges,
 - (viii) plates,
 - (ix) wires,
 - (x) pins,
 - (xi) clips, or
 - (xii) connectors.

(10) Where justified in view of well-established technologies, similar to those used in the devices listed in paragraph (9)(b), and where justified in order to protect the health and safety of individuals or to protect public health generally, the Secretary of State may by regulations amend the list in paragraph (9)(b) by adding or removing devices from the list.

(11) In the case of products without an intended medical purpose listed in Schedule 16—

- (a) the requirement to demonstrate a clinical benefit in accordance with this Part must be understood as a requirement to demonstrate the performance of the device;
- (b) clinical evaluations of these products must be based on relevant data concerning safety (including data from post-market surveillance, PMCF and where applicable specific clinical evaluation);
- (c) clinical investigations must be performed for these products unless reliance on existing clinical data from an analogous medical device is duly justified.

(12) Without prejudice to paragraph (5), where the demonstration of conformity with general safety and performance requirements based on clinical data is not deemed appropriate, adequate justification for any such exception—

- (a) must be given based on the results of the manufacturer's risk management and on consideration of the specifics of the interaction between the device and the human body, the clinical performance intended and the claims of the manufacturer;
- (b) the manufacturer must duly substantiate in the technical documentation referred to in Schedule 4 why it considers a demonstration of conformity with general safety and performance requirements that is based on the results of non-clinical testing methods alone, including performance evaluation, bench testing and pre-clinical evaluation, to be adequate.

(13) The clinical evaluation and its documentation must be updated throughout the life cycle of the device concerned with—

- (a) clinical data obtained from the implementation of the manufacturer's PMCF plan in accordance with Part B of Schedule 14 and the post-market surveillance plan referred to in regulation 122;
- (b) for Class III devices and implantable devices, the PMCF evaluation report and, if indicated, the summary of safety and clinical performance referred to in regulation 96 must be updated at least annually.

(14) The clinical evaluation, its results and the clinical evidence derived from it must be documented in a clinical evaluation report as referred to in paragraph 4 of Schedule 14, which, except for custom-made devices, must be part of the technical documentation referred to in Schedule 4 relating to the device concerned.

General requirements regarding clinical investigations conducted to demonstrate conformity of devices

103.—(1) Where they are carried out as part of a clinical evaluation for the purposes of a conformity assessment with a view to placing a device on the market, clinical investigations must be designed, authorised, conducted, recorded and reported in accordance with the provisions of this regulation and in particular regulations 104 to 119 and Schedule 15, and carried out for one or more of the following purposes—

- (a) to establish and verify that, under normal conditions of use, a device is designed, manufactured and packaged in such a way that falls within the definition of a medical device in regulation 69, and achieves the performance intended as specified by its manufacturer;
- (b) to establish and verify the clinical benefits of a device as specified by its manufacturer;
- (c) to establish and verify the clinical safety of the device and to determine any undesirable side-effects, under normal conditions of use of the device, and assess whether they constitute acceptable risks when weighed against the benefits to be achieved by the device.

(2) Where the sponsor of a clinical investigation is not established in the United Kingdom—

- (a) that sponsor must ensure that a person is established in the United Kingdom as its legal representative;

- (b) such legal representative must be responsible for ensuring compliance with the sponsor's obligations pursuant to this Part, and must be the addressee for all communications with the sponsor provided for in this Part;
 - (c) any communication with that legal representative must be deemed to be a communication with the sponsor.
- (3) Clinical investigations must be designed and conducted in such a way that—
- (a) the rights, safety, dignity and well-being of the subjects participating in a clinical investigation are protected and prevail over all other interests;
 - (b) the clinical data generated are scientifically valid, reliable and robust.
- (4) Clinical investigations must be subject to a scientific and ethical review for which—
- (a) the ethical review must be performed by an ethics committee;
 - (b) the Secretary of State must ensure that the procedures for review by ethics committees are compatible with the procedures set out in this Part for the assessment of the application for authorisation of a clinical investigation;
 - (c) at least one lay person must participate in the ethical review.
- (5) A clinical investigation as referred to in paragraph (1) may be conducted only where all of the following conditions are met—
- (a) the clinical investigation is the subject of an authorisation by the Secretary of State, in accordance with this Part;
 - (b) an ethics committee has not issued a negative opinion in relation to the clinical investigation;
 - (c) the sponsor, or its legal representative or a contact person pursuant to paragraph (2), is established in the United Kingdom;
 - (d) vulnerable populations and subjects are appropriately protected in accordance with regulations 105 to 108;
 - (e) the anticipated benefits to the subjects or to public health justify the foreseeable risks and inconveniences and compliance with this condition is constantly monitored;
 - (f) unless regulation 108 applies, the subject or, where the subject is not able to give informed consent, the subject's legally designated representative has given informed consent in accordance with regulation 104;
 - (g) the subject or, where the subject is not able to give informed consent, the subject's legally designated representative, has been provided with the contact details of an entity where further information can be received in case of need;
 - (h) the rights of the subject to physical and mental integrity, to privacy and to the protection of the data concerning the subject in accordance with the Data Protection Act 2018 are safeguarded;
 - (i) the clinical investigation has been designed to involve as little pain, discomfort, fear and any other foreseeable risk as possible for the subjects, and both the risk threshold and the degree of distress are specifically defined in the clinical investigation plan and constantly monitored;
 - (j) the medical care provided to the subjects is the responsibility of an appropriately qualified medical doctor or, where appropriate, a qualified dental practitioner or any other authorised health professional entitled to provide the relevant patient care under clinical investigation conditions;
 - (k) no undue influence, including that of a financial nature, is exerted on the subject, or, where applicable, on the subject's legally designated representative, to participate in the clinical investigation;
 - (l) the investigational device in question—

- (i) conforms to the applicable general safety and performance requirements set out in Schedule 3, apart from the aspects covered by the clinical investigation;
- (ii) with regard to the aspects covered by the clinical investigation, every precaution has been taken to protect the health and safety of the subjects which includes, where appropriate, technical and biological safety testing and pre-clinical evaluation, as well as provisions in the field of occupational safety and accident prevention, taking into consideration the state of the art;
- (m) the requirements of Schedule 15 are fulfilled;
- (n) the sponsor, the sponsor's legal representative and as appropriate the investigator must have sufficient insurance (or equivalent financial resources) in place to cover their liability arising from the clinical investigation.

(6) Any subject, or, where the subject is not able to give informed consent, the subject's legally designated representative, may, without any resulting detriment and without having to provide any justification, withdraw from the clinical investigation at any time by revoking his or her informed consent.

(7) Subject to the provisions of the Data Protection Act 2018, the withdrawal of the informed consent in accordance with paragraph (6) must not affect the activities already carried out and the use of data obtained based on informed consent before its withdrawal.

(8) The investigator must be an authorised health professional qualifying for the role of investigator on account of having the necessary scientific knowledge and experience in patient care and other personnel involved in conducting a clinical investigation must be authorised health professionals in the relevant medical field and in clinical research methodology,

(9) The facilities where the clinical investigation is to be conducted must be suitable for the clinical investigation and must be similar to the facilities where the device is intended to be used.

Informed consent

104.—(1) Informed consent—

- (a) must be written, dated and signed by the person performing the interview referred to in paragraph 104(2)(c), and by the subject or, where the subject is not able to give informed consent, the subject's legally designated representative after having been duly informed in accordance with paragraph 104(2);
- (b) may, where the subject is unable to write, be given and recorded through appropriate alternative means in the presence of at least one impartial witness and, in that case, the witness must sign and date the informed consent document;
- (c) must be documented and a copy of that document or record be provided to the subject or to the subject's legally designated representative;
- (d) is only valid if adequate time is given for the subject, or the subject's legally designated representative, to consider his or her decision to participate in the clinical investigation.

(2) Information given to the subject or, where the subject is not able to give informed consent, the subject's legally designated representative, for the purposes of obtaining his or her informed consent must—

- (a) enable the subject or the subject's legally designated representative to understand—
 - (i) the nature, objectives, benefits, implications, risks and inconveniences of the clinical investigation;
 - (ii) the subject's rights and guarantees regarding his or her protection, in particular the subject's right to refuse to participate in and the right to

withdraw from the clinical investigation at any time without any resulting detriment and without having to provide any justification;

(iii) the conditions under which the clinical investigation is to be conducted, including the expected duration of the subject's participation in the clinical investigation;

(iv) the possible treatment alternatives, including the follow-up measures if the participation of the subject in the clinical investigation is discontinued;

(b) be kept comprehensive, concise, clear, relevant, and understandable to the subject or his or her legally designated representative;

(c) be provided in a prior interview with a member of the investigating team who is appropriately qualified;

(d) include information about the applicable damage compensation system referred to in regulation 109;

(e) include information about the availability of the clinical investigation results in accordance with paragraph (5).

(3) The information referred to in paragraph (2) must be prepared in writing and be available to the subject or, where the subject is not able to give informed consent, the subject's legally designated representative.

(4) In the interview referred to in paragraph (2)(c)—

(a) special attention must be paid to the information needs of specific patient populations and of individual subjects, as well as to the methods used to give the information; and

(b) the member of the investigating team must ensure that the subject has understood the information.

(5) The subject must be informed that a clinical investigation report and a summary presented in terms understandable to the intended user will be made available irrespective of the outcome of the clinical investigation, and must be informed, to the extent possible, when they have become available.

(6) A minor who is capable of forming an opinion and assessing the information given to him or her, must also assent in order to participate in a clinical investigation.

(7) Where appropriate, this regulation is to be read subject to regulation 108 (Clinical investigations in emergency situations).

Clinical investigations on incapacitated subjects

105.—(1) In the case of incapacitated subjects who have not given, or have not refused to give, informed consent before the onset of their incapacity, a clinical investigation may be conducted only where, in addition to the conditions set out in regulation 103(5), all of the following conditions are met—

(a) unless regulation 108 applies, the informed consent of their legally designated representative has been obtained;

(b) unless regulation 108 applies, the incapacitated subjects have received the information referred to in regulation 104(2) in a way that is adequate in view of their capacity to understand it;

(c) the explicit wish of an incapacitated subject who is capable of forming an opinion and assessing the information referred to in regulation 104(2) to refuse participation in, or to withdraw from, the clinical investigation at any time, is respected by the investigator;

(d) no incentives or financial inducements are given to subjects or their legally designated representatives, except for compensation for expenses and loss of earnings directly related to the participation in the clinical investigation;

- (e) the clinical investigation is essential with respect to incapacitated subjects and data of comparable validity cannot be obtained in clinical investigations on persons able to give informed consent, or by other research methods;
 - (f) the clinical investigation relates directly to a medical condition from which the subject suffers;
 - (g) there are scientific grounds for expecting that participation in the clinical investigation will produce a direct benefit to the incapacitated subject outweighing the risks and burdens involved.
- (2) The subject, as far as possible, should take part in the informed consent procedure.

Clinical investigations on minors

106. A clinical investigation on minors may be conducted only where, in addition to the conditions set out in regulation 103(5), all of the following conditions are met—

- (a) unless regulation 108 applies, the informed consent of their legally designated representative has been obtained;
- (b) unless regulation 108 applies, the minors have received the information referred to in regulation 104(2) in a way adapted to their age and mental maturity and from investigators or members of the investigating team who are trained or experienced in working with children;
- (c) the explicit wish of a minor who is capable of forming an opinion and assessing the information referred to in regulation 104(2) to refuse participation in, or to withdraw from, the clinical investigation at any time, is respected by the investigator;
- (d) no incentives or financial inducements are given to the subject or his or her legally designated representative except for compensation for expenses and loss of earnings directly related to the participation in the clinical investigation;
- (e) the clinical investigation is intended to investigate treatments for a medical condition that only occurs in minors or the clinical investigation is essential with respect to minors to validate data obtained in clinical investigations on persons able to give informed consent or by other research methods;
- (f) the clinical investigation either relates directly to a medical condition from which the minor concerned suffers or is of such a nature that it can only be carried out on minors;
- (g) there are scientific grounds for expecting that participation in the clinical investigation will produce a direct benefit to the minor subject outweighing the risks and burdens involved;
- (h) the minor must take part in the informed consent procedure in a way adapted to his or her age and mental maturity;
- (i) if, during a clinical investigation, a person reaches the age of 16 years, that person's express informed consent must be obtained before they can continue to participate in the clinical investigation.

Clinical investigations on pregnant or breastfeeding women

107. A clinical investigation on a pregnant or breastfeeding woman may be conducted only where, in addition to the conditions set out in regulation 103(5), all of the following conditions are met—

- (a) the clinical investigation has the potential to produce a direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, outweighing the risks and burdens involved;
- (b) where research is undertaken on breastfeeding women, particular care is taken to avoid any adverse impact on the health of the child;

- (c) no incentives or financial inducements are given to the subject except for compensation for expenses and loss of earnings directly related to the participation in the clinical investigation.

Clinical investigations in emergency situations

108.—(1) Informed consent to participate in a clinical investigation may be obtained, and information on the clinical investigation may be given, after the decision to include the subject in the clinical investigation, provided that decision is taken at the time of the first intervention on the subject in accordance with the clinical investigation plan for that clinical investigation and that all of the following conditions are fulfilled—

- (a) due to the urgency of the situation, caused by a sudden life-threatening or other sudden serious medical condition, the subject is unable to provide prior informed consent and to receive prior information on the clinical investigation;
- (b) there are scientific grounds to expect that participation of the subject in the clinical investigation will have the potential to produce a direct clinically relevant benefit for the subject resulting in a measurable health-related improvement alleviating the suffering or improving the health of the subject, or in the diagnosis of its condition;
- (c) it is not possible within the therapeutic window to supply all prior information to and obtain prior informed consent from the subject's legally designated representative;
- (d) the investigator certifies that they are not aware of any objections to participate in the clinical investigation previously expressed by the subject;
- (e) the clinical investigation relates directly to the subject's medical condition because of which it is not possible, within the therapeutic window, to obtain prior informed consent from the subject or from his or her legally designated representative and to supply prior information, and the clinical investigation is of such a nature that it may be conducted exclusively in emergency situations;
- (f) the clinical investigation poses a minimal risk to, and imposes a minimal burden on, the subject in comparison with the standard treatment of the subject's condition.

(2) Where paragraph (1) applies, informed consent in accordance with regulation 104 must be sought to continue the participation of the subject in the clinical investigation, and information on the clinical investigation must be given, in accordance with the following requirements—

- (a) for incapacitated subjects and minors, the informed consent must be sought by the investigator from his or her legally designated representative without undue delay and the information referred to in regulation 104(2) must be given as soon as possible to the subject and to the subject's legally designated representative;
- (b) for all other subjects, the informed consent must be sought by the investigator without undue delay from the subject or the subject's legally designated representative, whichever can be done sooner, and the information referred to in regulation 104(2) must be given as soon as possible to the subject or his or her legally designated representative, as applicable.

(3) For the purposes of paragraph (2)(b), where informed consent has been obtained from the legally designated representative, informed consent to continue the participation in the clinical investigation must be obtained from the subject as soon as the subject is capable of giving informed consent.

(4) Where consent is not given, the subject or, where applicable, the subject's legally designated representative must be informed of the right to object to the use of data obtained from the clinical investigation.

Damage compensation

109. Sponsors must, taking account of the risk class of a device, the type of device and the size of the enterprise, hold sufficient insurance (or equivalent financial resources) to meet any potential financial liability arising from damage caused by a clinical investigation.

Application for clinical investigations

110.—(1) The sponsor of a clinical investigation must submit an application to the Secretary of State accompanied by the documentation referred to in Chapter II of Schedule 15.

(2) Within 10 days of receiving the application, the Secretary of State must notify the sponsor as to whether the clinical investigation falls within the scope of this Part and as to whether the application dossier is complete in accordance with Chapter II of Schedule 15.

(3) Within one week of any change occurring in relation to the documentation referred to in Chapter II of Schedule 15, the sponsor must—

- (a) up-date the relevant data;
- (b) make that change to the documentation clearly identifiable;
- (c) notify the Secretary of State of the update.

(4) Where the Secretary of State finds that the clinical investigation applied for does not fall within the scope of this Part or that the application dossier is not complete, the Secretary of State must inform the sponsor and must set a time limit of maximum 10 days for the sponsor to comment, but the Secretary of State may extend this period by a maximum of 20 days where appropriate.

(5) Where—

- (a) the sponsor has not provided comments within the time limit referred to in the paragraph (4), the application must be deemed to have lapsed;
- (b) the sponsor considers the application does fall under the scope of this Part or is complete but the Secretary of State does not agree, the application must be considered to have been rejected.

(6) The Secretary of State must notify the sponsor within 5 days of receipt of the comments or of the requested additional information, whether the clinical investigation is considered as falling within the scope of this Part or that the application is complete.

(7) The Secretary of State may extend the notification periods referred to in paragraphs (2) and (6) each by a further 5 days.

(8) The validation date of the application is to be considered—

- (a) the date on which the sponsor is notified in accordance with paragraphs (2) and (6); or
- (b) where the sponsor is not notified, the last day of the periods referred to in paragraph (4).

(9) The sponsor may start a clinical investigation in the following circumstances—

- (a) in the case of —
 - (i) investigational Class I devices or non-invasive Class IIa and Class IIb devices, immediately after the validation date of the application pursuant to paragraph (8); or
 - (ii) investigational devices, other than those referred to in paragraph (i) as soon as the Secretary of State has notified the sponsor of the Secretary of State's authorisation; and
- (b) in both cases, provided a negative opinion has not been issued by an ethics committee in the United Kingdom in respect of the clinical investigation.

(10) For the purposes of paragraph (9)(a)(ii), the Secretary of State must notify the sponsor of the authorisation within 45 days of the validation date referred to in paragraph (8) and the Secretary of State may extend this period by a further 20 days for the purpose of consulting with experts.

Assessment by Secretary of State

111.—(1) The Secretary of State must ensure that the persons validating and assessing the clinical investigation application, or deciding on it do not have conflicts of interest and in particular are—

- (a) independent of—
 - (i) the sponsor;
 - (ii) the investigators involved;
 - (iii) the person financing the clinical investigation; and
- (b) free of any undue influence.

(2) The Secretary of State must ensure that the assessment is done jointly by an appropriate number of persons who collectively have the necessary qualifications and experience.

(3) The Secretary of State—

- (a) must assess whether the clinical investigation is designed in such a way that potential remaining risks to subjects or third persons, after risk minimization, are justified, when weighed against the clinical benefits to be expected;
- (b) must, while taking into account applicable designated standards, examine in particular—
 - (i) the demonstration of compliance of the investigational device with the applicable general safety and performance requirements, apart from the aspects covered by the clinical investigation, and whether, with regard to those aspects, every precaution has been taken to protect the health and safety of the subjects and this includes, where appropriate, assurance of technical and biological safety testing and pre-clinical evaluation;
 - (ii) whether the risk-minimisation solutions employed by the sponsor are described in designated standards and, in those cases where the sponsor does not use those standards, whether the risk-minimisation solutions provide a level of protection that is equivalent to that provided by those designated standards;
 - (iii) whether the measures planned for the safe installation, putting into service and maintenance of the investigational device are adequate;
 - (iv) the reliability and robustness of the data generated in the clinical investigation, taking account of statistical approaches, design of the investigation and methodological aspects, including sample size, comparator and endpoints;
 - (v) whether the requirements of Schedule 15 are met;
 - (vi) in the case of devices for sterile use, evidence of the validation of the manufacturer's sterilisation procedures or information on the reconditioning and sterilisation procedures which have to be conducted by the investigation site;
 - (vii) the demonstration of the safety, quality and usefulness of any components of animal or human origin or of substances, which may be considered medicinal products in accordance with the Human Medicines Regulations 2012.

(4) The Secretary of State must refuse the authorisation of the clinical investigation if—

- (a) the application dossier submitted remains incomplete;

- (b) the device or the submitted documents, especially the investigation plan and the investigator’s brochure, do not correspond to the state of scientific knowledge, and the clinical investigation, in particular, is not suitable for providing evidence for the safety, performance characteristics or benefit of the device on subjects or patients;
- (c) the requirements of regulation 103 (General requirements for clinical investigations conducted to demonstrate the conformity of devices) are not met; or
- (d) any assessment under paragraph (3) is negative.

Appeal rights relating to regulations (1) and (1)

112.—(1) Where the sponsor is dissatisfied with a decision taken by the Secretary of State under regulation 110(6) or regulation 111(4), the sponsor or the sponsor’s legal representative in the United Kingdom may require the Secretary of State to seek advice from such person as the Institute determines as to—

- (a) whether the clinical investigation falls within this Part; or
- (b) whether the Secretary of State correctly refused the authorisation.

(2) Where the sponsor acts in accordance with paragraph (1), the sponsor is responsible for the fees, costs and expenses of the Institute and of the person appointed by the Institute.

(3) In this regulation, “Institute” means the charitable organisation with registered number 803725 and known as the Chartered Institute of Arbitrators.

Conduct of a clinical investigation

113.—(1) The sponsor and the investigator must ensure that the clinical investigation is conducted in accordance with the approved clinical investigation plan.

(2) The sponsor—

- (a) must ensure adequate monitoring of the conduct of the clinical investigation in order to—
 - (i) verify that the rights, safety and wellbeing of the subjects are protected;
 - (ii) that the reported data are reliable and robust;
 - (iii) that the conduct of the clinical investigation is in compliance with the requirements of this Part;
- (b) must determine the extent and nature of the monitoring on the basis of an assessment taking into consideration all the characteristics of the clinical investigation including the following—
 - (i) the objective and methodology of the clinical investigation;
 - (ii) the degree of deviation of the intervention from normal clinical practice.

(3) All clinical investigation information must be recorded, processed, handled, and stored by the sponsor or investigator, as applicable, in such a way that it can be accurately reported, interpreted and verified while the confidentiality of records and the personal data of the subjects remain protected in accordance with the Data Protection Act 2018.

(4) Appropriate technical and organisational measures must be implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss, in particular where the processing involves transmission over a network.

(5) The Secretary of State must inspect, at an appropriate level, investigation sites to check that clinical investigations are conducted in accordance with the requirements of this Part and with the approved investigation plan.

(6) The sponsor must establish a procedure for emergency situations which enables the immediate identification and, where necessary, an immediate recall of the devices used in the investigation.

Clinical investigations regarding devices bearing a CE marking within the intended purpose of those devices

114.—(1) Where—

- (a) a clinical investigation is to be conducted to further assess, within the scope of its intended purpose, a device which already bears the CE marking in accordance with regulation 85, ('PMCF investigation'); and
- (b) the investigation would involve submitting subjects to procedures additional to those performed under the normal conditions of use of the device and those additional procedures are invasive or burdensome,

the sponsor must notify the Secretary of State at least 30 days prior to its commencement.

(2) The sponsor must include documentation referred to in Chapter II of Schedule 15 as part of the notification.

(3) The following provisions apply to PMCF investigations—

- (a) sub-paragraphs (b) to (k) and (m) of regulation 103(5);
- (b) regulations 116 to 118;
- (c) regulation 119(6);
- (d) the relevant provisions of Schedule 15.

Clinical investigations regarding devices bearing a CE marking outside the intended purpose of those devices

115. Regulations 103 to 120 apply where a clinical investigation is to be conducted to assess, outside the scope of its intended purpose, a device which already bears the CE marking in accordance with regulation 85.

Substantial modifications to clinical investigations

116.—(1) If a sponsor intends to introduce modifications to a clinical investigation that are likely to have a substantial impact on the safety, health or rights of the subjects or on the robustness or reliability of the clinical data generated by the investigation, the sponsor must—

- (a) within one week of deciding to introduce modifications, notify the Secretary of State of the reasons for and the nature of those modifications;
- (b) include an updated version of the relevant documentation referred to in Chapter II of Schedule 15 as part of the notification;
- (c) ensure that changes to the relevant documentation are clearly identifiable.

(2) The Secretary of State must assess any substantial modification to the clinical investigation in accordance with the procedure laid down in regulation 111.

(3) The sponsor may implement the modifications referred to in paragraph (1) at the earliest 38 days after the notification referred to in that paragraph, unless—

- (a) the Secretary of State has notified the sponsor of the Secretary of State's refusal based on the grounds referred to in regulation 111(4) or on considerations of public health, subject and user safety or health, of public policy, or
- (b) an ethics committee has issued a negative opinion in relation to the substantial modification to the clinical investigation.

(4) The Secretary of State may extend the period referred to in paragraph (3) by a further 7 days, for the purpose of consulting with experts.

Corrective measures to be taken by the Secretary of State

117.—(1) Where the Secretary of State has grounds for considering that the requirements set out in this Part are not met, the Secretary of State may take any of the following measures—

- (a) revoke the authorisation for the clinical investigation;
- (b) suspend or terminate the clinical investigation;
- (c) require the sponsor to modify any aspect of the clinical investigation.

(2) Before the Secretary of State takes any of the measures referred to in paragraph (1), the Secretary of State must, except where immediate action is required, ask the sponsor or the investigator or both for their opinion which must be delivered within 7 days.

Information from the sponsor at the end of a clinical investigation or in the event of a temporary halt or early termination

118.—(1) Subject to paragraph (2), if the sponsor has temporarily halted a clinical investigation or has terminated a clinical investigation early, the sponsor must inform the Secretary of State within 15 days of the temporary halt or early termination, providing a justification for that halt or termination.

(2) Where the sponsor has temporarily halted the clinical investigation or terminated early it early on safety grounds, the sponsor must inform the Secretary of State of that halt or termination within 24 hours.

(3) The end of a clinical investigation is deemed to coincide with the last visit of the last subject unless another point in time for such end is set out in the clinical investigation plan.

(4) The sponsor must notify the Secretary of State of the end of a clinical investigation and that notification must be made within 15 days of the end of the clinical investigation.

(5) Irrespective of the outcome of the clinical investigation but subject to paragraph (7), within one year of the end of the clinical investigation or within 3 months of the early termination or temporary halt, the sponsor must submit to the Secretary of State a clinical investigation report as referred to in paragraph 2(8) of Chapter I and paragraph 7 of Chapter III of Schedule 15.

(6) The clinical investigation report must—

- (a) be accompanied by a summary presented in terms that are easily understandable to the intended user;
- (b) be submitted by the sponsor to the Secretary of State along with that summary.

(7) Where, for scientific reasons, it is not possible to submit the clinical investigation report within one year of the end of the investigation, it must—

- (a) be submitted as soon as it is available;
- (b) specify in the clinical investigation plan, referred to in paragraph 3 of Chapter II of Schedule 15, when the results of the clinical investigation are going to be available, together with a justification for why the report cannot be submitted within one year of the end of the investigation.

(8) The Secretary of State—

- (a) may issue guidelines regarding the content and structure of the summary of the clinical investigation report;
- (b) may issue guidelines for the formatting and sharing of raw data, for cases where the sponsor decides to share raw data on a voluntary basis (and may take as a basis and adapt, where possible, existing guidelines for sharing of raw data in the field of clinical investigations).

(9) The summary and the clinical investigation report referred to in paragraph (6) must—

- (a) in circumstances other than those provided for in sub-paragraphs (b) and (c), be made publicly accessible, at the latest when the device is registered in accordance with regulation 93 and before it is placed on the market;
- (b) in cases of early termination or temporary halt, become publicly accessible immediately after submission; or
- (c) if the device is not registered in accordance with regulation 93, become publicly accessible within one year of the summary and the report having been submitted pursuant to paragraph (5).

Recording and reporting of adverse events that occur during clinical investigations

119.—(1) The sponsor must fully record all of the following—

- (a) any adverse event of a type identified in the clinical investigation plan as being critical to the evaluation of the results of that clinical investigation;
- (b) any serious adverse event;
- (c) any device deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate;
- (d) any new findings in relation to any event referred to in sub-paragraphs (a) to (c);

(2) The sponsor must report, without delay (but having regard to paragraph (3)), to the Secretary of State, all of the following—

- (a) any serious adverse event that has a causal relationship with the investigational device, the comparator or the investigation procedure or where such causal relationship is reasonably possible;
- (b) any device deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate;
- (c) any new findings in relation to any event referred to in sub-paragraphs (a) and (b).

(3) The period for reporting must take account of the severity of the event and, where necessary to ensure timely reporting, the sponsor may submit an initial report that is incomplete followed up by a complete report.

(4) Upon request by the Secretary of State, the sponsor must provide all information referred to in paragraph (1).

(5) The sponsor must also report to the Secretary of State any event referred to in paragraph (2) that occurred in a country outside the United Kingdom in which a clinical investigation is performed under the same clinical investigation plan as the one applying to a clinical investigation covered by this Part.

(6) This regulation does not apply to PMCF investigations referred to in regulation 114 but the provisions on vigilance provided for in regulations 125 to 128 apply instead of this regulation.

Requirements regarding other clinical investigations

120.—(1) Clinical investigations, not performed pursuant to any of the purposes listed in regulation 103(1), must comply with the provisions of regulation 103(2) to 103(3), sub-paragraphs (b), (c), (d), (f), (h), and (l) of regulation 103(5) and regulation 103(8).

(2) In order to protect the rights, safety, dignity and well-being of subjects and the scientific and ethical integrity of clinical investigations not performed for any of the purposes listed in regulation 103(1), Secretary of State may by regulations define any additional requirements for such investigations.

POST-MARKET SURVEILLANCE, VIGILANCE AND MARKET SURVEILLANCE

Post-market surveillance

Post-market surveillance system of the manufacturer

121.—(1) For each device, manufacturers must plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device and that system must be an integral part of the manufacturer's quality management system referred to in regulation 76(14).

(2) The post-market surveillance system must be suited to—

- (a) actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device throughout its entire lifetime;
- (b) drawing the necessary conclusions;
- (c) determining, implementing and monitoring any preventive and corrective actions.

(3) The manufacturer must ensure that—

- (a) data gathered by the manufacturer's post-market surveillance system is used in particular—
 - (i) to update the benefit-risk determination and to improve the risk management as referred to in Part 1 of Schedule 3;
 - (ii) to update the design and manufacturing information, the instructions for use and the labelling;
 - (iii) to update the clinical evaluation;
 - (iv) to update the summary of safety and clinical performance referred to in regulation 96;
 - (v) for the identification of needs for preventive, corrective or field safety corrective action;
 - (vi) for the identification of options to improve the usability, performance and safety of the device;
 - (vii) when relevant, to contribute to the post-market surveillance of other devices;
 - (viii) to detect and report trends in accordance with regulation 126;
- (b) the technical documentation is updated accordingly.

(4) If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer must—

- (a) implement the appropriate measures and inform the Secretary of State and, where applicable, the notified body;
- (b) where a serious incident is identified or a field safety corrective action is implemented, report that incident in accordance with regulation 125.

Post-market surveillance plan

122. The post-market surveillance system referred to in regulation 121 must be based on a post-market surveillance plan, the requirements for which are set out in paragraph 1(2) of Schedule 5 and, for devices other than custom-made devices, the post-market surveillance plan must be part of the technical documentation specified in Schedule 4.

Post-market surveillance report

123.—(1) Manufacturers of Class I devices must prepare a post-market surveillance report summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in

regulation 122 together with a rationale and description of any preventive and corrective actions taken.

(2) The report must be updated when necessary and made available to the Secretary of State upon request.

Periodic safety update report

124.—(1) Manufacturers of Class IIa, Class IIb and Class III devices must prepare a periodic safety update report ('PSUR') for each device and where relevant for each category or group of devices summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in regulation 122 together with a rationale and description of any preventive and corrective actions taken.

(2) Throughout the lifetime of the device concerned, that PSUR must set out—

- (a) the conclusions of the benefit-risk determination;
- (b) the main findings of the PMCF;
- (c) the volume of sales of the device and an estimate evaluation of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.

(3) Manufacturers of Class IIb and Class III devices must—

- (a) update the PSUR at least annually;
- (b) ensure that, except in the case of custom-made devices, the PSUR is part of the technical documentation as specified in Schedules 4 and 5.

(4) Manufacturers of Class IIa devices must—

- (a) update the PSUR when necessary and at least every 2 years;
- (b) ensure that, except in the case of custom-made devices, the PSUR is part of the technical documentation as specified in Schedules 4 and 5.

(5) For custom-made devices, the PSUR must be part of the documentation referred to in paragraph 12(2) of Schedule 13.

(6) For Class III or implantable devices a manufacturer must—

- (a) submit the PSUR to the notified body involved in the conformity assessment;
- (b) make available to the Secretary of State the evaluation of the PSUR made by the notified body.

(7) For devices other than Class III devices a manufacturer must—

- (a) make the PSUR available to the notified body involved in the conformity assessment;
- (b) upon request by the Secretary of State, make the PSUR available to the Secretary of State.

Reporting of serious incidents and field safety corrective actions

125.—(1) Manufacturers of devices made available on the market, other than investigational devices, must report, to the Secretary of State the following—

- (a) any serious incident involving devices made available on the market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to regulation 126;
- (b) any field safety corrective action in respect of devices made available on the market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the market, if the

reason for the field safety corrective action is not limited to the device made available in the third country.

(2) The period for the reporting referred to in paragraph (1) must take account of the severity of the serious incident.

(3) Subject to paragraphs (4) and (5), manufacturers must report any serious incident as referred to in paragraph (1)(a) immediately after they have established the causal relationship between that incident and their device, or that such causal relationship is reasonably possible, and not later than 15 days after they become aware of the incident.

(4) In the event of a serious public health threat, the report referred to in paragraph (1) must be provided not later than 2 days after the manufacturer becomes aware of the threat.

(5) In the event of death or an unanticipated serious deterioration in a person's state of health, the report must be provided immediately after the manufacturer has established or as soon as it suspects a causal relationship between the device and the serious incident but not later than 10 days after the date on which the manufacturer becomes aware of the serious incident.

(6) Where necessary to ensure timely reporting, the manufacturer may submit an initial report that is incomplete followed up by a complete report.

(7) If, after becoming aware of a potentially reportable incident, the manufacturer is uncertain about whether the incident is reportable, it must nevertheless submit a report within the timeframe required in accordance with paragraphs (2) to (5).

(8) Except in cases of urgency in which the manufacturer needs to undertake field safety corrective action immediately, the manufacturer must, without undue delay, report the field safety corrective action referred to in paragraph (1)(b) in advance of the field safety corrective action being undertaken.

(9) For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a field safety corrective action implemented or where the incidents are common and well documented, the manufacturer may provide periodic summary reports instead of individual serious incident reports, on condition that the Secretary of State, has agreed with the manufacturer on the format, content and frequency of the periodic summary reporting.

(10) The Secretary of State must—

- (a) take appropriate measures such as organising targeted information campaigns, to encourage and enable healthcare professionals, users and patients to report to the Secretary of State suspected serious incidents referred to in paragraph (1)(a);
- (b) record reports received from healthcare professionals, users and patients.

(11) Where the Secretary of State obtains such reports on suspected serious incidents referred to in paragraph (1)(a) from healthcare professionals, users or patients, the Secretary of State must take the necessary steps to ensure that the manufacturer of the device concerned is informed of the suspected serious incident without delay.

(12) Where the manufacturer of the device concerned considers that an incident is a serious incident, it must provide a report in accordance with paragraphs (1) to (5) on that serious incident to the Secretary of State and must take the appropriate follow-up action in accordance with regulation 127.

(13) Where—

- (a) the manufacturer of the device considers that an incident is not a serious incident or is an expected undesirable side-effect which will be covered by trend reporting in accordance with regulation 126, the manufacturer must provide an explanatory statement;
- (b) the Secretary of State does not agree with the conclusion of the explanatory statement, the Secretary of State may require the manufacturer—
 - (i) to provide a report in accordance with paragraphs (1) to (5);

- (ii) to ensure that appropriate follow-up action is taken in accordance with regulation 127.

Trend reporting

126.—(1) Manufacturers must report to the Secretary of State any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects that could have a significant impact on the benefit-risk analysis referred to in paragraphs (1) and (5) of Schedule 3 and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits.

(2) The significant increase must be established in comparison to the foreseeable frequency or severity of such incidents in respect of the device, or category or group of devices in question, during a specific period as specified in the technical documentation and product information.

(3) The manufacturer must specify how to manage the incidents referred to in paragraph (1) and the methodology used for determining any statistically significant increase in the frequency or severity of such incidents, as well as the observation period, in the post-market surveillance plan referred to in regulation 122.

(4) The Secretary of State may conduct assessments on the trend reports referred to in paragraph (1) and require the manufacturer to adopt appropriate measures in accordance with this Part in order to ensure the protection of public health and patient safety.

Analysis of serious incidents and field safety corrective actions

127.—(1) Following the reporting of a serious incident pursuant to regulation 125(1), a manufacturer must—

- (a) without delay, perform the necessary investigations in relation to the serious incident and the devices concerned;
- (b) include a risk assessment of the incident and field safety corrective action taking into account criteria as referred to in paragraph (4)(a) as appropriate.

(2) A manufacturer must—

- (a) cooperate with the Secretary of State during the investigations referred to in paragraph (1);
- (b) not perform any investigation which involves altering the device or a sample of the batch concerned in a way which may affect any subsequent evaluation of the causes of the incident, prior to informing the Secretary of State of such action.

(3) The Secretary of State must take the necessary steps to ensure that any information regarding a serious incident that has occurred, or a field safety corrective action that has been or is to be undertaken, and that is brought to the Secretary of State's knowledge in accordance with regulation 125, is evaluated, if possible together with the manufacturer and, where relevant the notified body concerned.

(4) For the purposes of the evaluation referred to in paragraph (3), the Secretary of State must evaluate—

- (a) the risks arising from the reported serious incident and evaluate any related field safety corrective actions, taking into account the protection of public health and criteria such as—
 - (i) causality, detectability and probability of recurrence of the problem;
 - (ii) frequency of use of the device;
 - (iii) probability of occurrence of direct or indirect harm;
 - (iv) the severity of that harm;
 - (v) the clinical benefit of the device;

- (vi) the intended and potential users;
 - (vii) the population affected;
 - (b) the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for, and kind of, any other corrective action, in particular taking into account the principle of inherent safety contained in Schedule 3.
- (5) Upon request by the Secretary of State, manufacturers must provide all documents necessary for the risk assessment.
- (6) The Secretary of State must monitor the manufacturer's investigation of a serious incident and where necessary, the Secretary of State may intervene in a manufacturer's investigation or initiate an independent investigation.
- (7) A manufacturer must provide a final report to the Secretary of State setting out its findings from the investigation which must set out conclusions and where relevant indicate corrective actions to be taken.
- (8) In the case of devices referred to in regulation 68(8) and where the serious incident or field safety corrective action may be related to a substance which, if used separately, would be considered to be a medicinal product, the Secretary of State must ensure that those responsible for licensing medicinal products are informed of that serious incident or field safety corrective action.
- (9) In the case of —
- (a) devices referred to in regulation 68(6)(h);
 - (b) devices falling under regulation 68(14),
- and where the serious incident or field safety corrective action may be related to the derivatives of tissues or cells of human origin utilised for the manufacture of the device, the Secretary of State must inform the Human Tissue Authority.
- (10) A manufacturer must ensure that information about the field safety corrective action taken—
- (a) is brought without delay to the attention of users of the device in question by means of a field safety notice;
 - (b) except in cases of urgency, the content of the draft field safety notice must be submitted to the Secretary of State to allow the Secretary of State to make comments.
- (11) The field safety notice must—
- (a) allow the correct identification of the device or devices involved;
 - (b) explain, in a clear manner, without understating the level of risk, the reasons for the field safety corrective action with reference to the device malfunction and associated risks for patients, users or other persons;
 - (c) clearly indicate all the actions to be taken by users;
 - (d) be accessible to the public.

Analysis of vigilance data

128.—(1) The Secretary of State must put in place systems and processes to actively monitor the data available, in order to identify trends, patterns or signals in the data that may reveal new risks or safety concerns.

(2) Where a previously unknown risk is identified or the frequency of an anticipated risk significantly and adversely changes the benefit-risk determination, the Secretary of State must inform the manufacturer, or where applicable the UK responsible person, which must then take the necessary corrective actions.

Electronic system on vigilance and on post market surveillance

129.—(1) The Secretary of State must set up and manage an electronic system to collate and process the following information—

- (a) the reports by manufacturers on serious incidents and field safety corrective actions;
- (b) the periodic summary reports by manufacturers;
- (c) the reports by manufacturers on trends;
- (d) the PSURs;
- (e) the field safety notices by manufacturers.

(2) The Secretary of State must ensure that healthcare professionals and the public receive appropriate information contained in the electronic system referred to in paragraph (1).

(3) The Secretary of State—

- (a) may make arrangements with other countries or international organisations for the purpose of granting access (at an appropriate level) to the electronic system referred to in paragraph (1);
- (b) must only make any such arrangements on the basis of reciprocity;
- (c) must base any such arrangements on data protection rules equivalent to those applicable in the United Kingdom.

Market surveillance

Market surveillance activities

130.—(1) The Secretary of State must—

- (a) perform appropriate checks on the conformity characteristics and performance of devices including, where appropriate, a review of documentation and physical or laboratory checks on the basis of adequate samples;
- (b) take account of established principles regarding risk assessment and risk management, vigilance data and complaints.

(2) The Secretary of State must—

- (a) draw up an annual surveillance activity plan;
- (b) allocate a sufficient number of material and competent human resources in order to carry out those activities.

(3) In order to fulfil the obligations laid down in paragraph (1), the Secretary of State—

- (a) may require economic operators to make available the documentation and information necessary for the purpose of carrying out those activities and, where justified, to provide the necessary samples of devices or access to devices free of charge;
- (b) must carry out both announced and, if necessary, unannounced inspections of the premises of economic operators, suppliers or subcontractors, and, where necessary, at the facilities of professional users.

(4) The Secretary of State must prepare and publish an annual summary of the results of surveillance activity.

(5) The Secretary of State may confiscate, destroy or otherwise render inoperable devices that present an unacceptable risk or are falsified devices where the Secretary of State deems it necessary to do so in the interests of the protection of public health.

(6) Following each inspection carried out for the purposes referred to in paragraph (1), the Secretary of State must—

- (a) draw up a report on the findings of the inspection that concern compliance with the legal and technical requirements applicable under this Part;
 - (b) set out in the report any corrective actions needed.
- (7) The Secretary of State must—
- (a) communicate the content of the report referred to in paragraph (6) to the economic operator that has been the subject of the inspection;
 - (b) before adopting the final report, give that economic operator the opportunity to submit comments.
- (8) The Secretary of State must—
- (a) at least every 4 years, review and assess the functioning of market surveillance activities;
 - (b) make a summary of the results accessible to the public.
- (9) Where appropriate, the Secretary of State must cooperate with the authorities of third countries with a view to exchanging information, providing technical support and promoting activities relating to market surveillance.

Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance

131. Where the Secretary of State, based on data obtained by vigilance or market surveillance activities or on other information, has reason to believe that a device—

- (a) may present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health; or
- (b) otherwise does not comply with the requirements laid down in this Part,

the Secretary of State must carry out an evaluation covering all requirements laid down in this Part relating to the risk presented by the device, or to any other non-compliance of the device and the relevant economic operators must cooperate with the Secretary of State.

Procedure for dealing with devices presenting an unacceptable risk to health and safety

132.—(1) Where, having performed an evaluation pursuant to regulation 131, the Secretary of State finds that the device presents an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, the Secretary of State must—

- (a) without delay, require a manufacturer of the devices, and all other relevant economic operators established in the United Kingdom, to take all appropriate and duly justified corrective action to bring the device into compliance with the requirements of this Part relating to the risk presented by the device;
- (b) in a manner that is proportionate to the nature of the risk, restrict the making available of the device on the market, subject the making available of the device for specific requirements, withdraw the device from the market, or recall it, within a reasonable period that is clearly defined and communicated to the relevant economic operator.

(2) The economic operators as referred to in paragraph (1) must, without delay, ensure that all appropriate corrective action is taken throughout the United Kingdom in respect of all the devices concerned that they have made available on the market.

(3) Where the economic operator as referred to in paragraph (1) does not take adequate corrective action within the period referred to in paragraph (1), the Secretary of State must take all appropriate measures to prohibit or restrict the making available of the device on the market, to withdraw the device or to recall it.

Other non-compliance

133.—(1) Where, having performed an evaluation pursuant to regulation 131, the Secretary of State finds that a device does not comply with the requirements laid down in this Part but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, the Secretary of State must require the relevant economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance.

(2) Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph (1), the Secretary of State must, without delay, take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market.

Preventive health protection measures

134. Where the Secretary of State, after having performed an evaluation which indicates a potential risk related to a device or a specific category or group of devices, considers that, in order to protect the health and safety of patients, users or other persons or other aspects of public health, the making available on the market or putting into service of a device or a specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled, the Secretary of State may take any necessary and justified measures in accordance with Part VII of these Regulations or under relevant consumer protection legislation.

Regulations

135.—(1) Regulations under this Part may—

- (a) make different provision for different purposes or different areas;
- (b) make consequential, incidental, transitional or supplemental provision.

(2) A power to make regulations under this Part is exercisable by the Secretary of State by statutory instrument.

(3) A statutory instrument which contains regulations under this Part is subject to annulment in pursuance of a resolution of each House of Parliament.”.

PART 3

New part IX of the Medical Devices Regulations

11. After regulation 135 (as inserted by regulation 10) insert—

“PART IX

The rights, powers, liabilities, obligations, restrictions, remedies and procedures recognised under the in vitro diagnostic Medical Devices Regulation (see regulation 4P)

Scope and definitions

Subject matter and scope

136.—(1) This Part lays down the rules for and applies to the placing on the market, the making available on the market and the putting into service of—

- (a) in vitro diagnostic medical devices for human use; and
- (b) accessories to such medical devices.

(2) This Part also applies to performance studies concerning in vitro diagnostic medical devices and accessories to such devices.

(3) For the purposes of this Part and Schedules 17 to 28 in vitro diagnostic medical devices and accessories to in vitro diagnostic medical devices are referred to as ‘devices’.

(4) This Part does not apply to—

- (a) relevant devices placed on the market in accordance with Part IV;
- (b) products for general laboratory use or research-use only products, unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination;
- (c) invasive sampling products or products which are directly applied to the human body for the purpose of obtaining a specimen;
- (d) internationally certified reference materials;
- (e) materials used for external quality assessment schemes.

(5) Any device which, when placed on the market or put into service, incorporates, as an integral part, a medical device as defined in regulation 69 is governed by Part VIII, but the requirements of this Part apply to the in vitro diagnostic medical device part.

(6) Where a device is also machinery within the meaning of the Supply of Machinery (Safety) Regulations 2008(a) and where—

- (a) a hazard under that legislation exists;
- (b) the provisions of that legislation are more specific than the general safety and performance requirements set out in Schedule 17,

the device must meet the essential health and safety requirements set out in Part 1 of Schedule 2 to the Supply of Machinery (Safety) Regulations 2008.

(7) This Part does not affect the application of the Ionising Radiation (Basic Safety Standards) (Miscellaneous Provisions) Regulations 2018 or any of the other measures which immediately before exit day transposed Directive 2013/59/Euratom and which are retained EU law .

(8) This Part does not affect the power of the Secretary of State to restrict the use of any specific type of device in relation to aspects not covered by this Part.

(9) This Part does not affect the organisation, delivery or financing of health services and medical care, including—

- (a) the rules relating to the supply of devices on a medical prescription;
- (b) requirements relating to—
 - (i) the dispensing of devices by certain health professionals or health care institutions; use certain devices;
 - (ii) the use of certain devices being accompanied by specific professional counselling.

(10) This Part does not restrict the freedom of the press or freedom of expression.

Definitions

137. In this Part and Schedules 17 to 28—

“accessory for an in vitro diagnostic medical device” means an article which, whilst not being itself an in vitro diagnostic medical device, is intended by its manufacturer to be used together with one or several particular in vitro diagnostic medical devices to

(a) S.I. 2008/1597.

specifically enable the in vitro diagnostic medical devices to be used in accordance with its intended purpose or to specifically and directly assist the medical functionality of the in vitro diagnostic medical device in terms of its intended purpose;

“adverse event” means any untoward medical occurrence, inappropriate patient management decision, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, in the context of a performance study, whether or not related to the device for performance study;

“analytical performance” means the ability of a device to correctly detect or measure a particular analyte;

“authorised representative” means any person established outside the United Kingdom but within the European Economic Area, who has received and accepted a written mandate from a manufacturer, located outside the European Economic Area, to act on the manufacturer’s behalf in carrying out certain obligations under Regulation (EU) 2017/746;

“benefit risk determination” means the analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer;

“calibrator” means a measurement reference material used in the calibration of a device;

“CE marking of conformity” or “CE marking” means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Part and other applicable legislation providing for its affixing;

“clinical benefit” means the positive impact of a device related to its function, such as that of screening, monitoring, diagnosis or aid to diagnosis of patients, or a positive impact on patient management or public health;

“clinical evidence” means clinical data and performance evaluation results, pertaining to a device of a sufficient number and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefits, when used as intended by the manufacturer;

“clinical performance” means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological or pathological process or state in accordance with the target population and intended user;

“common specifications” or “CS” must be construed in accordance with regulation 144;

“companion diagnostic” means device which is essential for the safe and effective use of a corresponding medicinal product to—

- (a) identify, before or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or
- (b) identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product;

“compatibility” is the ability of a device, including software, when used together with one or more other devices in accordance with its intended purpose to do any or all of the following—

- (a) perform without losing or compromising the ability to perform as intended;
- (b) integrate or operate without the need for modification or adaption of any part of the combined devices;
- (c) be used together without conflict, interference or adverse reaction;

“conformity assessment” means the process demonstrating whether the requirements of this Part relating to a device have been fulfilled;

“conformity assessment body” means a body that performs third-party conformity assessment activities including calibration, testing, certification and inspection;

“control material” means a substance, material or article intended by its manufacturer to be used to verify the performance characteristics of a device;

“corrective action” means action taken to eliminate the cause of a potential or actual non-conformity or other undesirable situation;

“designated standard” has the same meaning as in regulation 3A;

“device deficiency” in relation to a device for performance study, means any inadequacy in its identity, quality, durability, reliability, safety or performance including malfunction, use errors or inadequacy in information supplied by the manufacturer;

“device for near-patient testing” means any device that is not intended for self-testing but is intended to perform testing outside the laboratory environment, generally near to, or at the side of, the patient by a health professional;

“device for performance study” means a device intended by the manufacturer to be used in a performance study but does not include a device intended to be used for research purposes with no medical objective;

“device for self-testing” means any device intended by the manufacturer to be used by lay persons, including devices used for testing services offered to lay persons by means of information society services;

“diagnostic sensitivity” means the ability of a device to identify the presence of a target marker associated with a particular disease or condition;

“diagnostic specificity” means the ability of a device to recognise the absence of a target marker associated with a particular disease or condition;

“distributor” means any person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service;

“economic operator” means a manufacturer, an authorised representative, a UK responsible person, an importer or a distributor;

“ethics committee” means an independent body established or recognised under the Care Act 2014;

“falsified device” means any device with a false presentation of its identity, of its source or its CE marking certificates or documents relating to CE marking procedures, but a device is not a falsified device where any non-compliance is unintentional;

“field safety corrective action” means corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market;

“field safety notice” means a communication sent by a manufacturer to users or customers in relation to a field safety corrective action;

“fully refurbishing” for the purposes of the definition of manufacturer, means the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it into conformity with this Part, combined with the assignment of a new lifetime to the refurbished device;

“generic device group” means a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

“health institution” means an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health;

“importer” means any person established within the United Kingdom that places a device on the market from a country outside the United Kingdom;

“incident” in relation to a device made available on the market, means—

- (a) any malfunction or deterioration in its characteristics or performance, including use-error due to its ergonomic features and any inadequacy in the information supplied by the manufacturer;
- (b) any harm as a consequence of a medical decision; or
- (c) action taken or not taken on the basis of information or results provided by the device;

“informed consent” means a subject’s free and voluntary expression of his or her willingness to participate in a particular performance study, after having been informed of all aspects of the performance study that are relevant to the subject’s decision to participate or, in the case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the performance study;

“instructions for use” means the information provided by the manufacturer to inform the user of a device’s intended purpose and proper use and of any precautions to be taken;

“intended purpose” means the use for which a device is intended as set out in—

- (a) the data supplied by the manufacturer on the label;
- (b) the instructions for use; or
- (c) the promotional or sales materials or statements or as specified by the manufacturer in the performance evaluation;

“interoperability” is the ability of 2 or more devices, including software, from the same manufacturer or from different manufacturers to do any or all of the following—

- (a) exchange information and use the information that has been exchanged for the correct execution of a specified function without changing the content of the data;
- (b) communicate with each other;
- (c) work together as intended;

“interventional clinical performance study” means a clinical performance study where the test results may influence patient management decisions or may be used to guide treatment;

“investigator” means an individual responsible for the conduct of a performance study at a performance study site;

“in vitro diagnostic medical device” means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following—

- (a) concerning a physiological or pathological process or state;
- (b) concerning congenital physical or mental impairments;
- (c) concerning the predisposition to a medical condition or a disease;
- (d) to determine the safety and compatibility with potential recipients;
- (e) to predict treatment response or reactions;
- (f) to define or monitor therapeutic measures; and

specimen receptacles must also be deemed to be in vitro diagnostic medical devices;

“kit” means a set of components that are packaged together and intended to be used to perform a specific in vitro diagnostic examination;

“label” means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices;

“lay person” means an individual who does not have formal education in a relevant field of healthcare or medical discipline;

“legally designated representative”, has the meaning given to the term “legal representative” in Part 1 of Schedule 1 to the Medicines for Human Use (Clinical Trials) Regulations 2004;

“likelihood ratio” means the likelihood of a given result arising in an individual with the target clinical condition or physiological state compared to the likelihood of the same result arising in an individual without that clinical condition or physiological state;

“making available on the market” means any supply of a device, other than a device for performance study, for distribution, consumption or use on the United Kingdom market in the course of a commercial activity, whether in return for payment or free of charge;

“manufacturer” means a person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trade mark;

“market surveillance” means the activities carried out and measures taken by public authorities to check and ensure that devices comply with the requirements set out in the relevant legislation and do not endanger health, safety or any other aspect of public interest protection;

“medical device” has the same meaning as in regulation 69;

“negative predictive value” means the ability of a device to separate true negative results from false negative results for a given attribute in a given population;

“notified body” means a conformity assessment body designated in accordance with Regulation (EU) 2017/746;

“performance of a device” means the ability of a device to achieve its intended purpose as claimed by the manufacturer and consists of the analytical and, where applicable, the clinical performance supporting that intended purpose;

“performance evaluation” means an assessment and analysis of data to establish or verify the scientific validity, the analytical and, where applicable, the clinical performance of a device;

“performance study” means a study undertaken to establish or confirm the analytical or clinical performance of a device;

“performance study plan” means a document that describes the rationale, objectives, design methodology, monitoring, statistical considerations, organisation and conduct of a performance study;

“placing on the market” means the first making available of a device, other than a device for performance study, on the United Kingdom market;

“positive predictive value” means the ability of a device to separate true positive results from false positive results for a given attribute in a given population;

“post-market surveillance” means all activities carried out by manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from devices they place on the market, make available on the market or put into service for the purpose of identifying any need to immediately apply any necessary corrective or preventive actions;

“post-market performance follow-up” (PMPF) means a continuous process of updating the performance evaluation;

“predictive value” means the probability that a person with a positive device test result has a given condition under investigation, or that a person with a negative device test result does not have a given condition;

“putting into service” means the making available of a device, other than a device for performance study, to the final user as being ready for use on the United Kingdom market for the first time for its intended purpose;

“recall” means any measure aimed at achieving the return of a device that has already been made available to the end user;

“Regulation (EU) 2017/746” means Regulation (EU) 2017/746 of the European Parliament and of the Council of 5th April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU(a) as it has effect in European Union Law;

“risk” means the combination of the probability of occurrence of harm and the severity of that harm;

“scientific validity of an analyte” means the association of an analyte with a clinical condition or a physiological state;

“serious adverse event” means any adverse event that led to any of the following—

- (a) a patient management decision resulting in death or an imminent life-threatening situation for the individual being tested, or in the death of the individual’s offspring;
- (b) death;
- (c) serious deterioration in the health of the individual being tested or the recipient of tested donations or materials, that resulted in any of the following—
 - (i) life-threatening illness or injury;
 - (ii) permanent impairment of a body structure or a body function;
 - (iii) hospitalisation or prolongation of patient hospitalisation;
 - (iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function;
 - (v) chronic disease;
- (d) foetal distress, foetal death or a congenital physical or mental impairment or birth defect;

“serious incident” means any incident that directly or indirectly led, might have led or might lead to any of the following—

- (a) the death of a patient, user or other person;
- (b) the temporary or permanent serious deterioration of a patient’s, user’s or other person’s state of health;
- (c) serious public health threat;

“serious public health threat” means an event which could result in imminent risk of death, serious deterioration in a person’s state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time;

“single-use device” means a device that is intended to be used during a single procedure;

“specimen receptacle” means a device, whether of a vacuum-type or not, specifically intended by its manufacturer for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination;

“sponsor” means any individual, company, institution or organisation which takes responsibility for the initiation, for the management and setting up of the financing of the performance study;

(a) OJ No. L 117 5.5.2017, p.176

“subject” means an individual who participates in a performance study and whose specimens undergo in vitro examination by a device for performance study or by a device used for control purposes;

“UK responsible person” has the same meaning as in regulation 2;

“Unique Device Identifier” (“UDI”) means a series of numeric or alphanumeric characters that is created through internationally recognised and accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market;

“UDI system”, “UDI database” and related expressions have the meaning given in, or are to be construed in accordance with, in Part C of Schedule 22;

“user” means any healthcare professional or lay person who uses a device;

“withdrawal” means any measure aimed at preventing a device in the supply chain from being further made available on the market.

Regulatory status of products

138.—(1) Subject to paragraph (2), the Secretary of State may by regulations determine whether or not a specific product, category or group of products, falls within the definition of an in vitro diagnostic medical device or an accessory to an in vitro diagnostic medical device.

(2) Before making regulations under paragraph (1), the Secretary of State must consult such persons, agencies, or bodies as the Secretary of State considers appropriate to consult.

Genetic information, counselling and informed consent

139.—(1) The Secretary of State must ensure that where a genetic test is used on individuals, in the context of healthcare and for the medical purposes of diagnostics, improvement of treatment, predictive or prenatal testing—

- (a) the individual being tested or, where applicable, his or her legally designated representative is provided with relevant information on the nature, the significance and the implications of the genetic test, as appropriate;
- (b) subject to paragraph (2), there is appropriate access to counselling in the case of the use of genetic tests that provide information on the genetic predisposition for medical conditions or diseases which are generally considered to be untreatable according to the state of science and technology.

(2) Paragraph (1)(b) does not apply in cases where a diagnosis of a medical condition or a disease which the individual being tested is already known to have is confirmed by a genetic test or in cases where a companion diagnostic is used.

Making available on the market and putting into service of devices, obligations of economic operators, CE marking

Placing on the market and putting into service

140.—(1) A device to which this Part applies may be placed on the market or put into service only if it complies with this Part when duly supplied and properly installed, maintained and used in accordance with its intended purpose.

(2) A device to which this Part applies must meet the general safety and performance requirements set out in Schedule 17 which apply to it, taking into account its intended purpose.

(3) Demonstration of conformity with the general safety and performance requirements must include a performance evaluation in accordance with regulation 167.

(4) Devices that are manufactured and used within health institutions, with the exception of devices for performance studies, must be considered as having been put into service.

(5) With the exception of the relevant general safety and performance requirements set out in Schedule 17, the requirements of this Part do not apply to a device which is manufactured and used only within a health institution, provided that all of the following conditions are met—

- (a) the device is not transferred to another legal entity;
- (b) manufacture and use of the devices occur under appropriate quality management systems;
- (c) the laboratory of the health institution is compliant with standard EN ISO 15189 and, where applicable, provisions regarding accreditation;
- (d) the health institution justifies in its documentation that the specific needs of the target patient group cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market;
- (e) on request from the Secretary of State, the health institution provides the Secretary of State with information (which must include justification for its manufacturing, modification and use of such devices) on the use of the device to the Secretary of State;
- (f) the health institution draws up a declaration which it must make publicly available, including—
 - (i) the name and address of the manufacturing health institution;
 - (ii) the details necessary to identify the devices;
 - (iii) a declaration that the device meets the general safety and performance requirements set out in Schedule 17 and, where applicable, information on which requirements are not fully met and a reasoned justification for not meeting those requirements;
- (g) for Class D devices (and for other classes of device in accordance with the rules set out in Schedule 23) the health institution draws up a document which makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices and the intended purpose, and which is sufficiently detailed to enable the Secretary of State to ascertain that the general safety and performance requirements set out in Schedule 17 are met;
- (h) the Secretary of State may apply the provisions of sub-paragraph (g) also to Class A, B or C devices in accordance with the rules set out in Schedule 23;
- (i) the health institution must take all necessary measures to ensure that all devices are manufactured in accordance with the document referred to in sub-paragraph (g);
- (j) the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions.

(6) The Secretary of State may require a health institution which has complied with paragraph (5) to submit to the Secretary of State any further relevant information about such devices which it has manufactured and used.

(7) The Secretary of State may restrict the manufacture and use of a specified type of device manufactured in accordance with paragraph (5) and, for the purposes of considering such a restriction, must be permitted access to inspect the activities of the health institutions.

(8) Paragraph (5) does not apply to the devices that are manufactured on an industrial scale.

Distance sales

141.—(1) A device offered by means of information society services to a person established in the United Kingdom must comply with this Part.

- (2) A device which is—
- (a) not placed on the market;
 - (b) used for the provision of a diagnostic or therapeutic service used in the context of a commercial activity, whether in return for payment or free of charge; and
 - (c) offered by means of information society services or by other means of communication (whether directly or through intermediaries) to a person in the United Kingdom,

must comply with this Part.

(3) The Secretary of State may require a person offering a device, as described in paragraph (1) or providing a service described in paragraph (2) relating to the device.

(4) In this regulation “information society service” means a “service” within the meaning of Article 1(1)(b) of Directive 2015/1535/EU of the European Parliament and of the Council of 9th September 2015 (as it has effect in European Union Law).

Claims

142. In the labelling, instructions for use, making available, putting into service and advertising of devices, a person must not use text, names, trademarks, pictures and figurative or other signs which may mislead the user or the patient with regard to the device’s intended purpose, safety and performance by—

- (a) ascribing functions and properties to the device which the device does not have;
- (b) creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have;
- (c) failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose; or
- (d) suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out.

Use of standards

143.—(1) Devices that are in conformity with the designated standards, or the relevant parts of those standards, are presumed to be in conformity with the requirements of this Part which cover those designated standards or relevant parts of those standards.

(2) Paragraph (1) also applies to system or process requirements to be fulfilled in accordance with this Part by economic operators or sponsors, including those relating to quality management systems, risk management, post market surveillance systems, performance studies, clinical evaluation or post-market performance follow-up (‘PMPF’).

Common specifications

144.—(1) Subject to paragraphs (5) and (6), in this Part “common specifications” (CS) means common specifications which are—

- (a) adopted by the European Commission in accordance with the procedure set down in Article 9(1) of Regulation (EU) 2017/746;
- (b) designated by the Secretary of State by publishing a reference to the CS and maintaining that publication in a manner in which the Secretary of State considers appropriate.

(2) Devices that comply with CS adopted and designated in accordance with paragraph (1) or specified in regulations made under paragraph (5) are presumed to be in conformity with the requirements of this Part covered by CS or the relevant parts of the CS.

(3) Manufacturers must comply with CS adopted and designated in accordance with paragraph (1), or specified in regulations made under paragraph (6), unless they can justify

that they have adopted solutions that ensure a level of safety and performance that is at least equivalent to the CS.

(4) When considering whether the manner of publication of a reference is appropriate in accordance with paragraph (1)(b), the Secretary of State must have regard to whether the publication will draw the CS to the attention of any person who may have an interest in the CS.

(5) The Secretary of State may cancel the designation by removing from publication the reference to the CS published in accordance with paragraph (1)(b) and, where he does so, that CS is no longer a CS.

(6) Where the European Commission have not adopted a common specification but the Secretary of State is of the opinion that a common specification is necessary to address urgent public health concerns, the Secretary of State may by regulations specify a CS and designate it in accordance with paragraph (1)(b).

General obligations of manufacturers

145.—(1) When placing their devices on the market or putting them into service, manufacturers must ensure that they have been designed and manufactured in accordance with the requirements of this Part.

(2) Manufacturers must establish, document, implement and maintain a system for risk management as described in paragraph 3 of Schedule 17.

(3) Manufacturers must conduct a performance evaluation in accordance with the requirements set out in regulation 167 and Schedule 27, including a PMPF.

(4) Manufacturers must draw up and keep up to date the technical documentation for their devices.

(5) The technical documentation mentioned in paragraph (4) must—

(a) be such as to allow the conformity of the device with the requirements of this Part to be assessed;

(b) include the elements set out in Schedules 18 and 19.

(6) Where the Secretary of State considers it necessary in the light of technical progress, the Secretary of State may by regulations amend Schedules 18 and 19.

(7) Where compliance with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than devices for performance study, must draw up a declaration of conformity in accordance with regulation 151, and affix the CE marking of conformity in accordance with regulation 152.

(8) Manufacturers must comply with the obligations relating to the UDI system referred to in regulation 157 and with the registration obligations referred to in regulations 158 and 160.

(9) Manufacturers must keep the technical documentation, the declaration of conformity and, if applicable, a copy of the relevant certificate (including any amendments and supplements) available for the Secretary of State for a period of at least 10 years after the last device covered by the declaration of conformity has been placed on the market.

(10) The Secretary of State may require a manufacturer to provide the technical documentation and such a request may be for the entirety of the documentation or for a summary.

(11) A manufacturer with place of business outside the United Kingdom must ensure that the person placing the product on the market has the necessary documentation permanently available.

(12) Manufacturers must ensure that procedures are in place to keep series production in conformity with the requirements of this Part including—

- (a) ensuring that changes in product design or characteristics and changes in the standards or CS by reference to which the conformity of a product is declared are adequately, and in a timely manner, taken into account;
 - (b) ensuring that for devices (other than devices for performance study) a quality management system, which is proportionate to the risk class and type of device is established, documented, implemented, maintained, kept up to date and continually improved.
- (13) The quality management system required by paragraph (12) must—
- (a) cover all parts and elements of a manufacturer’s organisation dealing with the quality of processes, procedures and devices;
 - (b) govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of this Part;
 - (c) provide details of at least the following—
 - (i) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system;
 - (ii) the identification of applicable general safety and performance requirements and exploration of options to address those requirements;
 - (iii) the responsibility of the management;
 - (iv) resource management, including selection and control of suppliers and sub-contractors;
 - (v) risk management as set out in paragraph 3 of Schedule 17;
 - (vi) performance evaluation, in accordance with regulation 167 and Schedule 27, including PMPF;
 - (vii) product realisation, including planning, design, development, production and service provision;
 - (viii) verification of the UDI assignments made in accordance with regulation 157 to all relevant devices and ensuring consistency and validity of information provided in accordance with regulation 158;
 - (ix) setting-up, implementation and maintenance of a post-market surveillance system, in accordance with regulation 185;
 - (x) processes for handling communication with the Secretary of State (and authorities in other states), notified bodies, other economic operators, customers and any other stakeholders;
 - (xi) management of corrective and preventive actions and verification of their effectiveness;
 - (xii) processes for monitoring and measurement of output, data analysis and product improvement.
- (14) Manufacturers of devices must implement and keep up to date the post-market surveillance system in accordance with regulation 185.
- (15) Manufacturers must ensure that—
- (a) the device is accompanied by the information set out in paragraph 20 of Schedule 17 in English;
 - (b) the label is indelible, easily legible and clearly comprehensible to the intended user or patient.
- (16) Manufacturers that consider or have reason to believe that a device which they have placed on the market or put into service is not in conformity with this Part must—
- (a) immediately take the necessary corrective action to bring that device into conformity, to withdraw it or to recall it, as appropriate;

- (b) inform the distributors of the device in question and, where applicable, the authorised representative, the UK responsible person and importers accordingly;
 - (c) where the device presents a serious risk, immediately inform the Secretary of State and, where applicable, the notified body that issued a certificate for the device in particular, of the non-compliance and of any corrective action taken.
- (17) Manufacturers must have a system for recording and reporting of incidents and field safety corrective actions as described in regulations 190 and 191.
- (18) Manufacturers must, when they are required to do so by the Secretary of State—
- (a) provide the Secretary of State with all the information and documentation necessary to demonstrate the conformity of the device;
 - (b) cooperate with the Secretary of State on any corrective action needed to eliminate or, if that is not possible, mitigate the risks posed by the device which they have placed on the market or put into service;
 - (c) provide samples of the device free of charge or, where that is impracticable, grant access to the device.
- (19) A manufacturer who fails to cooperate with a requirement imposed by paragraph (18) or who provides documentation which is incomplete or incorrect, may be subject to enforcement action under Part VII or to any other enforcement measures available to the Secretary of State under consumer protection legislation.
- (20) Subject to the Data Protection Act 2018(a) and to the protection of any intellectual property rights, the Secretary of State must, where there is reason to believe that a device has caused damage and where a request is made in writing by a person in sub-paragraph (a), (b) or (c), facilitate the provision of the information and documentation mentioned in paragraph (18) to—
- (a) any person who has been or could have been injured by the device;
 - (b) any person entitled to bring an action on behalf of the person in sub-paragraph (a); or
 - (c) any other person reasonably believed to have been affected by the damage caused by the device.
- (21) The Secretary of State need not comply with the requirement in paragraph (20) where the disclosure of the information and documentation is to be dealt with in legal proceedings.
- (22) Where a manufacturer has entered into an arrangement with another person to design or manufacture a device the identity of that other person must form part of the documentation submitted in accordance with regulation 160.
- (23) Manufacturers must, taking account of the risk class of a device, the type of device and the size of the enterprise, hold sufficient insurance (or equivalent financial resources) to meet any potential financial liability arising from damage caused by a device.

UK responsible person

146. A person regarded as the UK responsible person must—

- (a) ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;
- (b) keep available for inspection by the Secretary of State a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements;

(a) 2018 c. 12.

- (c) in response to a request from the Secretary of State, provide the Secretary of State with all the information and documentation necessary to demonstrate the conformity of a device;
- (d) forward to the manufacturer any request by the Secretary of State for samples, or access to a device and ensure that the Secretary of State receives the samples or has been given access to the device;
- (e) cooperate with the Secretary of State on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;
- (f) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;
- (g) terminate the legal relationship with the manufacturer if the manufacturer acts contrary to its obligations under these Regulations and inform the Secretary of State and, if applicable, the relevant notified body of that termination.

General obligations of importers

147.—(1) Importers must place on the market only devices which are in conformity with this Part.

(2) In order to place a device on the market, importers must ensure that—

- (a) the device has been CE marked and that the declaration of conformity of the device has been drawn up;
- (b) its manufacturer or, if applicable, its authorised representative, is identified;
- (c) the device is labelled in accordance with this Part and accompanied by the required instructions for use;
- (d) where applicable, a UDI has been assigned by the manufacturer in accordance with regulation 157.

(3) Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Part, the importer must—

- (a) not place the device on the market until it has been brought into conformity;
- (b) inform the manufacturer and, if applicable, the manufacturer's authorised representative and UK responsible person;

(4) Where the importer considers or has reason to believe that the device presents a serious risk or is a falsified device, the importer must also inform the Secretary of State.

(5) Importers must indicate on the device or on its packaging or in a document accompanying the device—

- (a) their name;
- (b) if applicable, their registered trade name or registered trade mark;
- (c) if applicable, their registered place of business;
- (d) the address at which they can be contacted.

(6) Importers must ensure that any additional label does not obscure any information on the label provided by the manufacturer.

(7) Importers must verify that the device has been registered with the Secretary of State and must add their name to the registration.

(8) Importers must —

- (a) ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Schedule 17;
- (b) comply with any conditions set by the manufacturer.

(9) Importers must keep a register of —

- (a) complaints about devices;
- (b) non-conforming devices;
- (c) recalls of devices;
- (d) withdrawals of devices;

and must provide the manufacturer and distributors with any information reasonably requested by them, in order to allow them to investigate complaints.

(10) Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Part must—

- (a) immediately inform the manufacturer and, if applicable, the manufacturer's authorised representative and UK responsible person;
- (b) cooperate with the manufacturer, the manufacturer's authorised representative and UK responsible person and the Secretary of State to ensure that the necessary corrective action to bring that device into conformity, to withdraw or recall it, is taken.

(11) Where a device presents a serious risk, importers must immediately inform the Secretary of State and, if applicable, the notified body that issued a certificate, and must give details, in particular, of the non-compliance giving rise to the risk and of any corrective action taken.

(12) Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market must immediately forward this information to the manufacturer and, if applicable, the manufacturer's authorised representative and UK responsible person.

(13) Importers must keep a copy of the declaration of conformity and any relevant certificate, for the period referred to in regulation 145(9).

(14) Importers must, if required by the Secretary of State to do so—

- (a) cooperate with the Secretary of State on any action to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market;
- (b) provide samples of a device or, if that is impractical, grant the Secretary of State access to the device.

General obligations of distributors

148.—(1) When making a device available on the market, distributors must, in the context of their activities, comply with the requirements of this Part.

(2) Before making a device available on the market, distributors must ensure that all the following requirements are met—

- (a) the device has been CE marked and that the declaration of conformity of the device has been drawn up;
- (b) the device is accompanied by the information supplied by the manufacturer in accordance with regulation 145(15);
- (c) for imported devices, the importer has complied with the requirements set out in regulation 147(8);
- (d) where applicable, a UDI has been assigned by the manufacturer.

(3) In order to meet the requirements of sub-paragraphs (a), (b) and (d) of paragraph (2) the distributor may apply a sampling method that is representative of the devices supplied by the distributor.

(4) Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Part, the distributor must—

- (a) not make the device available on the market until it has been brought into conformity;
- (b) inform the manufacturer;
- (c) where applicable, inform the importer.

(5) Where a distributor considers or has reason to believe that the device presents a serious risk or is a falsified device, the distributor must, in addition to complying with paragraph (4) also inform the Secretary of State.

(6) Distributors must ensure that, while the device is under their responsibility, storage and transport conditions comply with the conditions set by the manufacturer.

(7) Where a distributor considers or has reason to believe that a device which it has made available on the market is not in conformity with this Part, the distributor must—

- (a) inform the manufacturer and where applicable, the manufacturer's authorised representative, UK responsible person and the importer;
- (b) cooperate with the manufacturer, with the Secretary of State, where applicable, with the manufacturer's authorised representative, the UK responsible person and with the importer to ensure the necessary corrective action to bring the device into conformity, to withdraw or to recall the device, is taken.

(8) Where the distributor considers or has reason to believe that a device which it has made available on the market presents a serious risk it must immediately inform the Secretary of State.

(9) Distributors must, unless the relevant information will be provided by another economic operator, upon request by the Secretary of State, provide the Secretary of State with all the information at their disposal and necessary to demonstrate the conformity of the device.

(10) Distributors must, at the Secretary of State's request—

- (a) cooperate with the Secretary of State on any action taken to eliminate the risks posed by devices which they have made available on the market;
- (b) provide free samples of the device or, if that is impractical, grant the Secretary of State access to the device.

Person responsible for regulatory compliance

149.—(1) Subject to paragraph (4), manufacturers must have available within their organisation at least one person who is responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices.

(2) Subject to paragraph (3), the requisite expertise in paragraph may be demonstrated by either of the following—

- (a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised by the Secretary of State as equivalent in—
 - (i) law;
 - (ii) medicine;
 - (iii) pharmacy;
 - (iv) engineering; or
 - (v) another relevant scientific discipline,
 and at least one year of professional experience in regulatory affairs management relating to medical devices;
- (b) 4 years of professional experience in—
 - (i) regulatory affairs; or
 - (ii) in quality management systems relating to in vitro diagnostic medical devices.

(3) Where a manufacturer manufactures custom-made devices the requisite experience may be demonstrated by having at least 2 years of professional expertise within a relevant field of manufacturing.

(4) Micro and small businesses, within the meaning of Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises^(a) (as it applies in European Union law), are not required to have a person responsible for regulatory compliance within their organisation but must have such a person permanently and continuously at their disposal.

(5) The person responsible for regulatory compliance must at least be responsible for ensuring that—

- (a) the conformity of devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before the device is released;
- (b) the technical documentation and declaration of conformity are drawn up and kept up-to date;
- (c) the post market surveillance obligations are complied with in accordance with regulation 145(14);
- (d) the reporting obligations referred to in regulations 190 to 193 are fulfilled;
- (e) in the case of investigational devices, the statement referred to in paragraph 3(a) of Chapter II of Schedule 28 is issued.

(6) If a number of persons are jointly responsible for regulatory compliance their respective areas of responsibility must be stipulated in writing.

(7) The person responsible for regulatory compliance must not suffer any disadvantage within the manufacturer's organisation in relation to the person's proper fulfilment of their duties, regardless of whether or not they are employees of the organisation.

Cases in which obligations of manufacturers apply to importers, distributors or other persons

150.—(1) A distributor, importer or other person has the obligations of a manufacturer if that person does any of the following—

- (a) makes available on the market a device under its name, registered trade name or registered mark, except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Part;
- (b) changes the intended purpose of a device already placed on the market or put into service;
- (c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected;

(2) Paragraph (1) does not apply to a person who, without changing its intended purpose, assembles or adapts for an individual patient a device which is already on the market.

(3) For the purposes of paragraph (1)(c) the following are not to be considered to be a modification of a device that could affect its compliance with the applicable requirements—

- (a) provision of information supplied by the manufacturer, in accordance with paragraph 20 of Schedule 17, relating to a device already on the market and of further information which is necessary in order to market the device;
- (b) changes to the outer packaging of a device already placed on the market, including a change of the pack size, if the repackaging is carried out in such conditions that

(a) OJ L 124, 20.5.2003, p. 36.

the original condition of the device cannot be affected but, for devices placed on the market in a sterile condition, the original condition of the device must be presumed to be adversely affected if the packaging necessary for maintaining the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.

(4) A distributor or importer that carries out any of the activities mentioned in paragraph (3) must indicate on the device or, where that is impractical, on the packaging or in a document accompanying the device—

- (a) the activity carried out;
- (b) the name of the importer or distributor;
- (c) any registered trade name or trade mark of the importer or distributor;
- (d) the registered place of business and the address at which the importer or distributor can be contacted.

(5) Distributors and importers who carry out the activities in paragraph (3) must have a quality management system in place which—

- (a) ensures that the activities in paragraph (3) are performed by a means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy;
- (b) contains procedures which ensure that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in order to respond to safety issues or to bring the device into conformity with this Part.

(6) At least 28 days prior to making the relabelled or repackaged device available on the market, distributors or importers carrying out any of the activities in paragraph (3) must—

- (a) inform the manufacturer and the Secretary of State of the intention to make a relabelled or repackaged device available;
- (b) upon request, provide the manufacturer and the Secretary of State with a sample or mock-up of the relabelled or repackaged device (including any translated label and instructions for use);
- (c) submit to the Secretary of State a certificate, issued by a notified body designated for the type of devices that are subject to activities mentioned in paragraph (3), attesting that the quality management system of the distributor or importer complies with the requirements laid down in paragraphs (4) and (5).

Declaration of conformity

151.—(1) The declaration of conformity must state that the requirements specified in this Part, or the equivalent provisions of Regulation (EU) 2017/746, have been fulfilled in relation to the device that is covered and the manufacturer must continuously update the declaration of conformity.

(2) The declaration of conformity must, at least, contain the information set out in Schedule 20 and must be in English.

(3) Where a device is subject to other legislation which requires a declaration of conformity by the manufacturer, a single declaration of conformity must be drawn up in respect of all the legislation applicable to the device and must contain the information required for identification of the legislation to which the declaration relates.

(4) By drawing up the declaration of conformity, the manufacturer assumes responsibility for compliance with the requirements of this Part and all other legislation applicable to the device.

CE marking of conformity

152.—(1) Devices, other than custom-made or investigational devices, considered to be in conformity with the requirements of this Part must bear the CE marking of conformity, as presented in Schedule 21.

(2) The CE marking—

- (a) must be affixed visibly, legibly and indelibly to the device or its sterile packaging;
- (b) where such affixing is not possible or not warranted on account of the nature of the device, must be affixed to the packaging;
- (c) must also appear in any instructions for use and on any sales packaging.

(3) The CE marking must be affixed before the device is placed on the market and it may be followed by a pictogram or any other mark indicating a special risk or use.

(4) Where applicable, the CE marking must be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in regulation 163 and the identification number must also be indicated in any promotional material which mentions that a device fulfils the requirements for CE marking.

(5) Where devices are subject to other legislation which also provides for the affixing of the CE marking, the CE marking must indicate that the devices also fulfil the requirements of that other legislation.

Devices for special purposes

153.—(1) The Secretary of State must not create obstacles to devices for performance study being supplied to an investigator for the purpose of a clinical investigation if they meet the requirements of this Part.

(2) The devices to which paragraph (1) relates must not bear a CE marking.

(3) The Secretary of State must not create obstacles to the showing of devices, which do not comply with this Part, at trade fairs, exhibitions, demonstrations or similar events provided that the following conditions are met—

- (a) a visible sign clearly indicates that such a device are intended for presentation or demonstration purposes;
- (b) that such a device cannot be made available until it has been brought into compliance with this Part.

Parts and components

154.—(1) Any person who makes available on the market an item specifically intended to replace an identical or similar integral part or component of a device that is defective or worn in order to maintain or restore the function of the device without changing its performance or safety characteristics or its intended purpose, must—

- (a) ensure that the item does not adversely affect the safety and performance of the device;
- (b) keep supporting evidence available for the Secretary of State.

(2) An item that is intended specifically to replace a part or component of a device and that significantly changes the performance or safety characteristics or the intended purpose of the device is considered to be a device and must meet the requirements laid down in this Part.

Identification within the supply chain

155.—(1) Distributors and importers must cooperate with manufacturers (or the manufacturer’s authorised representative and UK responsible person) to achieve an appropriate level of traceability of devices.

(2) Economic operators must, where applicable, be able to identify the following to the Secretary of State, for the period referred to in regulation 145(9)—

- (a) any economic operator to whom they have directly supplied a device;
- (b) any economic operator who has directly supplied them with a device;
- (c) any health institution or healthcare professional to which they have directly supplied a device.

Medical devices nomenclature

156.—(1) The Secretary of State must ensure that an internationally recognised medical devices nomenclature is available free of charge to manufacturers and other persons required by this Part to use that nomenclature.

(2) The Secretary of State must also endeavour to ensure that nomenclature is available to other stakeholders free of charge, where reasonably practicable.

Unique device identification system

157.—(1) ‘UDI system’ must consist of –

- (a) production of a UDI that comprises—
 - (i) a UDI device identifier (‘UDI-DI’) specific to a manufacturer and a device, providing access to the information laid down in Part B of Schedule 22;
 - (ii) a UDI production identifier (‘UDI-PI’) that identifies the unit of device production and if applicable the packaged devices, as specified in Part C of Schedule 22;
- (b) placing of the UDI on the label of the device or on its packaging;
- (c) storage of the UDI by economic operators, health institutions and healthcare professionals, in accordance with the conditions laid down in paragraphs (8) and (9) respectively;
- (d) establishment of an electronic system for Unique Device Identification (‘UDI database’) in accordance with regulation 159.

(2) Before placing a device, other than a device for performance study, on the market, the manufacturer must assign to the device and, if applicable, to all higher levels of packaging, a UDI created in compliance with the rules of an issuing entity.

(3) Before a device, other than a device for performance study, is placed on the market the manufacturer must ensure that the information referred to in Part B of Schedule 22 about the device is correctly submitted and transferred to the UDI database referred to in regulation 92.

(4) UDI carriers must be placed on the label of the device and on all higher levels of packaging but “higher levels of packaging” does not include shipping containers.

(5) The UDI must be used for reporting serious incidents and field safety corrective actions in accordance with regulation 190.

(6) The Basic UDI-DI of the device must appear on the declaration of conformity referred to in regulation 151.

(7) As part of the technical documentation referred to in Schedule 18 the manufacturer must keep up-to-date a list of the UDIs that it has assigned.

(8) Economic operators must store and keep, preferably by electronic means, the UDI of the devices which they have supplied or with which they have been supplied, if those devices belong to the devices, categories or groups of devices determined by regulations made under paragraph (10).

(9) The Secretary of State may require healthcare institutions or healthcare professionals to store and keep, preferably by electronic means, the UDI of the devices with which they have been supplied.

(10) The Secretary of State may by regulations—

- (a) determine the devices, categories or groups of devices mentioned in paragraph (8);
- (b) amend the list of information set out in Part B of Schedule 22 in the light of technical progress;
- (c) amend Schedule 22 in the light of international developments and technical progress.

(11) In this regulation and regulation 158 “issuing entity” means an organisation designated by the European Commission for the purpose of issuing UDIs pursuant to Regulation 2017/746 of the European Parliament and the Council of 5th April 2017 as it applies in the European Union^(a).

Registration of devices (ex Art 26)

158.—(1) Before placing a device, other than a custom-made device, on the market, the manufacturer must, in accordance with the rules of the issuing entity referred to in regulation 157(2), assign a Basic UDI-DI to the device and must provide it to the UDI database together with the other core data elements referred to in Part B of Schedule 22 related to that device.

(2) Where a manufacturer is not established in the United Kingdom, the UK responsible person must ensure that the manufacturer has complied with paragraph (1).

Electronic system for registration of economic operators

159.—(1) The Secretary of State must set up and manage an electronic system to create a registration number for the purpose of identifying the manufacturer and, where applicable, the importer, authorised representative, the UK responsible person and distributor.

(2) The details of the information to be provided to the electronic system are set out in paragraph 1 of Part A of Schedule 22.

Registration of economic operators

160.—(1) No person may place a device on the market unless that person is—

- (a) established in the United Kingdom;
- (b) has complied with paragraph (2).

(2) Before placing a device on the market—

- (a) a manufacturer must register with the electronic system referred to in regulation 159 and provide the information set out in paragraph 1 of Part A of Schedule 22;
- (b) where there is no manufacturer established in the United Kingdom, the person placing the product on the market is to be regarded as the UK responsible person and that person must register with the electronic system referred to in regulation 159.

(a) OJ no. L 117, 5.5.2017, p.1.

(3) Unless they have already registered as a person within paragraph (2)(b), importers must also provide the relevant information in paragraph 1 of Part A of Schedule 22.

(4) Within one week of a change occurring in the information referred to in paragraph (2), the person must update the information in the electronic system referred to in regulation 159.

(5) Not later than one year after the submission of the information referred to in paragraph (2), and every second year after that, the person must confirm the accuracy of the information.

(6) Notwithstanding the person's responsibility for the accuracy of the information, the Secretary of State must verify the information provided under paragraph (2).

(7) The information entered in the electronic system must be accessible to the public.

(8) The Secretary of State may use the information provided under paragraph (2) for the purpose of charging a fee in connection with carrying out the activities set out in this Part.

Summary of safety and performance

161.—(1) For Class C and D devices, other than devices for performance studies, a manufacturer must draw up a summary of safety and performance.

(2) The summary of safety and performance must be written in a way that is clear to the intended user and, if applicable, to the patient and must be made available to the public.

(3) The manufacturer must state on the label or the instructions for use where the summary of safety and performance can be found.

(4) The summary of safety and clinical performance must include at least the following—

- (a) identification of the device and the manufacturer including the Basic UDI-DI;
- (b) the intended purpose of the device, any indications or contraindications and the target populations;
- (c) a description of the device, including a reference to any previous generations or variants and a description of the differences;
- (d) where relevant, a description of any accessories, other devices and products which are intended to be used in combination with the device;
- (e) possible diagnostic therapeutic alternatives;
- (f) the summary of performance evaluation as referred to in Schedule 27, and relevant information on PMPF;
- (g) suggested profile and training for users;
- (h) information on any residual risks and any undesirable side effects, warnings and precautions.

(5) The Secretary of State may by regulations set out the form and presentation of the data elements to be included in the summary of safety and performance.

Classification of devices

162. Devices to which this Part applies must be divided into Classes A, B, C and D, according to the classification rules in Schedule 23.

Conformity assessment procedures

163.—(1) Before placing a device on the market, putting a device into service or making a device available on the market, a person must ensure that the manufacturer has undertaken an assessment of the conformity of the device in accordance with the applicable conformity assessment procedures outlined in paragraphs (2) to (10) and set out in Schedules 24 to 26.

- (2) Class D devices, other than devices for performance study, must be subject to—
- (a) a conformity assessment as specified in Parts 1 and 3 of Schedule 24; or
 - (b) a conformity assessment as specified in Schedule 25 coupled with a conformity assessment as specified in Schedule 26.
- (3) In addition to the procedures in paragraph (2) for Class D devices for self-testing and near patient testing, the manufacturer must follow the procedure for technical documentation assessment set out in paragraph 3 of Schedule 24.
- (4) Class C devices, other than devices for performance study, must be subject to conformity assessment procedure—
- (a) as specified in Parts 1 and 3 of Schedule 24, including an assessment of the technical documentation of at least one representative device per generic device group; or
 - (b) as specified in Schedule 25 coupled with a conformity assessment as specified in Schedule 26 (except for paragraph 4).
- (5) In addition to the procedures in paragraph (4) for Class C devices for self-testing and near patient testing, the manufacturer must follow the procedure for technical documentation assessment set out in paragraph 3 of Schedule 24.
- (6) Class B devices, other than devices for performance study, must be subject to a conformity assessment as specified in Parts 1 and 3 of Schedule 24, including an assessment of the technical documentation for at least one representative device per category of devices.
- (7) In addition to the procedures in paragraph (6) for Class B devices for self-testing and near patient testing, the manufacturer must follow the procedure for technical documentation assessment set out in paragraph 3 of Schedule 24.
- (8) Subject to paragraph (9), Class A devices, other than devices for performance study, must declare the conformity of their products by issuing a declaration of conformity referred to in regulation 151, after drawing up the technical documentation set out in Schedules 18 and 19.
- (9) If Class A devices are placed on the market in a sterile condition, the manufacturer must apply the procedures set out in Schedule 24 or in Schedule 26.
- (10) Devices for performance study must be subject to the requirements of regulations 168 to 185.

Involvement of notified bodies

164.—(1) Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of its choice, provided that the chosen notified body is designated for conformity assessment activities related to the types of devices concerned.

(2) The manufacturer may not lodge an application in parallel with another notified body for the same conformity assessment procedure.

Exceptions to conformity assessment and CE marking etc.

165.—(1) The requirements of regulation 164 do not apply where—

- (a) on request, the Secretary of State has authorised the placing on the market, making available on the market or putting into service within the United Kingdom of a specific device;
- (b) where that authorisation is granted for the purpose of protecting public health or patient safety or health.

(2) Except for the requirement to register in accordance with regulations 158 or 160, the requirements of this Part do not apply where the Secretary of State directs that a relevant

device (or a class of relevant devices), which meets other requirements or standards (or which is marked other than with a CE marking) which the Secretary of State considers to be equivalent to the requirements and standards imposed by this Part, may be placed on the market.

(3) In paragraph (2), a standard or requirement is equivalent to a standard or requirement imposed by this Part if, in respect of the relevant device (or class of relevant devices), the standard or requirement provides for an equivalent level of safety and quality to that imposed by this Part.

Certificate of free sale

166.—(1) For the purpose of export and upon request by a manufacturer, the Secretary of State must issue a certificate of free sale declaring that the manufacturer has its registered place of business in the United Kingdom and that the device in question, bearing the CE marking in accordance with this Part, may be marketed in the United Kingdom.

(2) The certificate of free sale must set out the Basic UDI-DI of the device as provided to the UDI database under regulation 92 and, where a notified body has issued a certificate, the certificate of free sale must set out the unique number identifying the certificate issued by the notified body.

Clinical evaluation, performance evaluation and performance studies

Performance evaluation and clinical evidence

167.—(1) Confirmation of conformity with relevant general safety and performance requirements set out in Schedule 17, in particular those concerning the performance characteristics referred to in Part 1 and paragraph 9 of Schedule 17, under the normal conditions of the intended use of the device, and the evaluation of the interference and cross-reactions and of the acceptability of the benefit-risk ratio referred to in paragraphs 1 and 8 of Schedule 17, must be based on scientific validity, analytical and clinical performance data providing sufficient clinical evidence, including where applicable relevant data as referred to in Schedule 19.

(2) The manufacturer must specify and justify the level of the clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements and that level of clinical evidence must be appropriate in view of the characteristics of the device and its intended purpose.

(3) Manufacturers must plan, conduct and document a performance evaluation in accordance with this regulation and with Part A of Schedule 27.

(4) The clinical evidence must support the intended purpose of the device as stated by the manufacturer and be based on a continuous process of performance evaluation, following a performance evaluation plan.

(5) A performance evaluation must follow a defined and methodologically sound procedure for the demonstration of the following, in accordance with this regulation and with Part A of Schedule 27—

- (a) scientific validity;
- (b) analytical performance;
- (c) clinical performance.

(6) The data and conclusions drawn from the assessment of the elements in paragraph (5) must constitute the clinical evidence for the device and the clinical evidence must be such as to scientifically demonstrate, by reference to the state of the art in medicine, that the intended clinical benefit will be achieved and that the device is safe.

(7) The clinical evidence derived from the performance evaluation must provide scientifically valid assurance, that the relevant general safety and performance requirements set out in Schedule 17, are fulfilled, under normal conditions of use.

(8) Clinical performance studies in accordance with paragraph 2 of Part A of Schedule 27 must be carried out unless it is duly justified to rely on other sources of clinical performance data.

(9) The scientific validity data, the analytical performance data and the clinical performance data, their assessment and the clinical evidence derived from that data, shall be documented in the performance evaluation report referred to in paragraph 1(21) to (22) of Part A of Schedule 27.

(10) The performance evaluation report must be part of the technical documentation, referred to in Schedule 18, relating to the device concerned.

(11) The performance evaluation and its documentation shall be updated throughout the life cycle of the device concerned with data obtained from implementation of the manufacturer's PMPF plan in accordance with Part B of Schedule 27 and the post-market surveillance plan referred to in regulation 187.

(12) The performance evaluation report for Class C and D devices must be updated when necessary, but at least annually, with the data referred to in the paragraph (11) and the summary of safety and performance referred to in regulation 161 must be updated as soon as possible, where necessary.

General requirements regarding performance studies

168.—(1) The manufacturer must ensure that a device for performance study complies with the general safety and performance requirements set out in Schedule 17 apart from the aspects covered by the performance study and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the patient, user and other persons.

(2) Where appropriate, performance studies must be performed in circumstances similar to the normal conditions of use of the device.

(3) Performance studies must be designed and conducted in such a way that the rights, safety, dignity and well-being of the subjects participating in such performance studies are protected and prevail over all other interests and the data generated are scientifically valid, reliable and robust.

Additional requirements for certain performance studies

169.—(1) Any performance study—

- (a) in which surgically invasive sample-taking is done only for the purpose of the performance study;
- (b) that is an interventional clinical performance study; or
- (c) where the conduct of the study involves additional invasive procedures or other risks for the subjects of the studies,

must, in addition to meeting the requirements set out in regulation 168 and Schedule 27, be designed, authorised, conducted, recorded and reported in accordance with this regulation, regulations 170 to 185 and Schedule 28.

(2) Performance studies involving companion diagnostics must be subject to the same requirements as the performance studies listed in paragraph (1).

(3) Paragraph (2) does not apply to performance studies involving companion diagnostics using only left-over samples but such studies must be notified to the Secretary of State.

(4) Performance studies must be subject to scientific and ethical review performed by an ethics committee whose procedures for review are compatible with the procedures for the assessment of an application for authorisation of a performance study set out in this Part.

(5) Where the sponsor of a performance study is not established in the United Kingdom—

- (a) that sponsor shall ensure that a person is established in the United Kingdom as its legal representative;
- (b) such legal representative shall be responsible for ensuring compliance with the sponsor's obligations pursuant to this Part, and must be the addressee for all communications with the sponsor provided for in this Part; and
- (c) any communication with that legal representative must be deemed to be a communication with the sponsor.

(6) A performance study as referred to in paragraph (1) may be conducted only where all of the following conditions are met—

- (a) the performance study is the subject of an authorisation by the Secretary of State in accordance with this Part, unless otherwise stated;
- (b) an ethics committee has not issued a negative opinion in relation to the performance study;
- (c) the sponsor or its legal representative or a contact person pursuant to paragraph (5) is established in the United Kingdom;
- (d) vulnerable populations and subjects are appropriately protected in accordance with regulations 170 to 174;
- (e) the anticipated benefits to the subjects or to public health justify the foreseeable risks and inconveniences and compliance with this condition is constantly monitored;
- (f) the subject or, where the subject is not able to give informed consent, his or her legally designated representative has given informed consent, in accordance with regulation 170;
- (g) the subject or, where the subject is not able to give informed consent, his or her legally designated representative, has been provided with the contact details of an entity where further information can be received in case of need;
- (h) the rights of the subject to physical and mental integrity, to privacy and to the protection of the data concerning him or her in accordance with the Data Protection Act 2018 are safeguarded;
- (i) the performance study has been designed to involve as little pain, discomfort, fear and any other foreseeable risk as possible for the subjects, and both the risk threshold and the degree of distress are specifically defined in the performance study plan and constantly monitored;
- (j) the medical care provided to the subjects is the responsibility of an appropriately qualified medical doctor or, where appropriate, any other person authorised health professional entitled to provide the relevant patient care under performance study conditions;
- (k) no undue influence, including that of a financial nature, is exerted on the subject, or, where applicable, on his or her legally designated representatives, to participate in the performance study;
- (l) where appropriate, biological safety testing reflecting the latest scientific knowledge or any other test deemed necessary in the light of the device's intended purpose has been conducted;
- (m) in the case of clinical performance studies, the analytical performance has been demonstrated, taking into consideration the state of the art;
- (n) in the case of interventional clinical performance studies, the analytical performance and scientific validity has been demonstrated, taking into

consideration the state of the art and where, for companion diagnostics, the scientific validity is not established, the scientific rationale for the use of the biomarker shall be provided;

- (o) the technical safety of the device with regard to its use has been proven, taking into consideration the state of the art as well as provisions in the field of occupational safety and accident prevention;
- (p) the requirements of Schedule 28 are fulfilled.

(7) Any subject, or, where the subject is not able to give informed consent, his or her legally designated representative, may, without any resulting detriment and without having to provide any justification, withdraw from the performance study at any time by revoking his or her informed consent.

(8) Subject to the Data Protection Act 2018, the withdrawal of the informed consent in accordance with paragraph (7) must not affect the activities already carried out and the use of data obtained based on informed consent before its withdrawal.

(9) The investigator must be an authorised health professional qualifying for the role of investigator on account of having the necessary scientific knowledge and experience in patient care or laboratory medicine and other personnel involved in conducting a performance study must be suitably qualified, by education, training or experience in the relevant medical field and in clinical research methodology, to perform their tasks.

(10) Where appropriate, the facilities where the performance study involving subjects is to be conducted must be suitable for the performance study and shall be similar to the facilities where the device is intended to be used.

Informed consent

170.—(1) Informed consent—

- (a) must be written, dated and signed by the person performing the interview referred to in paragraph 170(2)(c), and by the subject or, where the subject is not able to give informed consent, his or her legally designated representative after having been duly informed in accordance with paragraph 170(2);
- (b) may, where the subject is unable to write, be given and recorded through appropriate alternative means in the presence of at least one impartial witness and, in that case, the witness must sign and date the informed consent document;
- (c) must be documented and a copy of that document or record must be provided to the subject or the subject's legally designated representative;
- (d) is only valid if adequate time is given for the subject, or the subject's legally designated representative to consider their decision to participate in the performance study.

(2) Information given to the subject or, where the subject is not able to give informed consent, his or her legally designated representative for the purposes of obtaining his or her informed consent must—

- (a) enable the subject or his or her legally designated representative to understand—
 - (i) the nature, objectives, benefits, implications, risks and inconveniences of the performance study;
 - (ii) the subject's rights and guarantees regarding his or her protection, in particular his or her right to refuse to participate in and the right to withdraw from the performance study at any time without any resulting detriment and without having to provide any justification;
 - (iii) the conditions under which the performance study is to be conducted, including the expected duration of the subject's participation in the performance study;

- (iv) the possible treatment alternatives, including the follow-up measures if the participation of the subject in the performance study is discontinued;
 - (b) be kept comprehensive, concise, clear, relevant, and understandable to the subject or the subject's legally designated representative;
 - (c) be provided in a prior interview with a member of the investigating team who is appropriately qualified; and
 - (d) include information about the applicable damage compensation system referred to in regulation 175.
- (3) The information referred to in paragraph (2) must be prepared in writing and be available to the subject or, where the subject is not able to give informed consent, his or her legally designated representative.
- (4) In the interview referred to in paragraph (2)(c)—
- (a) special attention must be paid to the information needs of specific patient populations and of individual subjects, as well as to the methods used to give the information;
 - (b) the member of the investigating team must ensure that the subject has understood the information.
- (5) The subject must be informed that a performance study report and a summary presented in terms understandable to the intended user will be made available irrespective of the outcome of the performance study, and must be informed, to the extent possible, when they have become available.
- (6) A minor who is capable of forming an opinion and assessing the information given to him or her, must also assent in order to participate in a clinical investigation.

Performance studies on incapacitated subjects

- 171.**—(1) In the case of incapacitated subjects who have not given, or have not refused to give, informed consent before the onset of their incapacity, a performance study may be conducted only where, in addition to the conditions set out in regulation 169(6), all of the following conditions are met—
- (a) unless regulation 174 applies, the informed consent of their legally designated representative has been obtained;
 - (b) unless regulation 174 applies, the incapacitated subjects have received the information referred to in regulation 171 in a way that is adequate in view of their capacity to understand it;
 - (c) the explicit wish of an incapacitated subject who is capable of forming an opinion and assessing the information referred to in regulation 170(2) to refuse participation in, or to withdraw from, the performance study at any time, is respected by the investigator;
 - (d) no incentives or financial inducements are given to subjects or their legally designated representatives, except for compensation for expenses and loss of earnings directly related to the participation in the performance study;
 - (e) the performance study is essential with respect to incapacitated subjects and data of comparable validity cannot be obtained in performance studies on persons able to give informed consent, or by other research methods;
 - (f) the performance study relates directly to a medical condition from which the subject suffers;
 - (g) there are scientific grounds for expecting that participation in the performance study will produce—
 - (i) a direct benefit to the incapacitated subject outweighing the risks and burdens involved; or

- (ii) some benefit for the population represented by the incapacitated subject concerned when the performance study will pose only minimal risk to, and will impose minimal burden on, the incapacitated subject concerned in comparison with the standard treatment of the incapacitated subject's condition.

(2) The subject must, as far as possible, take part in the informed consent procedure.

Performance studies on minors

172. A performance study on minors may be conducted only where, in addition to the conditions set out in regulation 169(6) all of the following conditions are met—

- (a) the informed consent of their legally designated representative has been obtained;
- (b) the minors have received the information referred to in regulation 170(2) in a way adapted to their age and mental maturity and from investigators or members of the investigating team who are trained or experienced in working with children;
- (c) the explicit wish of a minor who is capable of forming an opinion and assessing the information referred to in regulation 170(2) to refuse participation in, or to withdraw from, the performance study at any time, is respected by the investigator;
- (d) no incentives or financial inducements are given to subjects or their legally designated representatives, except for compensation for expenses and loss of earnings directly related to the participation in the performance study;
- (e) the performance study is intended to investigate treatments for a medical condition that only occurs in minors or the performance study is essential with respect to minors to validate data obtained in performance studies on persons able to give informed consent or by other research methods;
- (f) the performance study either relates directly to a medical condition from which the minor concerned suffers or is of such a nature that it can only be carried out on minors;
- (g) there are scientific grounds for expecting that participation in the performance study will produce—
 - (i) a direct benefit to the minor subject outweighing the risks and burdens involved; or
 - (ii) some benefit for the population represented by the minor concerned when the performance study will pose only minimal risk to, and will impose minimal burden on, the minor concerned in comparison with the standard treatment of the minor's condition;
- (h) the minor must take part in the informed consent procedure in a way adapted to his or her age and mental maturity;
- (i) if, during a performance study, a person reaches the age of 16 years, that person's express informed consent must be obtained before they can continue to participate in the clinical investigation.

Performance studies on pregnant or breastfeeding women

173. A performance study on a pregnant or breastfeeding woman may be conducted only where, in addition to the conditions set out in regulation 169(6), all of the following conditions are met—

- (a) the performance study has the potential to produce a direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, outweighing the risks and burdens involved;
- (b) if such a performance study has no direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, it can be conducted only if—

- (i) a performance study of comparable effectiveness cannot be carried out on women who are not pregnant or breastfeeding;
- (ii) the performance study contributes to the attainment of results capable of benefitting pregnant or breastfeeding women or other women in relation to reproduction or other embryos, fetuses or children; and
- (iii) the performance study poses a minimal risk to, and imposes a minimal burden on, the pregnant or breastfeeding woman concerned, her embryo, fetus or child after birth;
- (c) where research is undertaken on breastfeeding women, particular care is taken to avoid any adverse impact on the health of the child;
- (d) no incentives or financial inducements are given to subjects, except for compensation for expenses and loss of earnings directly related to the participation in the performance study.

Performance studies in emergency situations

174.—(1) Informed consent to participate in a performance study may be obtained, and information on the performance studies may be given, after the decision to include the subject in the performance study, provided that that decision is taken at the time of the first intervention on the subject, in accordance with the clinical performance study plan for that performance study and that all of the following conditions are fulfilled—

- (a) due to the urgency of the situation, caused by a sudden life-threatening or other sudden serious medical condition, the subject is unable to provide prior informed consent and to receive prior information on the performance study;
- (b) there are scientific grounds to expect that participation of the subject in the performance study will have the potential to produce a direct clinically relevant benefit for the subject resulting in a measurable health-related improvement alleviating the suffering or improving the health of the subject, or in the diagnosis of its condition;
- (c) it is not possible within the therapeutic window to supply all prior information to and obtain prior informed consent from the subject's legally designated representative;
- (d) the investigator certifies that they are not aware of any objections to participate in the performance study previously expressed by the subject;
- (e) the performance study relates directly to the subject's medical condition because of which it is not possible within the therapeutic window to obtain prior informed consent from the subject or from his or her legally designated representative and to supply prior information, and the performance study is of such a nature that it may be conducted exclusively in emergency situations;
- (f) the performance study poses a minimal risk to, and imposes a minimal burden on, the subject in comparison with the standard treatment of the subject's condition.

(2) Where paragraph (1) applies, informed consent in accordance with regulation 170 must be sought to continue the participation of the subject in the performance study, and information on the performance study must be given, in accordance with the following requirements—

- (a) for incapacitated subjects and minors, the informed consent must be sought by the investigator from the subject's legally designated representative without undue delay and the information referred to in regulation 170(2) must be given as soon as possible to the subject and to the subject's legally designated representative;
- (b) for all other subjects, the informed consent must be sought by the investigator without undue delay from the subject or the subject's legally designated representative, whichever can be done sooner, and the information referred to in

regulation 170(2) must be given as soon as possible to the subject or his or her legally designated representative, as applicable.

(3) For the purposes of paragraph (2)(b), where informed consent has been obtained from the legally designated representative, informed consent to continue the participation in the performance study must be obtained from the subject as soon as the subject is capable of giving informed consent.

(4) Where consent is not given, the subject or, where applicable, the subject's legally designated representative must be informed of the right to object to the use of data obtained from the performance study.

Damage compensation

175. Sponsors must, taking account of the risk class of a device, the type of device and the size of the enterprise, hold sufficient insurance (or equivalent financial resources) to meet any potential financial liability arising from damage caused by a performance study.

Application for performance studies

176.—(1) The sponsor of a performance study must submit an application to the Secretary of State accompanied by the documentation referred to in paragraphs 2 and 3 of Schedule 27 and in Schedule 28.

(2) Within 10 days of receiving the application, the Secretary of State must notify the sponsor as to whether the performance study falls within the scope of this Part and as to whether the application dossier is complete in accordance with Part 1 of Schedule 28.

(3) Within one week of any change occurring in relation to the documentation referred to in Part 1 of Schedule 28, the sponsor must—

- (a) update the relevant data;
- (b) make that change to the documentation clearly identifiable;
- (c) notify the Secretary of State of the update.

(4) Where the Secretary of State finds that the performance study applied for does not fall within the scope of this Part or that the application dossier is not complete, the Secretary of State must inform the sponsor and must set a time limit of maximum 10 days for the sponsor to comment, but the Secretary of State may extend this period by a maximum of 20 days where appropriate.

(5) Where—

- (a) the sponsor has not provided comments within the time limit referred to in the paragraph (4), the application must be deemed to have lapsed;
- (b) the sponsor considers the application does fall under the scope of this Part or is complete but the Secretary of State does not, the application must be considered to have been rejected.

(6) The Secretary of State must notify the sponsor within 5 days of receipt of the comments or of the requested additional information, whether the performance study is considered as falling within the scope of this Part or, as the case maybe, whether the application is complete.

(7) The Secretary of State may extend the notification periods referred to in paragraphs (2) and (6) each by a further 5 days.

(8) The validation date of the application is to be considered—

- (a) the date on which the sponsor is notified in accordance with paragraphs (2) and (6); or
- (b) where the sponsor is not notified, the last day of the periods referred to in paragraph (4).

(9) The sponsor may start the clinical investigation in the following circumstances—

- (a) in the case of performance studies in which surgically invasive sample-taking is done only for the purpose of the performance study, provided that a negative opinion has not been issued by an ethics committee in the United Kingdom in respect of the performance study, immediately after the validation date of the application pursuant to paragraph (8);
- (b) in the case of performance studies, carried out pursuant to regulation 169(b) or (c) or performance studies other than those referred to in sub-paragraph (a), provided a negative opinion in respect of the clinical investigation has not been issued by an ethics committee in the United Kingdom, as soon as the Secretary of State has notified the sponsor of the Secretary of State's authorisation.

(10) For the purposes of paragraph (9)(b) the Secretary of State must notify the sponsor of the authorisation within 45 days of the validation date referred to in paragraph (8) and the Secretary of State may extend this period by a further 20 days for the purpose of consulting with experts.

Assessment by Secretary of State

177.—(1) The Secretary of State must ensure that the persons validating and assessing the performance study application, or deciding on it do not have conflicts of interest and in particular are—

- (a) independent of—
 - (i) the sponsor;
 - (ii) the investigators involved;
 - (iii) the person financing the performance study;
- (b) free of any undue influence.

(2) The Secretary of State must ensure that the assessment is done jointly by an appropriate number of persons who collectively have the necessary qualifications and experience.

(3) The Secretary of State—

- (a) must assess whether the performance study is designed in such a way that potential remaining risks to subjects or third persons, after risk minimization, are justified, when weighed against the clinical benefits to be expected;
- (b) must, while taking into account applicable CS or designated standards, examine in particular—
 - (i) the demonstration of compliance of the devices for performance study with the applicable general safety and performance requirements, apart from the aspects covered by the performance study, and whether, with regard to those aspects, every precaution has been taken to protect the health and safety of the subjects and this includes, where appropriate, the evaluation of the analytical performance, clinical performance and scientific validity, taking into consideration the state of the art;
 - (ii) whether the risk-minimisation solutions employed by the sponsor are described in designated standards and, in those cases where the sponsor does not use those standards, whether the risk-minimisation solutions provide a level of protection that is equivalent to that provided by those standards;
 - (iii) whether the measures planned for the safe installation, putting into service and maintenance of the device for performance study are adequate;
 - (iv) the reliability and robustness of the data generated in the performance study, taking account of statistical approaches, design of the investigation and methodological aspects, including sample size, comparator and endpoints;
 - (v) whether the requirements of Schedule 28 are met.

(4) The Secretary of State must refuse the authorisation of the performance study if—

- (a) the application dossier submitted remains incomplete;
- (b) the device or the submitted documents, especially the performance study plan and the investigator's brochure, do not correspond to the state of scientific knowledge, and the performance study, in particular, is not suitable for providing evidence for the safety, performance characteristics or benefit of the device on subjects or patients;
- (c) the requirements of regulation 168 are not met; or
- (d) any assessment under paragraph (3) is negative.

Appeal rights

178.—(1) Where the sponsor is dissatisfied with a decision taken by the Secretary of State under regulation 176(6) or regulation 177(4), the sponsor or the sponsor's legally designated representative in the United Kingdom may require the Secretary of State to seek advice from such a person as the Institute determines on—

- (a) whether the performance study falls within this Part; or
- (b) whether the Secretary of State correctly refused the authorisation.

(2) Where the sponsor acts in accordance with paragraph (1), the sponsor is responsible for the fees, costs and expenses of the Institute and of the person appointed by the Institute.

(3) In this regulation, "Institute" means the charitable organisation with registered number 803725 and known as the Chartered Institute of Arbitrators.

Conduct of performance study

179.—(1) The sponsor and the investigator must ensure that the performance study is conducted in accordance with the approved performance study plan.

(2) The sponsor—

- (a) must ensure adequate monitoring of the conduct of the performance study in order to—
 - (i) verify that the rights, safety and wellbeing of the subjects are protected;
 - (ii) that the reported data are reliable and robust;
 - (iii) that the conduct of the performance study is in compliance with the requirements of this Part;
- (b) must determine the extent and nature of the monitoring on the basis of an assessment taking into consideration all the characteristics of the performance study including the following—
 - (i) the objective and methodology of the performance study;
 - (ii) the degree of deviation of the intervention from normal clinical practice.

(3) All performance study information must be recorded, processed, handled, and stored by the sponsor or investigator, as applicable, in such a way that it can be accurately reported, interpreted and verified while the confidentiality of records and the personal data of the subjects remain protected in accordance with the Data Protection Act 2018.

(4) Appropriate technical and organisational measures must be implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss, in particular where the processing involves transmission over a network.

(5) The Secretary of State must inspect, at an appropriate level, performance study sites to check that performance studies are conducted in accordance with the requirements of this Part and with the approved investigation plan.

(6) The sponsor must establish a procedure for emergency situations which enables the immediate identification and, where necessary, an immediate recall of the devices used in the study.

Performance studies regarding devices bearing the CE marking -intended purpose

180.—(1) Where—

- (a) a performance study is to be conducted to further assess, within the scope of its intended purpose, a device which already bears the CE marking in accordance with regulation 152(1) ('PMPF study');
- (b) the performance study would involve submitting subjects to procedures additional to those performed under the normal conditions of use of the device and those additional procedures are invasive or burdensome;

the sponsor must notify the Secretary of State at least 30 days prior to its commencement.

(2) The sponsor must include the documentation referred to in paragraph 2 of Part A of Schedule 27 and in Schedule 28.

(3) The following provisions apply to PMPF studies—

- (a) sub-paragraphs (b) to (l) and (p) of paragraph 169;
- (b) regulations 182, 183, 184 and 185(6) and the relevant provisions of Schedules 27 and 28.

Performance studies regarding devices bearing the CE marking outside intended purpose

181. Where a performance study is to be conducted to assess, outside the scope of its intended purpose, a device which already bears the CE marking in accordance with regulation 152(1), regulations 168 to 185 apply.

Substantial modifications to performance studies

182.—(1) If a sponsor intends to introduce modifications to a performance study that are likely to have a substantial impact on the safety, health or rights of the subjects or on the robustness or reliability of the data generated by the study, the sponsor must—

- (a) within one week of deciding to introduce modifications, notify the Secretary of State of the reasons for and the nature of those modifications;
- (b) include an updated version of the relevant documentation referred to in Schedule 28 as part of the notification;
- (c) ensure that changes to the relevant documentation are clearly identifiable.

(2) The Secretary of State must assess any substantial modification to the performance study in accordance with the procedure laid down in regulation 177.

(3) The sponsor may implement the modifications referred to in paragraph (1) at the earliest 38 days after the notification referred to in paragraph (1)(a), unless—

- (a) the Secretary of State has notified the sponsor of its refusal based on the grounds referred to in regulation 177(4) or on considerations of public health, of subject and user safety or health, or of public policy; or
- (b) an ethics committee has issued a negative opinion in relation to the substantial modification to the performance study.

(4) The Secretary of State may extend the period referred to in paragraph (3) by a further 7 days, for the purpose of consulting experts.

Corrective measures to be taken by the Secretary of State on performance studies

183.—(1) Where the Secretary of State has grounds for considering that the requirements of this Part are not met, the Secretary of State may take any of the following actions—

- (a) revoke the authorisation for the performance study;
- (b) suspend or terminate the performance study;
- (c) require the sponsor to modify any aspect of the performance study.

(2) Before the Secretary of State takes any of the measures referred to in paragraph (1), the Secretary of State must, except where immediate action is required, ask the sponsor or the investigator for their opinion which must be delivered within 7 days.

Information from the sponsor at the end of a performance study or in the event of a temporary halt or early termination

184.—(1) Subject to paragraph (2) if the sponsor has temporarily halted a performance study or has terminated a performance study early, the sponsor must inform the Secretary of State of that halt or termination within 15 days of the date of the temporary halt or termination.

(2) Where the sponsor has temporarily halted the performance study or terminated early it early on safety grounds, the sponsor must inform the Secretary of State of that halt or termination within 24 hours.

(3) The end of a performance study is deemed to coincide with the last visit of the last subject unless another point in time for such an end is set out in the performance study plan.

(4) The sponsor must notify the Secretary of State of the end of the performance study and that notification must be made within 15 days of the end of the performance study.

(5) Irrespective of the outcome of the performance study but subject to paragraph (7), within one year of the end of the performance study or within 3 months of the early termination or temporary halt, the sponsor must submit to the Secretary of State a performance study report as referred to in paragraph 1(10) to (12) of Part A of Schedule 27.

(6) The performance study report must—

- (a) be accompanied by a summary presented in terms that are easily understandable to the intended user;
- (b) be submitted by the sponsor to the Secretary of State along with the summary.

(7) Where, for scientific reasons, it is not possible to submit the performance study report within one year of the end of the study it must—

- (a) be submitted as soon as it is available;
- (b) specify in the clinical performance study plan referred to in sub-paragraphs (6) to (8) of Part A of Schedule 27 when the results of the performance study are going to be available, together with a justification for why the report cannot be submitted within one year of the end of the investigation.

(8) The Secretary of State may—

- (a) issue guidelines regarding the content and structure of the summary of the performance study report;
- (b) issue guidelines for the formatting and sharing of raw data, for cases where the sponsor decides to share raw data on a voluntary basis (and may take as a basis and adapt, where possible, existing guidelines for sharing of raw data in the field of performance studies).

(9) The summary and performance study report referred to in paragraph (6) must—

- (a) in circumstances other than those provided for in sub-paragraphs (b) and (c), become publicly accessible at least when it is registered in accordance with regulation 158 and before it is placed on the market;

- (b) in cases of early termination or temporary halt, become publicly accessible after submission;
- (c) if the device is not registered in accordance with regulation 158, become publicly accessible within one year of the summary and the report having been submitted pursuant to paragraph (6).

Recording and reporting of adverse events that occur during performance studies

185.—(1) The sponsor must fully record all of the following—

- (a) any adverse event of a type identified in the performance study plan as being critical to the evaluation of the results of that performance study;
- (b) any serious adverse event;
- (c) any device deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate;
- (d) any new findings in relation to any event referred to in sub-paragraphs (a) to (c).

(2) The sponsor must report, without delay (but having regard to paragraph (3)) to the Secretary of State, all of the following—

- (a) any serious adverse event that has a causal relationship with the device, the comparator or the study procedure or where such causal relationship is reasonably possible;
- (b) any device deficiency that might have led to a serious adverse event if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate;
- (c) any new findings in relation to any event referred to in points (a) and (b).

(3) The period for reporting must take account of the severity of the event and, where necessary to ensure timely reporting, the sponsor may submit an initial report that is incomplete followed up by a complete report.

(4) Upon request by the Secretary of State, the sponsor shall provide all information referred to in paragraph (1).

(5) The sponsor must also report to the Secretary of State any event referred to in paragraph (2) that occurred in a country outside the United Kingdom in which a performance study is performed under the same clinical performance study plan as the one applying to a performance study covered by this Part.

(6) Subject to paragraph (7), this regulation does not apply to PMPF studies referred to in regulation 180 but the provisions on vigilance provided for in regulations 190 to 193 apply instead of this regulation.

(7) This regulation must apply where a causal relationship between the serious adverse event and the preceding performance study has been established.

Post-market surveillance, vigilance and market surveillance

Post market surveillance system of the manufacturer

186.—(1) For each device manufacturers must plan, establish, document, implement, maintain and update a post-market surveillance system in a manner that is proportionate to the risk class and appropriate for the type of device and that system must be an integral part of the manufacturer's quality management system referred to in regulation 145(13).

(2) The post-market surveillance system must be suited to—

- (a) actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device throughout its entire lifetime;

- (b) drawing the necessary conclusions; and
 - (c) determining, implementing and monitoring any preventive and corrective actions.
- (3) The manufacturer must ensure that—
- (a) data gathered by the manufacturer’s post-market surveillance system is used in particular—
 - (i) to update the benefit-risk determination and to improve the risk management as referred to in Part 1 of Schedule 17;
 - (ii) to update the design and manufacturing information, the instructions for use and the labelling;
 - (iii) to update the performance evaluation;
 - (iv) to update the summary of safety and performance referred to in regulation 161;
 - (v) for the identification of needs for preventive, corrective or field safety corrective action;
 - (vi) for the identification of options to improve the usability, performance and safety of the device;
 - (vii) when relevant, to contribute to the post-market surveillance of other devices; and
 - (viii) detect and report trends in accordance with 191;
 - (b) the technical documentation is updated accordingly.
- (4) If, in the course of the post-market surveillance, a need for preventive or corrective action or both is identified, the manufacturer must—
- (a) implement the appropriate measures and inform the Secretary of State and, where applicable, the notified body;
 - (b) where a serious incident is identified or a field safety corrective action is implemented, it must be reported in accordance with regulation 190.

Post-market surveillance plan

187. The post-market surveillance system referred to in regulation 186 must be based on a post-market surveillance plan which satisfies the requirements set out in paragraph 1 of Schedule 19 and must be part of the technical documentation specified in Schedule 18.

Post-market surveillance report

188.—(1) Manufacturers of Class A and B devices must prepare a post-market surveillance report summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in regulation 187 together with a rationale and description of any preventive and corrective actions taken.

(2) The report must be updated when necessary and made available to the notified body and the Secretary of State upon request.

Periodic safety update report

189.—(1) Manufacturers of Class C and Class D devices must prepare a periodic safety update report (‘PSUR’) for each device and where relevant for each category or group of devices summarising the results and conclusions of the analyses of the post-market surveillance data gathered as a result of the post-market surveillance plan referred to in regulation 187, together with a rationale and description of any preventive and corrective actions taken.

(2) Throughout the lifetime of the device concerned, that PSUR must set out—

- (a) the conclusions of the benefit-risk determination;
 - (b) the main findings of the PMPF; and
 - (c) the volume of sales of the device and an estimate of the size and other characteristics of the population using the device and, where practicable, the usage frequency of the device.
- (3) Manufacturers of Class C and D devices must—
- (a) update the PSUR at least annually;
 - (b) ensure that the PSUR is part of the technical documentation as specified in Schedules 18 and 19.
- (4) Manufacturers of Class D devices must—
- (a) submit PSUR to the notified body involved in the conformity assessment of such devices in accordance with regulation (1);
 - (b) make the PSUR available to the Secretary of State.
- (5) For Class C devices, manufacturers must make PSURs available to the notified body involved in the conformity assessment and, upon request, to the Secretary of State.

Reporting of serious incidents and field safety corrective actions

190.—(1) Manufacturers of devices, made available on the market, other than devices for performance study must report to the Secretary of State the following—

- (a) any serious incident involving devices made available on the market, except expected erroneous results which are clearly documented and quantified in the product information, in the technical documentation and are subject to trend reporting pursuant to regulation 1(1);
- (b) any field safety corrective action in respect of devices made available on the market, including any field safety corrective action undertaken in a country outside the United Kingdom in relation to a device which is also legally made available on the market, if the reason for the field safety corrective action is not limited to the device made available in the country outside the United Kingdom.

(2) The period for the reporting referred to in paragraph (1) must take account of the severity of the serious incident.

(3) Manufacturers must report any serious incident as referred to in paragraph (1)0 immediately after they have established a causal relationship between that incident and their device or that such causal relationship is reasonably possible, and not later than 15 days after they become aware of the incident.

(4) Notwithstanding paragraph (3), in the event of a serious public health threat the report referred to in paragraph (1) shall be provided immediately, and not later than 2 days after the manufacturer becomes aware of that threat.

(5) Notwithstanding paragraph (3), in the event of death or an unanticipated serious deterioration in a person's state of health the report shall be provided immediately after the manufacturer has established or as soon as it suspects a causal relationship between the device and the serious incident but not later than 10 days after the date on which the manufacturer becomes aware of the serious incident.

(6) Where necessary to ensure timely reporting, the manufacturer may submit an initial report that is incomplete followed up by a complete report.

(7) If, after becoming aware of a potentially reportable incident, the manufacturer is uncertain about whether the incident is reportable, it shall nevertheless submit a report within the timeframe required in accordance with paragraphs 0 to 0.

(8) Except in cases of urgency in which the manufacturer needs to undertake field safety corrective action immediately, the manufacturer shall, without undue delay, report the field

safety corrective action referred to in paragraph (1)0, in advance of the field safety corrective action being undertaken.

(9) For similar serious incidents that occur with the same device or device type and for which the root cause has been identified or a field safety corrective action implemented or where the incidents are common and well documented, the manufacturer may provide periodic summary reports instead of individual serious incident reports, on condition that the Secretary of State has agreed with the manufacturer on the format, content and frequency of the periodic summary reporting.

(10) The Secretary of State must—

- (a) take appropriate measures such as organising targeted information campaigns, to encourage and enable healthcare professionals, users and patients to report to the Secretary of State suspected serious incidents referred to in paragraph (1)0;
- (b) record reports received from healthcare professionals, users and patients.

(11) Where the Secretary of State obtains reports on suspected serious incidents referred to in paragraph (1)0 from healthcare professionals, users or patients, the Secretary of State must take the necessary steps to ensure that the manufacturer of the device concerned is informed of the suspected serious incident without delay.

(12) Where the manufacturer of the device concerned considers that the incident is a serious incident, it shall provide a report in accordance with paragraphs (1) to 0 on that serious incident to the Secretary of State and shall take the appropriate follow-up action in accordance with Article 1(1).

(13) Where—

- (a) the manufacturer of the device concerned considers that the incident is not a serious incident or is to be treated as an increase in expected erroneous results, which will be covered by trend reporting in accordance with regulation 1(1), the manufacturer must provide an explanatory statement; and
- (b) the Secretary of State does not agree with the conclusion of the explanatory statement, the Secretary of State may require the manufacturer—
 - (i) to provide a report in accordance with paragraphs (1) to 0; and
 - (ii) to ensure that appropriate follow-up action is taken in accordance with regulation 1(1).

Trend reporting

191.—(1) Manufacturers must report to the Secretary of State any statistically significant increase in the frequency or severity of incidents that are not serious incidents that could have a significant impact on the benefit-risk analysis referred to in paragraphs 1 and 5 of Schedule 17 and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons or of any significant increase in expected erroneous results established in comparison to the stated performance of the device as referred to in paragraph 9(1) of Schedule 17 and specified in the technical documentation and product information.

(2) The manufacturer must specify how to manage the incidents referred to in paragraph (1) and the methodology used for determining any statistically significant increase in the frequency or severity of such events or change in performance, as well as the observation period, in the post-market surveillance plan referred to in regulation 187.

(3) The Secretary of State may conduct assessments on the trend reports referred to in paragraph (1) and require the manufacturer to adopt appropriate measures in accordance with this Part in order to ensure the protection of public health and patient safety.

Analysis of serious incidents and field safety corrective actions

192.—(1) Following the reporting of a serious incident pursuant to regulation 190(1), the manufacturer must—

- (a) without delay, perform the necessary investigations in relation to the serious incident and the devices concerned;
- (b) include, as part of that investigation, a risk assessment of the incident and field safety corrective action taking into account the criteria as referred to in paragraph (4)(a) as appropriate.

(2) The manufacturer must—

- (a) cooperate with the Secretary of State and where relevant with the notified body concerned during the investigations referred to in paragraph (1);
- (b) not perform any investigation which involves altering the device or a sample of the batch concerned in a way which may affect any subsequent evaluation of the causes of the incident, prior to informing the Secretary of State of such action.

(3) The Secretary of State must take the necessary steps to ensure that any information regarding a serious incident that has occurred, or a field safety corrective action that has been or is to be undertaken, and that is brought to the Secretary of State's knowledge in accordance with regulation 190 is evaluated, if possible together with the manufacturer, and, where relevant, the notified body concerned.

(4) In the context of the evaluation referred to in paragraph (3), the Secretary of State must evaluate—

- (a) the risks arising from the reported serious incident and evaluate any field safety corrective actions, taking into account the protection of public health and criteria such as—
 - (i) causality, detectability and probability of recurrence of the problem;
 - (ii) frequency of use of the device;
 - (iii) probability of occurrence of direct or indirect harm;
 - (iv) the severity of that harm;
 - (v) the clinical benefit of the device;
 - (vi) the intended and potential users;
 - (vii) the population affected;
- (b) the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for, and kind of, any other corrective action, in particular taking into account the principle of inherent safety contained in Schedule 17.

(5) Upon request by the Secretary of State, manufacturers must provide for all documents necessary for the risk assessment.

(6) The Secretary of State must monitor the manufacturer's investigation of a serious incident and, where necessary, may intervene in a manufacturer's investigation or initiate an independent investigation.

(7) The manufacturer must provide a final report to the Secretary of State setting out the manufacturer's findings from the investigation which must set out conclusions and, where relevant, indicate corrective actions to be taken.

(8) The manufacturer must ensure that information about the field safety corrective action taken—

- (a) is brought without delay to the attention of users of the device in question by means of a field safety notice;

- (b) except in cases of urgency, the content of the draft field safety notice must be submitted to the Secretary of State to allow the Secretary of State to make comments.
- (9) The field safety notice must—
- (a) allow the correct identification of the device or devices involved;
 - (b) explain, in a clear manner, without understating the level of risk, the reasons for the field safety corrective action with reference to the device malfunction and associated risks for patients, users or other persons;
 - (c) must clearly indicate all the actions to be taken by users;
 - (d) be accessible to the public.

Analysis of vigilance data

193.—(1) The Secretary of State must put in place systems and processes to actively monitor the data available in order to identify trends, patterns or signals in the data that may reveal new risks or safety concerns.

(2) Where a previously unknown risk is identified or the frequency of an anticipated risk significantly and adversely changes the benefit-risk determination, the Secretary of State must inform the manufacturer, or where applicable the UK responsible person, which shall then take the necessary corrective actions.

Electronic system on vigilance and post-market surveillance

194.—(1) The Secretary of State must set up and manage an electronic system to collate and process the following information—

- (a) reports by manufacturers on serious incidents and field safety corrective actions;
- (b) the periodic summary reports by manufacturers;
- (c) the reports by manufacturers on trends;
- (d) the PSURs;
- (e) the field safety notices issued by manufacturers.

(2) The Secretary of State must ensure that healthcare professionals and the public receive appropriate information contained in the electronic system referred to in paragraph (1).

(3) The Secretary of State—

- (a) may make arrangements with other countries or international organisations for the purposes of granting access (at an appropriate level) to the electronic system in paragraph (1);
- (b) must only make such arrangements on the basis of reciprocity;
- (c) must base any such arrangements on data protection rules equivalent to those applicable in the United Kingdom.

Market surveillance

Market surveillance activities

195.—(1) The Secretary of State must—

- (a) perform appropriate checks on the conformity characteristics and performance of devices including, where appropriate, a review of documentation and physical or laboratory checks on the basis of adequate samples;
- (b) in doing so, take account of established principles regarding risk assessment and risk management, vigilance data and complaints.

(2) The Secretary of State must—

- (a) draw up annual surveillance activity plans;
 - (b) allocate a sufficient number of material and competent human resources in order to carry out those activities.
- (3) In order to fulfil the obligations in paragraph (1), the Secretary of State—
- (a) may require economic operators to make available the documentation and information necessary for the purpose of carrying out the authorities' activities and, where justified, to provide the necessary samples of devices or access to devices free of charge;
 - (b) must carry out both announced and, if necessary, unannounced inspections of the premises of economic operators, as well as suppliers or subcontractors, and, where necessary, at the facilities of professional users.
- (4) The Secretary of State must prepare and publish an annual summary of the results of surveillance activity.
- (5) The Secretary of State may confiscate, destroy or otherwise render inoperable devices that present an unacceptable risk or falsified devices where the Secretary of State deems it necessary to do so in the interests of the protection of public health.
- (6) Following each inspection carried out for the purposes referred to in paragraph (1), the Secretary of State must—
- (a) draw up a report on the findings of the inspection that concern compliance with the requirements under this Part;
 - (b) set out in the report any corrective actions needed.
- (7) The Secretary of State must—
- (a) communicate the content of the report referred to in paragraph (6) to the economic operator that has been the subject of the inspection;
 - (b) before adopting the final report, give that economic operator the opportunity to submit comments.
- (8) The Secretary of State must—
- (a) at least every 4 years, review and assess the functioning of the market surveillance activities; and
 - (b) make a summary of the results of that review available to the public.
- (9) Where appropriate, the Secretary of State must cooperate with other countries with a view to exchanging information, providing technical support and promoting activities relating to market surveillance.

Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance

196. Where the Secretary of State, based on data obtained by vigilance or market surveillance activities or on other information, has reason to believe that a device—

- (a) may present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health; or
- (b) otherwise does not comply with the requirements laid down in this Part,

the Secretary of State must carry out an evaluation of the device concerned covering all requirements laid down in this Part relating to the risk presented by the device or to any other non-compliance of the device and the relevant economic operators must cooperate with the Secretary of State.

Procedure for dealing with devices presenting an unacceptable risk to health and safety

197.—(1) Where, having performed an evaluation pursuant to regulation 196, the Secretary of State finds that the device presents an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, the Secretary of State—

- (a) must without delay require the manufacturer of the devices concerned and all other relevant economic operators to take all appropriate and duly justified corrective action to bring the device into compliance with the requirements of this Part relating to the risk presented by the device;
- (b) may, in a manner that is proportionate to the nature of the risk, restrict the making available of the device on the market, subject the making available of the device to specific requirements, withdraw the device from the market, or to recall it within a reasonable period that is clearly defined and communicated to the relevant economic operator.

(2) The economic operators referred to in paragraph (1) must, without delay, ensure that all appropriate corrective action is taken throughout the United Kingdom in respect of all the devices concerned that they have made available on the market.

(3) Where the economic operator as referred to in paragraph (1) does not take adequate corrective action within the period referred to in paragraph (1), the Secretary of State may take action in accordance with regulation 63 or Part II of the Consumer Protection Act 1987.

Other non-compliance

198.—(1) Where, having performed an evaluation pursuant to regulation 196, the Secretary of State finds that a device does not comply with the requirements laid down in this Part but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, the Secretary of State must require the relevant economic operator to bring the non-compliance concerned to an end within a reasonable period that is clearly defined and communicated to the economic operator and that is proportionate to the non-compliance.

(2) Where the economic operator does not bring the non-compliance to an end within the period referred to in paragraph (1), the Secretary of State may take action in accordance with regulation 62 or, following such action, Part II the Consumer Protection Act 1987.

Regulations

199.—(1) Regulations under this Part may—

- (a) make different provisions for different purposes or different areas;
- (b) make consequential, incidental, transitional or supplemental provision.

(2) A power to make regulations under this Part is exercisable by statutory instrument.

(3) A statutory instrument which contains regulations under this Part is subject to annulment in pursuance of a resolution of each House of Parliament.”.

PART 4

New Schedules to the 2002 Regulations

12. After Schedule 2 to the 2002 Regulations insert—

Modification of Annexes to Directives 90/385, 93/42, 98/79

PART 1

Modification of Annexes to Directive 90/385

1. The Annexes to Directive 90/385 are modified so that they read as if amended by paragraphs 2 to 8.

2. In Annex 1 for Section 10 substitute—

“10. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in regulation 2 of the Human Medicines Regulations 2012, and which is liable to act upon the body with an action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC as modified by Schedule 8B to the Human Medicines Regulations 2012(a).

Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes.”.

3. In Annex 2—

- (a) in Section 2, omit “established within the Community”;
- (b) in Section 3.3, for the first sentence substitute—

“The quality system shall be audited by the notified body to determine whether it meets the requirements referred to in Section 3.2.”;

- (c) of Section 3.4, in the second paragraph, for the first sentence substitute—

“The proposed modifications shall be evaluated by the notified body so as to verify whether the quality system so modified would still meet the requirements referred to in Section 3.2.”;

- (d) omit Section 4.3;
- (e) in Section 6.1, after “national authorities” insert “and the Secretary of State”;
- (f) for Section 6.2, substitute—

“6.2. On request, a UK notified body shall make available to other notified bodies and to the Secretary of State all relevant information relating to the withdrawal of its approval for a quality system.”;

- (g) in Section 7, for the words “issued by” to the end, substitute—

“a laboratory designated for the purpose by an EU Member State in accordance with Article 114(2) of Directive 2001/83/EC or a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012(b).”.

4. In Annex 3—

- (a) in Section 2, omit “established in the Community”;
- (b) omit Sections 4 and 5;

(a) Schedule 8B is inserted by the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019.
 (b) 2012 c. 7.

(c) for Section 7.1 substitute—

“7.1. On request, a UK notified body shall make available to other notified bodies (including other UK notified bodies) and to the Secretary of State all relevant information on EC type-examination certificates and addenda to those certificates.”;

(d) for Section 7.2 substitute—

“7.2. A UK notified body must cooperate with other notified bodies (including other UK notified bodies) with regard to making available copies of the EC type examination certificates or addenda to those certificates but, as regards copies of annexes to the certificates, must only make those available to other notified bodies with the consent of the manufacturer.”.

5. In Annex 4—

(a) in Sections 1 and 2, omit “established within the Community” in each place where those words appear;

(b) in Section 5, for the first sentence substitute—

“A product must have had, in respect of it, the appropriate examinations and tests carried out by a notified body to check the conformity of the product to the requirements of this Directive by examination and testing of products on a statistical basis as specified in Section 6.”;

(c) in Section 6.4, for the first two paragraphs substitute—

“Where the notified body has drawn up a written certificate of conformity in relation to a batch, all products in that batch to which that body has affixed, or caused to be affixed, an identification number may be placed on the market.”;

(d) in Section 7, for the words from “issued by” to the end, substitute “a laboratory designated for the purpose by an EU Member State in accordance with Article 114(2) of Directive 2001/83/EC or a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012.”.

6. In Annex 5—

(a) in Section 2, in the second paragraph, omit “established within the Community”;

(b) in Section 3.3, for the first sentence substitute—

“The quality system shall be audited by the notified body to determine whether it meets the requirements referred to in Section 3.2.”;

(c) in Section 3.4, for the first sentence of the second paragraph—

“The proposed modifications shall be evaluated by the notified body so as to verify whether the quality system modified would meet the requirements referred to in Section 3.2;”

7. In Annex 6, in Section 1, omit “established within the Community”.

8. In Annex 8—

(a) in the title for “when designating” substitute “by”;

(b) in Section 6, omit the words from “unless liability” to the end of that Section.

PART 2

Modification of Annexes to Directive 93/42

9. The Annexes to Directive 93/42 are modified so that they read as if amended by paragraphs 10 to 19.

10. In Annex I—

- (a) for Section 7.4 substitute—

“7.4. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in regulation 2 of the Human Medicines Regulations, and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC as modified by the Human Medicines Regulations;

Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the notified body shall be informed of the changes.”.

- (b) in Section 8.2, omit the second paragraph;
(c) in Section 13.3 in point (f), omit the second sentence.

11. In Annex II—

- (a) in Section 1 omit “Community”;
(b) in Section 3.3, for the first sentence substitute—

“The quality system must be audited by the notified body to determine whether it meets the requirements referred to in Section 3.2.”;

- (c) in Section 3.4, for the second sentence substitute—

“The proposed changes must be assessed by the notified body so as to verify whether the quality system after these changes would still meet the requirements referred to in Section 3.2.”;

- (d) omit Section 4.3;
(e) in Section 6.1, after “national authorities” insert “and the Secretary of State”;
(f) in Section 8, for the words “issued by” to the end of that Section, substitute “a laboratory designated for the purpose by an EU Member State in accordance with Article 114(2) of Directive 2001/83/EC or a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012.”.

12. In Annex III—

- (a) in Section 2, in the second indent, for the last line substitute, “The applicant shall provide samples as necessary at the request of the notified body,”;
(b) omit Sections 4 to 5;
(c) for Section 7.2 substitute—

“A UK notified body must cooperate with other notified bodies (including other UK notified bodies) with regard to making available copies of the EC type examination certificates or addenda to those certificates but, as regards copies of annexes to the certificates, must only make those available to other notified bodies with the consent of the manufacturer.”.

13. In Annex IV—

- (a) omit Sections 4 to 5.2;
(b) omit Sections 6.2 and 6.3;
(c) in Section 6.4, for the first two paragraphs, substitute—

“Where the notified body has drawn up a written certificate of conformity in relation to a batch, all products in that batch to which that body has affixed, or caused to be affixed, an identification number may be placed on the market.”;

- (d) in Section 7, after “national authorities” insert “and the Secretary of State”;

- (e) in Section 9, from the words “issued by” to the end of that Section, substitute “a laboratory designated for the purpose by an EU Member State in accordance with Article 114(2) of Directive 2001/83/EC or a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012.”.

14. In Annex V—

- (a) in Section 1, omit “Community”;
- (b) in Section 3.3 for the first sentence substitute—

“The quality system must be audited by the notified body to determine whether it meets the requirements referred to in Section 3.2.”;
- (c) in Section 3.4, for the last two paragraphs, substitute—

“The proposed changes must be evaluated by the notified body so as to verify whether the quality system after these changes would still meet the requirements referred to in Section 3.2.”;
- (d) in Section 5.1, after “national authorities”, insert “and the Secretary of State”;
- (e) omit Section 6.4.
- (f) in Section 7, for the words from “issued by” to the end of that Section, substitute—

“a laboratory designated for the purpose by an EU Member State in accordance with Article 114(2) of Directive 2001/83/EC or a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012.”.

15. In Annex VI—

- (a) in Section 3.3, for the first sentence substitute—

“The quality system must be audited by the notified body to determine whether it meets the requirements referred to in Section 3.2.”;
- (b) in Section 3.4, for the second paragraph substitute—

“The proposed changes must be assessed by the notified body so as to verify whether the quality system after these changes would still meet the requirements referred to in Section 3.2.”
- (c) in Section 5.1, after “national authorities”, insert “and the Secretary of State”.

16. In Annex VII—

- (a) in Section 2, after “national authorities”, insert “and the Secretary of State”;
- (b) in Section 4, after “competent authorities”, insert “and the Secretary of State”;
- (c) in Section 5, omit “and the intervention by the notified body.”.

17. In Annex VIII, in Section 3 after “national authorities”, insert “and the Secretary of State”.

18. In Annex X, in Section 2.3.5, after “competent authorities of the Member States”, insert “and the Secretary of State”.

19. In Annex XI—

- (a) in the title, for “for the designation of” substitute “by”;
- (b) in Section 2, for “national authorities” substitute “the Secretary of State”;
- (c) in Section 6, omit the words from “unless liability” to the end of that Section.

PART 3

Modification of Annexes to Directive 98/79

20. The Annexes to Directive 98/79 are modified so that they read as if amended by paragraphs 21 to 27.

21. In Annex I—

- (a) in Section 8.1, omit the sixth paragraph;
- (b) in Section 8.4, in point (a), after “distribution in the Community” insert “or the United Kingdom”.

22. In Annex III—

- (a) in Section 5, after “competent authorities”, insert “and the Secretary of State”;
- (b) omit Section 6.2;

23. In Annex IV—

- (a) in Section 3.3 for the first sentence substitute—

“The quality system must be audited by the notified body to determine whether it meets the requirements referred to in Section 3.2.”;

- (b) in Section 3.4, in the second paragraph, for the first sentence , substitute—

“The proposed changes must be assessed by the notified body so as to verify whether the quality system after these changes would meet the requirements referred to in Section 3.2.”;

- (c) omit Section 4.3.

24. In Annex V—

- (a) in Section 2, in the second paragraph, at the end of the second indent, omit “.The notified body may request other samples as necessary”;
- (b) omit Sections 4 and 5;
- (c) for Section 7 substitute—

“A UK notified body must cooperate with other notified bodies (including other UK notified bodies) with regard to making available copies of the EC type examination certificates or addenda to those certificates but, as regards copies of annexes to the certificates, must only make those available to other notified bodies with the consent of the manufacturer.”.

25. In Annex VI—

- (a) omit Sections 4 and 5;
- (b) omit Sections 6.2 and 6.3;
- (c) for the first two paragraphs of Section 6.4, substitute—

“Where the notified body has drawn up a written certificate of conformity in relation to a batch, all products in that batch to which that body has affixed, or caused to be affixed, an identification number may be placed on the market.”.

26. In Annex VII—

- (a) in Section 3.3 for the first sentence substitute—

“The quality system must be audited by the notified body to determine whether it meets the requirements referred to in Section 3.2.”;

- (b) for the second paragraph of Section 3.4, substitute—

“The proposed changes must be assessed by the notified body so as to verify whether the quality system after these changes would meet the requirements referred to in Section 3.2.”.

27. In Annex IX—

- (a) in the heading, omit the words “the designation of”;
- (b) in Section 2, for “national authorities” substitute “the Secretary of State”;
- (c) in Section 6, omit the words from “unless liability” to the end of that Section.

SCHEDULE 3

Regulation 1A

General safety and performance requirements for general medical devices

PART 1

General requirements

1. Devices must—

- (a) achieve the performance intended by their manufacturer;
- (b) be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose;
- (c) be safe and effective and not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.

2. The requirement in this Schedule to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.

3.—(1) Manufacturers must establish, implement, document and maintain a risk management system.

(2) Risk management is to be understood as a continuous iterative process throughout the entire lifecycle of a device, which requires regular systematic updating and, in carrying out risk management, manufacturers must—

- (a) establish and document a risk management plan for each device;
- (b) identify and analyse the known and foreseeable hazards associated with each device;
- (c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;
- (d) eliminate or control the risks referred to in sub-paragraph (c) in accordance with the requirements of paragraph 4;
- (e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability;
- (f) based on the evaluation of the impact of the information referred to in paragraph (e), if necessary amend control measures in line with the requirements of paragraph 4.

4.—(1) Risk control measures adopted by manufacturers for the design and manufacture of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.

(2) To reduce risks, manufacturers must manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable.

(3) In selecting the most appropriate solutions, manufacturers must, in the following order of priority—

- (a) eliminate or reduce risks as far as possible through safe design and manufacture;
- (b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and
- (c) provide information for safety (warnings, precautions, contra-indications) and, where appropriate, training to users;
- (d) inform users of any residual risks.

5. In eliminating or reducing risks related to use error, the manufacturer must—

- (a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety);
- (b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

6. The characteristics and performance of a device must not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.

7. Devices must be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.

8. All known and foreseeable risks, and any undesirable side-effects, must be minimised and be acceptable when weighed against the evaluated benefits to the patient or user arising from the achieved performance of the device during normal conditions of use.

9. For the devices referred to in Schedule 16, the general safety requirements set out in paragraphs 1 and 8 must be understood to mean that the device, when used under the conditions and for the purposes intended, does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons.

PART 2

Requirements regarding design and manufacture

Chemical, physical and biological properties

10.—(1) Devices must be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in paragraphs 1 to 9 are fulfilled.

(2) Particular attention must be paid to—

- (a) the choice of materials and substances used, particularly as regards toxicity and, where relevant, flammability;

- (b) the compatibility between the materials and substances used and biological tissues, cells and body fluids, taking account of the intended purpose of the device and, where relevant, absorption, distribution, metabolism and excretion;
- (c) the compatibility between the different parts of a device which consists of more than one implantable part;
- (d) the impact of processes on material properties;
- (e) where appropriate, the results of biophysical or modelling research the validity of which has been demonstrated beforehand;
- (f) the mechanical properties of the materials used, reflecting, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance;
- (g) surface properties;
- (h) the confirmation that the device meets any defined chemical or physical specifications.

(3) Devices must be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to—

- (a) patients, taking account of the intended purpose of the device;
- (b) persons involved in the transport, storage and use of the device,

and particular attention must be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure.

(4) Devices must be designed and manufactured in such a way that they can be used safely with the materials and substances, including gases, with which they enter into contact during their intended use.

(5) If the devices are intended to administer medicinal products they must—

- (a) be designed and manufactured in such a way as to be compatible with the medicinal products concerned in accordance with the provisions and restrictions governing those medicinal products;
- (b) ensure that the performance of both the medicinal products and of the devices is maintained in accordance with their respective indications and intended use.

Substances

Design and manufacture of devices

(6) Devices must be designed and manufactured in such a way as to reduce, as far as possible, the risks posed by substances or particles, including wear debris, degradation products and processing residues that may be released from the device.

(7) Devices, parts of those devices or materials used in those devices listed in sub-paragraph (8) may only contain the following substances in a concentration that is above 0.1% weight where that is justified in accordance with sub-paragraph (9)—

- (a) substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, and on the UK mandatory classification and labelling list established and maintained in accordance with Article 38A(a) of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006; or
- (b) substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with—

(a) Article 38A is inserted into Regulation (EC) No 1272/2008 by the Chemicals (Health and Safety) and Genetically modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019.

- (i) the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC; or
- (ii) Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out the scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) 528/2012 of the European Parliament and Council.

(8) The devices (or parts or materials) to which sub-paragraph (7) relates are devices which—

- (a) are invasive and come into direct contact with the human body;
- (b) administer or re-administer medicines, body liquids or other substances, including gases, to the body; or
- (c) transport or store medicines, body fluids or substances, including gases, to be administered or re-administered to the body.

(9) The justification for the presence of the substances listed in sub-paragraph (7) must be based upon—

- (a) an analysis and estimation of potential patient or user exposure to the substance;
- (b) an analysis of possible alternative substances, materials or designs, including, where available, information about independent research, peer-reviewed studies, scientific opinions from relevant scientific committees and an analysis of the availability of such alternatives;
- (c) arguments as to why possible substance or material substitutes, if available, or design changes, if feasible, are inappropriate in relation to maintaining the functionality, performance and the benefit-risk ratios of the product; including, where relevant having regard to the intended use of the device, taking account of the vulnerability to such substances or materials of particular patient groups including children and pregnant or breastfeeding women;
- (d) where applicable and available, the latest scientific guidelines relating to the risks and benefits (including the availability of alternative substances, materials, designs or treatments) of phthalates and other CMR and endocrine-disrupting substances.

Labelling

(10) Where the devices (parts or materials) referred to in sub-paragraph (7) contain the substances in paragraph (a) and (b) of sub-paragraph (7) in a concentration above 0.1% weight by weight (w/w), the presence of those substances must—

- (a) be labelled on the device itself or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances;
- (b) if the intended use of such devices includes treatment of particular patient groups (including children or pregnant or breastfeeding women) who are particularly vulnerable to those substances, be contained in information on residual risks for those patient groups and, if applicable, in appropriate precautionary measures in the instructions for use.

(11) Devices must be designed and manufactured in such a way as to reduce, as far as possible, the risks posed by the unintentional ingress of substances into the device, taking into account the device and the nature of the environment in which it is intended to be used.

(12) Unless they come into contact with intact skin only, devices must be designed and manufactured in such a way as to reduce, as far as possible, the risks linked to the size and

the properties of particles which are or can be released into the patient's or user's body, and special attention must be given to nanomaterials.

Infection and microbial contamination

11.—(1) Devices and their manufacturing processes must be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons and the design must—

- (a) reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries;
- (b) allow easy and safe handling;
- (c) reduce as far as possible any microbial leakage from the device or microbial exposure during use;
- (d) prevent microbial contamination of the device or its content such as specimens or fluids.

(2) Where necessary devices must be designed to facilitate their safe cleaning, disinfection or re-sterilisation.

(3) Devices labelled as having a specific microbial state must be designed, manufactured and packaged to ensure that they remain in that state when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.

(4) Devices delivered in a sterile state must—

- (a) be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened at the point of use;
- (b) ensure that the integrity of the packaging is clearly evident to the final user.

(5) Devices labelled as sterile must be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.

(6) Devices intended to be sterilised must be manufactured and packaged in appropriate and controlled conditions and facilities.

(7) Packaging systems for non-sterile devices must—

- (a) maintain the integrity and cleanliness of the product;
- (b) where the devices are to be sterilised prior to use, minimise the risk of microbial contamination;
- (c) be suitable taking account of the method of sterilisation indicated by the manufacturer.

(8) The labelling of the device must distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition in addition to the symbol used to indicate that devices are sterile.

Devices incorporating a substance considered to be a medicinal product and device that are composed of substances that are absorbed by or locally dispersed in the human body

12.—(1) In the case of devices referred to in regulation 68(8), the quality, safety and usefulness of the substance which, if used separately, would be considered to be a medicinal product within the meaning of regulation 2 of the Human Medicines Regulations 2002, must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC read subject to modifications made by the Human Medicines Regulations 2012, as required by the applicable conformity assessment procedure under Part VIII.

(2) Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body, and that are absorbed by or locally dispersed in the human body must comply, where applicable and in a manner limited to the aspects not covered by Part VIII, with the relevant requirements laid down in Annex I to

Directive 2001/83/EC read subject to the modifications made by the Human Medicines Regulations 2012 for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions, as required by the applicable conformity assessment procedure under Part VIII.

Devices incorporating materials of biological origin

13.—(1) For devices manufactured utilising derivatives of tissues or cells of human origin which are non-viable or are rendered non-viable which are covered by Part VIII in accordance with regulation 68(6)(g), the following apply—

- (a) donation, procurement and testing of the tissues and cells must be done in accordance with Human Tissue (Quality and Safety for Human Application) Regulations 2007;
- (b) processing, preservation and any other handling of those tissues and cells or their derivatives must be carried out so as to provide safety for patients, users and, where applicable, other persons and, in particular, safety with regard to viruses and other transmissible agents must be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process;
- (c) the traceability system for those devices must be complementary and compatible with the traceability and data protection requirements laid down in Human Tissue (Quality and Safety for Human Application) Regulations 2007 and in the Blood Safety and Quality Regulations 2005.

(2) For devices manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable the following apply—

- (a) where feasible taking into account the animal species, tissues and cells of animal origin, or their derivatives, the tissues or cells must originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues and information on the geographical origin of those animals must be retained by manufacturers;
- (b) sourcing, processing, preservation, testing and handling of tissues, cells and substances of animal origin, or their derivatives, must be carried out so as to provide safety for patients, users and, where applicable, other persons;
- (c) safety with regard to viruses and other transmissible agents must be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the clinical benefit of the device;
- (d) in the case of devices manufactured utilising tissues or cells of animal origin, or their derivatives, as referred to in the Regulation (EU) No 722/2012 the particular requirements laid down in that Regulation shall apply.

(3) For devices manufactured utilising non-viable biological substances other than those referred to in sub-paragraphs (1) and (2), the processing, preservation, testing and handling of those substances must be carried out so as to provide safety for patients, users and, where applicable, other persons, including in the waste disposal chain and, safety with regard to viruses and other transmissible agents, must be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

Construction of devices and interaction with the environment

14.—(1) If the device is intended for use in combination with other devices or equipment—

- (a) the whole combination, including the connection system must be safe and must not impair the specified performance of the devices;

- (b) any restrictions on use applying to such combinations must be indicated on the label or in the instructions for use;
 - (c) connections which the user has to handle, such as fluid, gas transfer, electrical or mechanical coupling, must be designed and constructed in such a way as to minimise all possible risks, such as misconnection.
- (2) Devices must be designed and manufactured in such a way as to remove or reduce as far as possible—
- (a) the risk of injury, in connection with their physical features, including the volume or pressure ratio, dimensional and where appropriate ergonomic features;
 - (b) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;
 - (c) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;
 - (d) the risks associated with the possible negative interaction between software and the information technology environment within which it operates and interacts;
 - (e) the risks of accidental ingress of substances into the device;
 - (f) the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given;
 - (g) risks arising where maintenance or calibration are not possible (as with implants), from ageing of materials used or loss of accuracy of any measuring or control mechanism.
- (3) Devices must be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition and particular attention must be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.
- (4) Devices must be designed and manufactured in such a way that adjustment, calibration and maintenance can be done safely and effectively.
- (5) Devices that are intended to be operate together with other devices or products must be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.
- (6) Any measurement, monitoring or display scale must be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used.
- (7) In relation to the safe disposal of devices and related waste substances—
- (a) devices must be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by the user, patient or other person;
 - (b) manufacturers must identify and test procedures and measures as a result of which their devices can be safely disposed after use and such procedures must be described in the instructions for use.

Devices with a diagnostic or measuring function

15.—(1) Diagnostic devices and devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods and the limits of accuracy shall be indicated by the manufacturer.

(2) The measurements made by devices with a measuring function shall be expressed in legal units conforming to the provisions of Units of Measurement Regulations 1986(a).

Protection against radiation

16.—(1) Devices must be designed, manufactured and packaged in such a way that exposure of patients, users and other persons to radiation is reduced as far as possible, and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

(2) The operating instructions for devices emitting hazardous or potentially hazardous radiation must contain—

- (a) detailed information as to—
 - (i) the nature of the emitted radiation, the means of protecting the patient and the user, and;
 - (ii) on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate;
- (b) information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure.

(3) Devices which are designed to emit hazardous, or potentially hazardous, levels of ionizing or non-ionizing radiation necessary for a specific medical purpose, the benefit of which is considered to outweigh the risks inherent to the emission, must—

- (a) make it possible for the user to control the emissions;
- (b) must be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance;
- (c) be fitted, where possible, with visual displays or audible warnings of those emissions;
- (d) be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible;
- (e) where possible and appropriate, ensure that methods are selected which reduce the exposure to radiation of patients, users and other persons who may be affected.

(4) Devices intended to emit ionizing radiation must—

- (a) be designed and manufactured taking into account the requirements of any retained EU law which transposed Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation;
- (b) be designed and manufactured in such a way as to ensure that, where possible, taking into account the intended use, the quantity, geometry and quality of the radiation emitted can be varied and controlled, and, if possible, monitored during treatment;
- (c) where the device is intended for diagnostic radiology, be designed and manufactured in such a way as to achieve an image or output quality that is appropriate to the intended medical purpose whilst minimising radiation exposure of the patient and user;
- (d) where the device is intended for therapeutic radiology, be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type, energy and, where appropriate, the quality of radiation.

(a) S.I. 1986/1082 amended by S.I. 2001/55.

Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves

17.—(1) Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, must—

- (a) be designed to ensure repeatability, reliability and performance in line with their intended use;
- (b) in the event of a single fault condition, be designed with appropriate means to eliminate or reduce as far as possible consequent risks or impairment of performance.

(2) For devices that incorporate software or for software that are devices in themselves, the software must be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.

(3) Software referred to in this paragraph that is intended to be used in combination with mobile computing platforms must be designed and manufactured taking into account the specific features of the mobile platform (for example size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).

(4) Manufacturers must set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

Active devices and devices connected to them

18.—(1) For non-implantable active devices, in the event of a single fault condition, appropriate means must be adopted to eliminate or reduce as far as possible consequent risks.

(2) Devices, where the safety of the patient depends on an internal power supply, must be equipped with—

- (a) a means of determining the state of the power supply;
- (b) an appropriate warning or indication for when the capacity of the power supply becomes critical, if necessary, such warning or indication must be given prior to the power supply becoming critical.

(3) Devices where the safety of the patient depends on an external power supply must include an alarm system to signal any power failure.

(4) Devices intended to monitor one or more clinical parameters of a patient must be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

(5) Devices must be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.

(6) Devices must be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference that is adequate to enable them to operate as intended.

(7) Devices must be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.

(8) Devices must be designed and manufactured in such a way as to protect, as far as possible, against unauthorised access that could hamper the device from functioning as intended.

Particular requirements for active implantable devices

19.—(1) Active implantable devices must be designed and manufactured in such a way as to remove or minimize as far as possible—

- (a) risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices;
- (b) risks connected with medical treatment, in particular those resulting from the use of defibrillators or high- frequency surgical equipment;
- (c) risks which may arise where maintenance and calibration are impossible, including—
 - (i) excessive increase of leakage currents;
 - (ii) ageing of the materials used;
 - (iii) excess heat generated by the device;
 - (iv) decreased accuracy of any measuring or control mechanism.

(2) Active implantable devices must be designed and manufactured in such a way as to ensure—

- (a) if applicable, the compatibility of the devices with the substances they are intended to administer;
- (b) the reliability of the source of energy.

(3) Active implantable devices and, if appropriate, their component parts must be identifiable to allow any necessary measure to be taken following the discovery of a potential risk in connection with the devices or their component parts.

(4) Active implantable devices must bear a code—

- (a) by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of device and its year of manufacture); and
- (b) which it is possible to read, if necessary, without the need for a surgical operation.

Protection against mechanical and thermal risks

20.—(1) Devices must be designed and manufactured in such a way as to protect patients and users against mechanical risks connected with, for example, resistance to movement, instability and moving parts.

(2) Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

(3) Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

(4) Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, must be designed and constructed in such a way as to minimise all possible risks.

(5) Errors likely to be made when fitting or refitting certain parts which could be a source of risk —

- (a) must be made impossible by the design and construction of such parts or by information given on the parts themselves or their housings; and
- (b) must contain the same information on moving parts or their housings where the direction of movement needs to be known in order to avoid a risk.

(6) Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal conditions of use.

Protection against the risks posed to the patient or user by devices supplying energy or substances

21.—(1) Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the amount to be delivered can be set and maintained accurately enough to ensure the safety of the patient and of the user.

(2) Devices must—

- (a) be fitted with the means of preventing or indicating any inadequacies in the amount of energy delivered or substances delivered which could pose a danger;
- (b) incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.

(3) The function of the controls and indicators—

- (a) must be clearly specified on devices;
- (b) where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.

Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons

22.—(1) Devices for use by lay persons must—

- (a) be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can be reasonably anticipated in the lay person's technique and environment; and
- (b) be provided by the manufacturer with information and instructions which are easy for the lay person to understand and apply.

(2) Devices for use by lay persons must be designed and manufactured in such a way as to—

- (a) ensure that the device can be used safely and accurately by the intended user at all stages of the procedure, if necessary after appropriate training or information;
- (b) reduce, as far as possible and appropriate, the risk from unintended cuts and pricks such as needle stick injuries; and
- (c) reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, in the interpretation of the results.

(3) Devices for use by lay persons must, where appropriate, include a procedure by which the lay person—

- (a) can verify that, at the time of use, the device will perform as intended by the manufacturer;
- (b) is warned if the device has failed to provide a valid result.

PART 3

Requirements regarding instructions for use

Label and instructions for use

23.—(1) Each device must be accompanied by the information (which may appear on the device itself, on the packaging or in the instructions for use) needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate.

(2) The information in paragraph (1) must, if the manufacturer has a website, be made available and kept up to date on the website.

(3) The label and instructions for use must take into account the following—

- (a) that the medium, format, content, legibility, and location of the label and instructions for use must be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended users and, in particular, instructions for use must be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams;
- (b) the information required on the label must be provided on the device itself or, if this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, or on the packaging of multiple devices;
- (c) labels must be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification ('RFID') or bar codes;
- (d) in general, instructions for use must be provided together with devices but, by way of exception, instructions for use are not required for Class I and Class IIa devices if such devices can be used safely without any such instructions and unless otherwise provided for elsewhere in this paragraph;
- (e) where multiple devices are supplied to a single user or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge;
- (f) instructions for use may be provided to the user in non-paper format (for example electronic) to the extent, and only under the conditions, set out in Regulation (EU) No 207/2012;
- (g) residual risks which are required to be communicated to the user or other person must be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer;
- (h) where appropriate, the information supplied by the manufacturer —
 - (i) must take the form of internationally recognised symbols;
 - (ii) must conform, in terms of any symbol or identification colour used, to the relevant standards; and
 - (iii) in areas for which no relevant standards exist, the symbols and colours must be described in the documentation supplied with the device.

Information on the label

- (4) The label must bear the following particulars—
- (a) the name or trade name of the device;
 - (b) the details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device;
 - (c) the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;
 - (d) if the manufacturer has its registered place of business outside the United Kingdom, the name and address of the person placing the device on the market;
 - (e) where applicable, an indication that the device contains or incorporates—
 - (i) a medicinal substance, including a human blood or plasma derivative, or tissues or cells, or their derivatives, of human origin; or
 - (ii) tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012;
 - (f) where applicable, information labelled in accordance with paragraph 10(10);
 - (g) the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate;
 - (h) the UDI carrier referred to in regulation 91(4) and Part C of Schedule 8;

- (i) an unambiguous indication of the time limit for using or implanting the device safely, expressed at least in terms of year and month, where this is relevant;
 - (j) where there is no indication of the date until when it may be used safely, the date of manufacture and this date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;
 - (k) an indication of any special storage or handling condition that applies;
 - (l) if the device is supplied sterile, an indication of its sterile state and the sterilisation method;
 - (m) warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device, and to any other person (this information may be kept to a minimum in which case, more detailed information must appear in the instructions for use, taking into account the intended users);
 - (n) if the device is intended for single use, an indication of that fact;
 - (o) if the device is a single-use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles;
 - (p) if the device is custom-made, the words ‘custom-made device’;
 - (q) an indication that the device is a medical device and, if the device is intended for clinical investigation only, the words ‘exclusively for clinical investigation’;
 - (r) in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, the overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible for achieving the principal intended action;
 - (s) for active implantable devices, the serial number, and for other implantable devices, the serial number or the lot number.
- (5) Where packaging maintains the sterile condition of the device (“sterile packaging”) the following particulars must appear on that sterile packaging—
- (a) an indication permitting the sterile packaging to be recognised as such;
 - (b) a declaration that the device is in a sterile condition;
 - (c) the method of sterilisation;
 - (d) the name and address of the manufacturer;
 - (e) a description of the device;
 - (f) if the device is intended for clinical investigations, the words ‘exclusively for clinical investigations’;
 - (g) if the device is custom-made, the words ‘custom-made device’;
 - (h) the month and year of manufacture;
 - (i) an unambiguous indication of the time limit for using or implanting the device safely expressed at least in terms of year and month;
 - (j) an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.

Information in instructions for use

- (6) The instructions for use must contain all the following particulars—
- (a) the particulars referred to in paragraphs (a), (c), (e), (f), (k), (l), (n) and (r) of paragraph 23(4);
 - (b) the device’s intended purpose with a clear specification of indications, contra-indications, the patient target group or groups, and of the intended users, as appropriate;

- (c) where applicable, a specification of the clinical benefits to be expected;
- (d) where applicable, links to the summary of safety and clinical performance referred to in regulation 96;
- (e) the performance characteristics of the device;
- (f) where applicable, information allowing the healthcare professional to verify if the device is suitable and select the corresponding software and accessories;
- (g) any residual risks, contra-indications and any undesirable side-effects, including information to be conveyed to the patient in this regard;
- (h) specifications the user requires to use the device appropriately, for example if the device has a measuring function, the degree of accuracy claimed for it;
- (i) details of any preparatory treatment or handling of the device before it is ready for use or during its use, such as sterilisation, final assembly, calibration, including the levels of disinfection required to ensure patient safety and all available methods for achieving those levels of disinfection;
- (j) any requirements for special facilities, or special training, or particular qualifications of the device user or other persons;
- (k) the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant—
 - (i) details of the nature, and frequency, of preventive and regular maintenance, and of any preparatory cleaning or disinfection;
 - (ii) identification of any consumable components and how to replace them;
 - (iii) information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime;
 - (iv) methods for eliminating the risks encountered by persons involved in installing, calibrating or servicing devices;
- (l) if the device is supplied sterile, instructions in the event of the sterile packaging being damaged or unintentionally opened before use;
- (m) if the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation;
- (n) if the device is reusable, information must be provided—
 - (i) on the appropriate processes for allowing reuse, including cleaning, disinfection, packaging and, where appropriate, the validated method of re-sterilisation; and
 - (ii) to identify when the device should no longer be reused, for example signs of material degradation or the maximum number of allowable reuses;
- (o) an indication, if appropriate, that a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements;
- (p) if the device bears an indication that it is for single use—
 - (i) information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used;
 - (ii) the information must be based on a specific section of the manufacturer's risk management documentation, where such characteristics and technical factors must be addressed in detail;
 - (iii) if, in accordance with sub-paragraph (3)(d), no instructions for use are required, this information must be made available to the user upon request;
- (q) for devices intended for use together with other devices or general purpose equipment—

- (i) information to identify such devices or equipment, in order to obtain a safe combination;
 - (ii) information on any known restrictions to combinations of devices and equipment;
- (r) if the device emits radiation for medical purposes—
- (i) detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation;
 - (ii) the means of protecting the patient, user, or other person from unintended radiation during use of the device;
- (s) information that allows the user or patient to be informed of, or as the case may be, briefed about any warnings, precautions, contra-indications, measures to be taken and limitations of use regarding the device and this information must cover, where appropriate—
- (i) warnings, precautions or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety;
 - (ii) warnings, precautions or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;
 - (iii) warnings, precautions or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment;
 - (iv) if the device is intended to administer medicinal products, tissues or cells of human or animal origin, or their derivatives, or biological substances, any limitations or incompatibility in the choice of substances to be delivered;
 - (v) warnings, precautions or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device; and
 - (vi) precautions related to materials incorporated into the device that contain or consist of CMR substances or endocrine-disrupting substances, or that could result in sensitisation or an allergic reaction by the patient or user;
- (t) in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, warnings and precautions, where appropriate, related to—
- (i) the general profile of interaction of the device and its products of metabolism with other devices, medicinal products and other substances;
 - (ii) contra-indications, undesirable side-effects and risks relating to overdose;
- (u) in the case of implantable devices, the overall qualitative and quantitative information on the materials and substances to which patients can be exposed;
- (v) warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it, which must, where appropriate cover—
- (i) infection or microbial hazards such as explants, needles or surgical equipment contaminated with potentially infectious substances of human origin, and
 - (ii) physical hazards such as from sharps;
 - (iii) if, in accordance with the sub-paragraph (3)(d), no instructions for use are required, this information must be made available to the user upon request;

- (w) for devices intended for use by lay persons, the circumstances in which the user should consult a healthcare professional;
- (x) for the devices covered by Part VIII of these Regulations pursuant to regulation 68(2)(b), information regarding the absence of a clinical benefit and the risks related to use of the device;
- (y) the date of issue of the instructions for use or, if they have been revised, the date of issue and the identifier of the latest revision of the instructions for use;
- (z) a notice to the user or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and to the Secretary of State;
- (aa) information to be supplied to the patient with an implanted device in accordance with regulation 83;
- (bb) for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, Information Technology networks characteristics and Information Technology security measures, including protection against unauthorised access, necessary to run the software as intended.

SCHEDULE 4

Regulation 1A

Technical Documentation

1. The technical documentation and, if applicable, the summary of that documentation drawn up by the manufacturer must be presented in clear, organised, readily searchable and unambiguous manner and must include the elements listed in this Schedule.

Device description and specification including variants and accessories

Device description and specification

- 2.—**(1) The description and specification of a device must contain the following—
- (a) the product or trade name and a general description of the device including its intended purpose and intended users;
 - (b) the Basic UDI-DI as referred to in Part C of Schedule 8 assigned by the manufacturer to the device in question, as soon as identification of this device becomes based on a UDI system, or otherwise a clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;
 - (c) the intended patient population and medical conditions to be diagnosed, treated or monitored and other considerations such as patient selection criteria, indications, contra-indications, warnings;
 - (d) principles of operation of the device and its mode of action, scientifically demonstrated if necessary;
 - (e) the rationale for the qualification of the product as a device;
 - (f) the risk class of the device and the justification for the classification rules applied in accordance with Schedule 9;
 - (g) an explanation of any novel features;
 - (h) a description of the accessories for the device, other devices and other products that are not devices, which are intended to be used in combination with it;
 - (i) a description or complete list of the various configurations or variants of the device that are intended to be made available on the market;
 - (j) a general description—

- (i) of the key functional elements, for example its parts or components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition; and
- (ii) which, where appropriate, must include labelled pictorial representations (for example diagrams, photographs, and drawings), clearly indicating key parts or components, including sufficient explanation to understand the drawings and diagrams;
- (k) a description of the raw materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body, for example during extracorporeal circulation of body fluids;
- (l) technical specifications, such as features, dimensions and performance attributes, of the device and any variants or configurations and accessories that would typically appear in the product specification made available to the user, for example in brochures, catalogues and similar publications.

Reference to previous and similar generations of the device

(2) Where applicable the technical documentation must contain—

- (a) an overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist;
- (b) an overview of identified similar devices available on the international markets, where such devices exist.

Information to be supplied by the manufacturer

3. The manufacturer must supply a complete set of—

- (a) the label or labels on the device and on its packaging, such as single unit packaging, sales packaging, transport packaging in case of specific management conditions in English; and
- (b) the instructions for use in English.

Design and manufacturing information

4. The following design and manufacturing information must be supplied—

- (a) information (including full data) to allow the design stages applied to the device to be understood;
- (b) complete information (including full data) and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing.

General safety and performance requirements

5.—(1) The documentation must contain information for the demonstration of conformity with the general safety and performance requirements set out in Schedule 3 that are applicable to the device taking into account its intended purpose, and must include a justification, validation and verification of the solutions adopted to meet those requirements.

(2) The demonstration of conformity in sub-paragraph (1) must include—

- (a) the general safety and performance requirements that apply to the device and an explanation as to why others do not apply;
- (b) the method or methods used to demonstrate conformity with each applicable general safety and performance requirement;
- (c) the standards or other solutions applied;
- (d) the precise identity of the controlled documents offering evidence of conformity with each standard, or other method applied to demonstrate conformity with the general safety and performance requirements; and

- (e) the information referred to paragraph (d) must incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.

Benefit-risk analysis and risk management

6. The technical documentation must contain information on—

- (a) the benefit-risk analysis referred to in paragraphs 1 and 8 of Schedule 3;
- (b) the solutions adopted and the results of the risk management referred to in paragraph 3 of Schedule 3.

Product verification and validation

7.—(1) The documentation must contain the results and critical analyses of all verifications and validation tests or studies undertaken to demonstrate conformity of the device with the requirements of Part VIII and in particular the applicable general safety and performance requirements.

Pre-clinical and clinical data.

(2) The documentation must contain the following pre-clinical and clinical data—

- (a) results of tests, such as engineering, laboratory, simulated use and animal tests, and evaluation of published literature applicable to the device, taking into account its intended purpose, or to similar devices, regarding the pre-clinical safety of the device and its conformity with the specifications;
- (b) detailed information regarding test design, complete test or study protocols, methods of data analysis, in addition to data summaries and test conclusions regarding in particular—
 - (i) the biocompatibility of the device including the identification of all materials in direct or indirect contact with the patient or user;
 - (ii) physical, chemical and microbiological characterisation;
 - (iii) electrical safety and electromagnetic compatibility;
 - (iv) software verification and validation which must—
 - (aa) describe the software design and development process and provide evidence of the validation of the software, as used in the finished device;
 - (bb) typically include the summary results of all verification, validation and testing performed both in-house and in a simulated or actual user environment prior to final release; and
 - (cc) address all of the different hardware configurations and, where applicable, operating systems identified in the information supplied by the manufacturer;
 - (v) stability, including shelf life; and
 - (vi) performance and safety.

(3) Where applicable, conformity with the Good Laboratory Practice Regulations 1999^(a) must be demonstrated.

(4) Where no new testing has been undertaken, the documentation must incorporate a rationale for that decision (for example, a rationale would be that biocompatibility testing on identical materials was conducted when those materials were incorporated in a previous version of the device that has been legally placed on the market or put into service).

(5) The documentation must also include—

^(a) S.I. 1999/3106; relevant amendment S.I. 2004/994.

- (a) the clinical evaluation report and its updates and the clinical evaluation plan referred to in regulation 102(14) and Part A of Schedule 14;
- (b) the PMCF plan and PMCF evaluation report referred to in Part B of Schedule 14 or a justification why a PMCF is not applicable.

Additional information required in specific cases

(6) The additional information specified is required as part of the technical documentation in the following cases—

- (a) where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product within the meaning of regulation 2(1) of the Human Medicines Regulations 2012 including a medicinal product derived from human blood or human plasma, as referred to in regulation 68(8)—
 - (i) a statement indicating this fact; and
 - (ii) documentation sufficient to identify the source of that substance and contain the data of the tests conducted to assess its safety, quality and usefulness, taking account of the intended purpose of the device;
- (b) where a device is manufactured utilising tissues or cells of human or animal origin, or their derivatives, and is covered by Part VIII in accordance with sub-paragraphs (g) and (h) of regulation 68(6), and where a device incorporates, as an integral part, tissues or cells of human origin or their derivatives that have an action ancillary to that of the device and is covered by Part VIII in accordance with regulation 68(14)—
 - (i) a statement indicating this fact; and
 - (ii) documentation sufficient to identify all materials of human or animal origin used and provide detailed information concerning the conformity with sub-paragraphs (1) and (2) of paragraph 13 of Schedule 3;
- (c) in the case of devices that are composed of substances or combinations of substances that are intended to be introduced into the human body and that are absorbed by or locally dispersed in the human body, detailed information, including test design, complete test or study protocols, methods of data analysis, and data summaries and test conclusions, regarding studies in relation to—
 - (i) absorption, distribution, metabolism and excretion;
 - (ii) possible interactions of those substances, or of their products of metabolism in the human body, with other devices, medicinal products or other substances, considering the target population, and its associated medical conditions;
 - (iii) local tolerance;
 - (iv) toxicity, including single-dose toxicity, repeat-dose toxicity, genotoxicity, carcinogenicity and reproductive and developmental toxicity, as applicable depending on the level and nature of exposure to the device and in the absence of such studies, a justification shall be provided;
- (d) in the case of devices containing CMR or endocrine-disrupting substances referred to in paragraph 10(7) of Schedule 3, the justification referred to in paragraph 10(9) of that Schedule;
- (e) in the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps;
- (f) in the case of devices placed on the market in a sterile condition—
 - (i) a description of the methods used; and
 - (ii) validation reports, with respect to packaging, sterilisation and maintenance of sterility which must address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues;

- (g) in the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications;
- (h) if the device is to be connected to other devices in order to operate as intended, a description of this combination or configuration including proof that it conforms to the general safety and performance requirements when connected to any such devices having regard to the characteristics specified by the manufacturer.

SCHEDULE 5

Regulation 1A

Technical documentation on post-market surveillance

1.—(1) The technical documentation on post-market surveillance drawn up by the manufacturer in accordance with regulations 121 to 123 must be presented in a clear, organised, readily searchable and unambiguous manner and must include in particular the elements described in sub-paragraphs (2) to (4) this Schedule.

(2) In the post-market surveillance plan drawn up in accordance with regulation 122, the manufacturer must prove that the requirements of regulation 121 have been met.

(3) The post-market surveillance plan must—

- (a) address the collection and utilization of available information, in particular—
 - (i) information concerning serious incidents, including information from PSURs, and field safety corrective actions;
 - (ii) records referring to non-serious incidents and data on any undesirable side-effects;
 - (iii) information from trend reporting;
 - (iv) information, including feedbacks and complaints, provided by users, distributors and importers;
 - (v) publicly available information about similar medical devices;
- (b) cover at least—
 - (i) a proactive and systematic process to collect any information referred to in sub-paragraph 1(2). The process must allow a correct characterisation of the performance of the devices and must also allow a comparison to be made between the device and similar products available on the market;
 - (ii) effective and appropriate methods and processes to assess the collected data;
 - (iii) suitable indicators and threshold values that must be used in the continuous reassessment of the benefit-risk analysis and of the risk management as referred to in paragraph 3 of Schedule 3;
 - (iv) effective and appropriate methods and tools to investigate complaints and analyse market-related experience collected in the field;
 - (v) methods and protocols to manage the events subject to the trend report as provided for in regulation 126, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period;
 - (vi) methods and protocols to communicate effectively to the Secretary of State, economic operators and users;
 - (vii) reference to procedures to fulfil the manufacturers obligations laid down in regulations 121, 122 and 124;
 - (viii) systematic procedures to identify and initiate appropriate measures including corrective actions;

- (ix) effective tools to trace and identify devices for which corrective actions might be necessary;
 - (x) a PMCF plan as referred to in Part B of Schedule 14, or a justification as to why a PMCF is not applicable.
- (4) The PSUR referred to in regulation 124 and the post-market surveillance report referred to in regulation 123.

SCHEDULE 6

Regulation 1A

Declaration of conformity

The declaration of conformity must contain the following information—

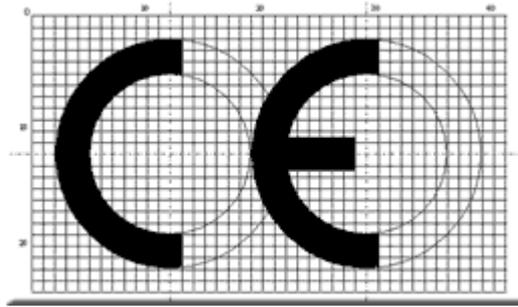
- (a) the name, registered trade name or registered trade mark of the manufacturer, and, if applicable, its authorised representative, and the address of their registered place of business or, if they have no such address, an address where they can be contacted and their location be established;
- (b) a statement that the declaration of conformity is issued under the sole responsibility of the manufacturer;
- (c) the Basic UDI-DI as referred to in Part C of Schedule 8;
- (d) the product and trade name;
- (e) the product code, catalogue number or other unambiguous reference allowing identification and traceability of the device (which can be provided by means of the UDI-DI referred to in paragraph (c)) covered by the declaration of conformity, such as a photograph;
- (f) the product's intended purpose;
- (g) the risk class of the device in accordance with the rules set out in Schedule 9;
- (h) a statement that the device, covered by the declaration, is in conformity with Part VIII or Regulation (EU) 2017/745 and, if applicable, with any other relevant product safety legislation that provides for the issuing of a declaration of conformity;
- (i) references to any designated standards used and in relation to which conformity is declared;
- (j) where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate or certificates issued;
- (k) where applicable, any additional information;
- (l) place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed;
- (m) a signature.

SCHEDULE 7

Regulation 1A

CE marking of conformity

1. The CE marking must consist of the initial 'CE' taking the following form—



2. If the CE marking is reduced or enlarged, the proportions given in the above graduated drawing must be respected.

3. The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm but this minimum dimension may be waived for small-scale devices.

SCHEDULE 8

Regulation 1A

Information to be submitted upon registration of devices and economic operators in accordance with regulations (1) and (1), core data elements to be provided to the UDI database together with the UDI-DI in accordance with regulations (1) and (1) and the UDI system

Part A

Information to be submitted upon the registration of devices and economic operators in accordance with regulations (1) and (1)

1. The information relating to the economic operator is as follows—
 - (a) type of economic operator (manufacturer, importer, authorised representative, UK responsible person or distributor);
 - (b) the name of the economic operator and the United Kingdom address and contact details for the economic operator;
 - (c) where submission of information is carried out by another person on behalf of any of the economic operators the name, address and contact details of that person;
 - (d) name, address and contact details of the person or persons responsible for regulatory compliance referred to in regulation 80.
2. The information relating to the device is as follows—
 - (a) basic UDI-DI;
 - (b) type, number and expiry date of the certificate issued by the notified body and the name or identification number of that notified body and the link to the information that appears on the certificate;
 - (c) if the device has been placed on the market of a state other than the United Kingdom before being placed on the United Kingdom market, the name of that state;
 - (d) in the case of Class IIa, Class IIb or Class III devices, the name of the state, other than the United Kingdom, where the device is or is to be made available;

- (e) the risk class of the device;
- (f) whether the device is a reprocessed single-use device;
- (g) the presence of a substance which, if used separately, may be considered to be a medicinal product and name of that substance;
- (h) the presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma and name of this substance;
- (i) whether tissues or cells of human origin, or their derivatives are present;
- (j) whether tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012 are present;
- (k) where applicable, the single identification number of the clinical investigation or investigations conducted in relation to the device or a link to the clinical investigation registration in the electronic system on clinical investigations;
- (l) in the case of devices listed in Schedule 16, specification as to whether the intended purpose of the device is other than a medical purpose;
- (m) in the case of devices designed and manufactured by another legal or natural person as referred in regulation 76(23), the name, address and contact details of that legal or natural person;
- (n) in the case of Class III or implantable devices, the summary of safety and clinical performance;
- (o) status of the device (on the market, no longer placed on the market, recalled, field safety corrective action initiated).

Part B

Core data elements to be provided to the UDI database together with the UDI-DI in accordance with regulations 1(1) and 1(1)

3. The person placing the product on the market must provide to the UDI database the UDI-DI and all of the following information relating to the manufacturer and the device—

- (a) the quantity per package configuration;
- (b) the Basic UDI-DI as referred to in regulation 93 and any additional UDI-DIs;
- (c) the manner in which production of the device is controlled (expiry date or manufacturing date, lot number, serial number);
- (d) if applicable, the unit of use UDI-DI (where a UDI is not labelled on the device at the level of its unit of use, a 'unit of use' DI shall be assigned so as to associate the use of a device with a patient);
- (e) the name and address of the manufacturer (as indicated on the label);
- (f) if applicable, name and address of the authorised representative (as indicated on the label);
- (g) the medical device nomenclature code as provided for in regulation 90;
- (h) risk class of the device;
- (i) if applicable, name or trade name;
- (j) if applicable, device model, reference or catalogue number;
- (k) if applicable, clinical size (including volume, length, gauge, diameter);
- (l) any additional product description;
- (m) if applicable, storage and handling conditions (as indicated on the label or in the instructions for use);
- (n) if applicable, additional trade names of the device;

- (o) whether the device is labelled as a single use device;
- (p) if applicable, the maximum number of reuses;
- (q) whether the device is labelled sterile;
- (r) whether there is a need for the device to be sterilised before use;
- (s) whether the device contains latex;
- (t) where applicable, information labelled in accordance with paragraph 10(10) of Schedule 3;
- (u) URL for additional information, such as electronic instructions for use (optional);
- (v) if applicable, critical warnings or contra-indications;
- (w) the status of the device (on the market, no longer placed on the market, recalled, field safety corrective action initiated).

Part C

The UDI system

Definitions

4. In this Schedule—

“automatic identification and data capture” or “(AIDC)” means a technology used to automatically capture data, for example, bar codes, smart cards, biometrics and RFID;

“Basic UDI-DI” is the primary identifier of a device model assigned at the level of the device unit and the main key for records in the UDI database which is referenced in the relevant certificates and declarations of conformity;

“configurable device” means a device that consists of several individual components (which can be devices in themselves) which can be assembled by the manufacturer in multiple configurations and includes: computed tomography (CT) systems, ultrasound systems, anaesthesia systems, physiological monitoring systems, radiology information systems (RIS);

“configuration” means a combination of items of equipment, as specified by the manufacturer, that operate together as a device to achieve an intended purpose and which may be modified, adjusted or customized to meet specific needs; examples of configurations include—

- (a) gantries, tubes, tables, consoles and other items of equipment that can be configured or combined to deliver an intended function in computed tomography;
- (b) ventilators, breathing circuits, vaporizers combined to deliver an intended function in anaesthesia;

“human readable interpretation (‘HRI’)” means a legible interpretation of the data characters encoded in the UDI carrier;

“packaging levels” means the various levels of device packaging that contain a defined quantity of devices, such as a carton or case;

“Radio Frequency Identification” or “RFID” means a technology that uses communication through the use of radio waves to exchange data between a reader and an electronic tag attached to an object, for the purpose of identification;

“shipping container” means a container in relation to which traceability is controlled by a process specific to logistics systems;

“UDI carrier” means the method of conveying (by for example ID or linear bar code, 2D Matrix bar code or RFID) the UDI by using AIDC and, if applicable, its HRI;

“UDI-DI” means a unique numeric or alphanumeric code specific to a model of device and that is also used as the ‘access key’ to information stored in a UDI database;

“unique device identifier” or “UDI”, which is comprised of the UDI-DI and UDI-PI, means a series of numeric or alphanumeric characters created through a globally accepted device identification and coding standard and which allows for the unambiguous identification of a specific device on the market;

“UDI-PI” means a numeric or alphanumeric code that identifies the unit of device production, and types of UDI-PI include serial number, lot number, software identification, manufacturing date or expiry date;

“units of use DI” means a device identifier used to associate the use of the device with the patient in instances in which a UDI is not labelled on the individual device at the level of its unit of use, for example where several units of the same device are packaged together.

General requirements

5.—(1) The affixing of the UDI is an additional requirement and does not replace any other marking or labelling requirements laid down in Schedule 3 to these regulations.

(2) The manufacturer must assign and maintain UDIs for its devices.

(3) Only the manufacturer may place the UDI on the device or its packaging.

(4) Only coding standards provided by issuing entities, as set out in regulation 91(2), may be used.

The UDI

6.—(1) A UDI must be assigned to the device itself or its packaging and higher levels of packaging must have their own UDI.

(2) Shipping containers are exempt from the requirement in sub-paragraph (1), for example, a UDI is not required on a logistics unit so that where a healthcare provider orders multiple devices using the UDI or model number of individual devices and the manufacturer places those devices in a container for shipping or to protect the individually packaged devices, the container (logistics unit) is not be subject to UDI requirements.

(3) The UDI must contain two parts: a UDI-DI and a UDI-PI.

(4) The UDI-DI must be unique at each level of device packaging.

(5) Where on the label there is—

(a) a lot number, serial number, software identification or expiry date, it must be part of the UDI-PI; or

(b) only a manufacturing date, this must be used as the UDI-PI,

but, where there is both a lot number, serial number, software identification or expiry date and a manufacturing date, the manufacturing date does not need to be included within the UDI-PI.

(6) Each component that is considered to be a device and is commercially available on its own must be assigned a separate UDI unless the components are part of a configurable device that is marked with its own UDI.

(7) Systems and procedure packs as referred to in regulation 87 must be assigned and bear their own UDI.

(8) The manufacturer must assign the UDI to a device following the relevant coding standard.

(9) A new UDI-DI is required whenever there is a change that could lead to misidentification of a device or ambiguity in its traceability and in particular, any change of one of the following UDI database data elements requires a new UDI-DI—

(a) name or trade name;

(b) device version or model;

(c) labelled as single use;

(d) packaged sterile;

- (e) need for sterilization before use;
- (f) quantity of devices provided in a package;
- (g) critical warnings or contra-indications for example, containing latex or Di (2-ethylhexyl) phthalate.

(10) Manufacturers that repackage or relabel devices, with their own label must retain a record of the original device manufacturer's UDI.

UDI carrier

7.—(1) The UDI carrier (AIDC and HRI representation of the UDI) must be placed on the label or on the device itself and on all higher levels of device packaging other than shipping containers.

(2) Where there are significant space constraints on the unit of use packaging, the UDI carrier may be placed on the next higher packaging level.

(3) Subject to paragraph (4), for single-use devices of Classes I and IIa, packaged and labelled individually, the UDI carrier is not required to appear on the packaging but it must appear on a higher level of packaging, for example a carton containing several individually packaged devices.

(4) When the healthcare provider is not expected to have access, in cases such as in home healthcare settings, to the higher level of device packaging, the UDI must be placed on the packaging of the individual device.

(5) For devices exclusively intended for retail sale the UDI-PIs in AIDC is not be required to appear on the point of sale packaging.

(6) When AIDC carriers other than the UDI carrier are part of the product labelling, the UDI carrier shall be readily identifiable.

(7) If linear bar codes are used the UDI-DI and UDI-PI may be concatenated or non-concatenated in two or more bar codes but all parts and elements of the linear bar code must be distinguishable and identifiable.

(8) Subject to paragraph (9), where there are significant constraints limiting the use of both AIDC and HRI on the label, only the AIDC format is required to appear on the label.

(9) For devices intended to be used outside healthcare facilities, such as devices for home care, the HRI must appear on the label even if this results in there being no space for the AIDC.

(10) The HRI format must follow the rules of the UDI code-issuing entity.

(11) If the manufacturer is using RFID technology, a linear or 2D bar code in line with the standard provided by the issuing entities shall also be provided on the label.

(12) Subject to sub-paragraph (13), devices that are reusable—

- (a) must bear a UDI carrier on the device itself; and
- (b) for reusable devices that require cleaning, disinfection, sterilisation or refurbishing between patient uses, the UDI carrier must be permanent and readable after each process performed to make the device ready for the subsequent use throughout the intended lifetime of the device.

(13) The requirements in sub-paragraph (12) do not apply to devices in the following circumstances—

- (a) any type of direct marking would interfere with the safety or performance of the device;
- (b) the device cannot be directly marked because it is not technologically feasible.

(14) The UDI carrier must be readable during normal use and throughout the intended lifetime of the device.

(15) If the UDI carrier is readily readable or, in the case of AIDC, scannable, through the device's packaging, the placing of the UDI carrier on the packaging is not required.

(16) In the case of single finished devices made up of multiple parts that must be assembled before their first use, it is sufficient to place the UDI carrier on only one part of each device.

(17) The UDI carrier must be placed in a manner such that the AIDC can be accessed during normal operation or storage.

(18) Bar code carriers that include both a UDI-DI and a UDI-PI may also include essential data for the device to operate or other data.

General principles of the UDI database

8.—(1) The UDI database must support the use of all core UDI database data elements referred to in Part B of this Schedule.

(2) Manufacturers must be responsible for the initial submission and updates of the identifying information and other device data elements in the UDI database.

(3) Appropriate methods or procedures for validation of the data provided must be implemented.

(4) Manufacturers must periodically verify the correctness of all of the data relevant to devices they have placed on the market, except for devices that are no longer available on the market.

(5) The presence of the device UDI-DI in the UDI database shall not be assumed to mean that the device is in conformity with Part VIII.

(6) The database must allow for the linking of all the packaging levels of the device.

(7) The data for new UDI-DIs must be available at the time the device is placed on the market.

(8) Manufacturers must update the relevant UDI database record within 30 days of a change being made to an element, which does not require a new UDI-DI.

(9) Internationally-accepted standards for data submission and updates must, wherever possible, be used by the UDI database.

(10) The user interface must be available in English.

(11) Data relating to devices that are no longer available on the market must be retained in the UDI database.

Rules for specific device types

Implantable devices

9.—(1) Implantable devices must, at their lowest level of packaging, be identified, or marked using AIDC, with a UDI (UDI-DI plus UDI-PI);

(2) The UDI-PI shall have at least the following characteristics—

(a) the serial number for active implantable devices,

(b) the serial number or lot number for other implantable devices.

(3) The UDI of the implantable device shall be identifiable prior to implantation.

Reusable devices requiring cleaning, disinfection, sterilisation or refurbishing between uses

(4) The UDI for reusable devices must be placed on the device and be readable after each procedure to make the device ready for the next use.

(5) The UDI-PI characteristics such as the lot or serial number shall be defined by the manufacturer.

Systems and procedure packs as referred to in regulation 89

10.—(1) The person referred to in regulation 89 is responsible for identifying the system or procedure pack with a UDI including both UDI-DI and UDI-PI.

(2) Device contents of system or procedure packs must bear a UDI carrier on their packaging or on the device itself except where—

- (a) individual single-use disposable devices, the uses of which are generally known to the persons by whom they are intended to be used, which are contained within a system or procedure pack, and which are not intended for individual use outside the context of the system or procedure pack, are not required to bear their own UDI carrier;
 - (b) devices that are exempted from bearing a UDI carrier on the relevant level of packaging shall not be required to bear a UDI carrier when included within a system or procedure pack.
- (3) The UDI carrier should be placed on system and procedure packs as follows—
- (a) the system or procedure pack UDI carrier must, as a general rule, be affixed to the outside of the packaging;
 - (b) the UDI carrier must be readable, or, in the case of AIDC, scannable, whether placed on the outside of the packaging of the system or procedure pack or inside transparent packaging.

Configurable devices

11.—(1) A UDI must be assigned to the configurable device in its entirety and shall be called the configurable device UDI.

(2) The configurable device UDI-DI must be assigned to groups of configurations, not per configuration within the group. A group of configurations is defined as the collection of possible configurations for a given device as described in the technical documentation.

(3) A configurable device UDI-PI must be assigned to each individual configurable device.

(4) The carrier of the configurable device UDI must be placed on the assembly that is most unlikely to be exchanged during the lifetime of the system and must be identified as the configurable device UDI.

(5) Each component that is considered a device and is commercially available on its own must be assigned a separate UDI.

Device software

12.—(1) The UDI assignment criteria for device software are—

- (a) the UDI must be assigned at the system level of the software but only software which is commercially available on its own and software which constitutes a device in itself is subject to that requirement;
- (b) the software identification must be considered to be the manufacturing control mechanism and must be displayed in the UDI-PI.

(2) A new UDI-DI is required whenever there is a modification that changes—

- (a) the original performance;
- (b) the safety or the intended use of the software; or
- (c) interpretation of the data;

and such modifications include new or modified algorithms, database structures, operating platform, architecture or new user interfaces or new channels for interoperability.

(3) Minor software revisions—

- (a) require a new UDI-PI and not a new UDI-DI;
- (b) are generally associated with bug fixes, usability enhancements that are not for safety purposes, security patches or operating efficiency; and
- (c) must be identified by a manufacturer-specific form of identification.

(4) the UDI placement criteria for software are—

- (a) where the software is delivered on a physical medium, for example CD or DVD, each packaging level must bear the human readable and AIDC representation of the complete UDI;
- (b) the UDI that is applied to the physical medium containing the software and its packaging must be identical to the UDI assigned to the system level software;
- (c) the UDI must be provided on a readily accessible screen for the user in an easily-readable plain-text format, such as an ‘about’ file, or included on the start-up screen;
- (d) software lacking a user interface such as middleware for image conversion, must be capable of transmitting the UDI through an application programming interface (API);
- (e) only the human readable portion of the UDI is required in electronic displays of the software but the marking of UDI using AIDC is not to be required in the electronic displays, such as on the ‘about’ menu or splash screen (a window consisting of an image or logo typically used to notify the user that a programme is in the process of loading) etc.;
- (f) the human readable format of the UDI for the software must include the Application Identifiers (AI) for the standard used by the issuing entities, so as to assist the user in identifying the UDI and determining which standard is being used to create the UDI.

SCHEDULE 9

Regulation 1A

Classification rules

Chapter 1

Definitions specific to classification rules

1. In this Schedule—

- (a) in relation to the duration of use—

“long term” means normally intended for continuous use for more than 30 days;

“short term” means normally intended for continuous use for between 60 minutes and 30 days;

“transient” means normally intended for continuous use for less than 60 minutes;

- (b) in relation to invasive and active devices—

“active device intended for diagnosis and monitoring” means any active device used, whether alone or in combination with other devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities;

“active therapeutic device” means any active device used, whether alone or in combination with other devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or disability;

“body orifice” means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma;

“central circulatory system” means the following blood vessels—

arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria

carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior and vena cava inferior;

“central nervous system” means the brain, meninges and spinal cord;

“injured skin or mucous membrane” means an area of skin or a mucous membrane presenting a pathological change or change following disease or a wound;

“reusable surgical instrument” means an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation have been carried out;

“surgically invasive device” means—

- (a) an invasive device which penetrates inside the body through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation; and
- (b) a device which penetrates other than through a body orifice;

Chapter 2

Implementing rules

2.—(1) Application of the classification rules must be governed by the intended purpose of the devices.

(2) If the device in question is intended to be used in combination with another device—

- (a) the classification rules must apply separately to each of the devices;
- (b) accessories for a medical device and for a product listed in Schedule 16 must be classified in their own right separately from the device with which they are used.

(3) Software, which drives a device or influences the use of a device, must fall within the same class as the device but, if the software is independent of any other device, it must be classified in its own right.

(4) If the device is not intended to be used solely or principally in a specific part of the body, it must be considered and classified on the basis of the most critical specified use.

(5) If several rules or, if, within the same rule, several sub-rules, apply to the same device based on the device’s intended purpose, the strictest rule and sub-rule resulting in the higher classification must apply.

(6) In calculating the duration of use referred to in paragraph 1(a), continuous use means—

- (a) the entire duration of use of the same device without regard to temporary interruption of use during a procedure or temporary removal for purposes such as cleaning or disinfection of the device (and, whether the interruption of use or the removal is temporary must be established in relation to the duration of the use prior to and after the period when the use is interrupted or the device removed);
- (b) the accumulated use of a device that is intended by the manufacturer to be replaced immediately with another of the same type.

(7) A device is considered to allow direct diagnosis when it provides the diagnosis of the disease or condition in question by itself or when it provides decisive information for the diagnosis.

Chapter 3

Classification rules

Non-invasive devices

Rule 1

3.—(1) All non-invasive devices are classified as Class I, unless one of the other rules set out in this Schedule applies.

Rule 2

(2) All non-invasive devices intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are classified as Class IIa—

- (a) if they may be connected to a Class IIa, Class IIb or Class III active device; or
- (b) if they are intended for use for channelling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues, except for blood bags which are classified as Class IIb;

such devices are classified as Class I, in all other cases.

Rule 3

(3) All non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or administration into the body are classified as Class IIb, unless the treatment for which the device is used consists of filtration, centrifugation or exchanges of gas, heat, in which case they are classified as Class IIa.

(4) All non-invasive devices consisting of a substance or a mixture of substances intended to be used in vitro in direct contact with human cells, tissues or organs taken from the human body or used in vitro with human embryos before their implantation or administration into the body are classified as Class III.

Rule 4

(5) All non-invasive devices which come into contact with injured skin or mucous membrane are classified as—

- (a) Class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates;
- (b) Class IIb if they are intended to be used principally for injuries to skin which have breached the dermis or mucous membrane and can only heal by secondary intent;
- (c) Class IIa if they are principally intended to manage the micro-environment of injured skin or mucous membrane;
- (d) Class IIa in all other cases.

This rule also applies to the invasive devices that come into contact with injured mucous membrane.

Invasive devices

Rule 5

4.—(1) All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active device or which are intended for connection to a Class I active device are classified as—

- (a) Class I if they are intended for transient use;
- (b) Class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity, in which case they are classified as class I;
- (c) Class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal

cavity and are not liable to be absorbed by the mucous membrane, in which case they are classified as class IIa.

All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to a Class IIa, Class IIb or Class III active device, are classified as Class IIa.

Rule 6

(2) All surgically invasive devices intended for transient use are classified as class IIa unless they—

- (a) are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as Class III;
- (b) are reusable surgical instruments, in which case they are classified as class I;
- (c) are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as Class III;
- (d) are intended to supply energy in the form of ionising radiation in which case they are classified as Class IIb;
- (e) have a biological effect or are wholly or mainly absorbed in which case they are classified as Class IIb; or
- (f) are intended to administer medicinal products by means of a delivery system, if such administration of a medicinal product is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are classified as Class IIb.

Rule 7

(3) All surgically invasive devices intended for short-term use are classified as Class IIa unless they—

- (a) are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III;
- (b) are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as Class III;
- (c) are intended to supply energy in the form of ionizing radiation in which case they are classified as Class IIb;
- (d) have a biological effect or are wholly or mainly absorbed in which case they are classified as Class III;
- (e) are intended to undergo chemical change in the body in which case they are classified as Class IIb, except if the devices are placed in the teeth; or
- (f) are intended to administer medicines, in which case they are classified as Class IIb.

Rule 8

(4) All implantable devices and long-term surgically invasive devices are classified as Class IIb unless they—

- (a) are intended to be placed in the teeth, in which case they are classified as Class IIa;
- (b) are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are classified as Class III;
- (c) are intended to undergo chemical change in the body in which case they are classified as Class III, except if the devices are placed in the teeth;
- (d) are intended to administer medicinal products, in which case they are classified as Class III;

- (e) are active implantable devices or their accessories, in which case they are classified as Class III;
- (f) are breast implants or surgical meshes, in which cases they are classified as Class III;
- (g) are total or partial joint replacements, in which case they are classified as Class III, with the exception of ancillary components such as screws, wedges, plates and instruments; or
- (h) are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as Class III with the exception of components such as screws, wedges, plates and instruments.

Active devices

Rule 9

5.—(1) All active therapeutic devices intended to administer or exchange energy are classified as Class IIa unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as Class IIb.

(2) All active devices intended to control or monitor the performance of active therapeutic Class IIb devices, or intended directly to influence the performance of such devices are classified as Class IIb.

(3) All active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance, are classified as Class IIb.

(4) All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as Class III.

Rule 10

(5) Active devices intended for diagnosis and monitoring are classified as Class IIa—

- (a) if they are intended to supply energy which will be absorbed by the human body, except for devices intended to illuminate the patient's body, in the visible spectrum, in which case they are classified as class I;
- (b) if they are intended to image in vivo distribution of radiopharmaceuticals;
- (c) if they are intended to image in vivo distribution of radiopharmaceuticals; or
- (d) if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters and the nature of variations of those parameters is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of the central nervous system, or they are intended for diagnosis in clinical situations where the patient is in immediate danger, in which cases they are classified as Class IIb.

(6) Active devices intended to emit ionizing radiation and intended for diagnostic or therapeutic radiology, including interventional radiology devices and devices which control or monitor such devices, or which directly influence their performance, are classified as Class IIb.

Rule 11

(7) Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as Class IIa, except if such decisions have an impact that may cause—

- (a) death or an irreversible deterioration of a person's state of health, in which case it is in class III; or
- (b) a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as Class IIb.

(8) Software intended to monitor physiological processes is classified as Class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as Class IIb.

(9) All other software is classified as Class I.

Rule 12

(10) All active devices intended to administer or remove medicinal products, body liquids or other substances to or from the body are classified as Class IIa, unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are classified as Class IIb.

Rule 13

(11) All other active devices are classified as Class I.

Special rules

Rule 14

6.—(1) All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in regulation 2(1) of the Human Medicines Regulations 2012, including a medicinal product derived from human blood or human plasma, and that has an action ancillary to that of the devices, are classified as Class III.

Rule 15

(2) All devices used for contraception or prevention of the transmission of sexually transmitted diseases are classified as Class IIb, unless they are implantable or long term invasive devices, in which case they are classified as class III.

Rule 16

(3) All devices intended specifically to be used for disinfecting, cleaning, rinsing or, where appropriate, hydrating contact lenses are classified as Class IIb.

(4) All devices intended specifically to be used for disinfecting or sterilising medical devices are classified as Class IIa, unless they are disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing, in which case they are classified as Class IIb.

(5) Rule 16 does not apply to devices that are intended to clean devices other than contact lenses by means of physical action only.

Rule 17

(6) Devices specifically intended for recording of diagnostic images generated by X-ray radiation are classified as Class IIa.

Rule 18

(7) All devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or rendered non-viable, are classified as class III, unless such devices are manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable and are devices intended to come into contact with intact skin only.

Rule 19

(8) All devices incorporating or consisting of nanomaterial are classified as—

- (a) Class III if they present a high or medium potential for internal exposure;
- (b) Class IIb if they present a low potential for internal exposure;
- (c) Class IIa if they present a negligible potential for internal exposure.

Rule 20

(9) All invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation are classified as

Class IIa, unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product or they are intended to treat life-threatening conditions, in which case they are classified as Class IIb.

Rule 21

(10) Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body are classified as—

- (a) Class III if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose;
- (b) Class III if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body;
- (c) Class IIa if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities;
- (d) Class IIb in all other cases.

Rule 22

(11) Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as Class III.

SCHEDULE 10

Regulation 1A

Conformity assessment based on quality management system on assessment of technical documentation

Chapter 1

Quality management system

1.—(1) The manufacturer must—

- (a) establish, document and implement a quality management system as described in regulation 76(13);
- (b) maintain the effectiveness of that system throughout the life cycle of the device concerned;
- (c) ensure the application of the quality management system as specified in subparagraphs (2) to (6);
- (d) comply with the surveillance requirements as specified in sub-paragraph (7).

Quality management system assessment

(2) The manufacturer must lodge an application for assessment of its quality management system with a notified body and that application must include—

- (a) the name of the manufacturer and address of its registered place of business and any additional manufacturing site covered by the quality management system, and, if the manufacturer's application is lodged by its authorised representative, the name of the authorised representative and the address of the authorised representative's registered place of business;
- (b) all relevant information on the device or group of devices covered by the quality management system;
- (c) a written declaration that no application has been lodged with any other notified body for the same device-related quality management system, or information about any previous application for the same device-related quality management system;

- (d) a draft of a declaration of conformity for the device model covered by the conformity assessment procedure;
- (e) the documentation on the manufacturer's quality management system;
- (f) a documented description of the procedures in place to fulfil the obligations arising from the quality management system and required under Part VIII and the undertaking by the manufacturer in question to apply those procedures;
- (g) the documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMCF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in regulations 125 to 129;
- (h) a description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in regulations 125 to 129, as well as the undertaking by the manufacturer to apply those procedures;
- (i) documentation on the clinical evaluation plan;
- (j) a description of the procedures in place to keep up to date the clinical evaluation plan, taking into account the state of the art.

(3) Implementation of the quality management system must ensure compliance with Part VIII and all the elements, requirements and provisions adopted by the manufacturer for its quality management system must be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures such as quality programmes, quality plans and quality records.

(4) The documentation to be submitted for the assessment of the quality management system must include an adequate description of, in particular—

- (a) the manufacturer's quality objectives;
- (b) the organisation of the business and in particular—
 - (i) the organisational structures with the assignment of staff responsibilities in relation to critical procedures, the responsibilities of the managerial staff and their organisational authority;
 - (ii) the methods of monitoring whether the operation of the quality management system is efficient and in particular the ability of that system to achieve the desired design and device quality, including control of devices which fail to conform;
 - (iii) where the design, manufacture, final verification and testing of the devices, or parts of any of those processes, is carried out by another party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party;
 - (iv) where applicable, the draft mandate for the designation of an authorised representative and a letter of intention from the authorised representative to accept the mandate;
- (c) the procedures and techniques for monitoring, verifying, validating and controlling the design of devices and the corresponding documentation as well as the data and records arising from those procedures and techniques.
- (d) those procedures and techniques must specifically cover—
 - (i) the strategy for regulatory compliance, including processes for identification of relevant legal requirements, qualification, classification, handling of equivalence, choice of and compliance with conformity assessment procedures;
 - (ii) risk management as referred to in paragraph 3 of Schedule 3;

- (iii) the clinical evaluation, pursuant to regulation 105 and Schedule 14, including post-market clinical follow-up;
 - (iv) solutions for fulfilling the applicable specific requirements regarding design and construction, including appropriate pre-clinical evaluation, in particular the requirements of Part 2 of Schedule 3;
 - (v) solutions for fulfilling the applicable specific requirements regarding the information to be supplied with the device, in particular the requirements of Part 3 of Schedule 3;
 - (vi) the device identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture;
 - (vii) management of design or quality management system changes;
 - (e) the verification and quality assurance techniques at the manufacturing stage and in particular the processes and procedures which are to be used, particularly as regards sterilisation and the relevant documents;
 - (f) the appropriate tests and trials which are to be carried out before, during and after manufacture including—
 - (i) the frequency with which they are to take place;
 - (ii) the test equipment to be used;
 - (iii) a means of adequately tracing back the calibration of that test equipment.
- (5) The manufacturers must grant the notified body access to the technical documentation referred to in Schedules 4 and 5.

(6) The manufacturer must inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system, or the device-range covered and the approval of any substantial change to the quality management system or the device-range covered must take the form of a supplement to the quality management system certificate.

Surveillance

- (7) The manufacturer must—
- (a) give authorisation to the notified body to carry out all the necessary audits, including on-site audits;
 - (b) supply the notified body with all relevant information, in particular—
 - (i) the documentation on its quality management system;
 - (ii) documentation on any findings and conclusions resulting from the application of the post-market surveillance plan, including the PMCF plan, for a representative sample of devices, and of the provisions on vigilance set out in regulations 125 to 129;
 - (iii) the data stipulated in the part of the quality management system relating to design, such as the results of analyses, calculations, tests and the solutions adopted regarding the risk-management as referred to in paragraph 4 of Schedule 3;
 - (iv) the data stipulated in the part of the quality management system relating to manufacture, such as quality control reports and test data, calibration data, and records on the qualifications of the personnel concerned.

Chapter 2

Assessment of technical documentation

2.—(1) In addition to the obligations laid down in paragraph 1, for Class III devices and those Class IIb implantable devices specified in regulation 98(4), the manufacturer must

lodge with the notified body an application for assessment of the technical documentation relating to the device which it plans to place on the market or put into service and which is covered by the quality management system referred to in paragraph 1.

(2) The application must describe the design, manufacture and performance of the device in question and must include the technical documentation as referred to in Schedules 4 and 5.

(3) Upon completing the manufacture of each batch of devices that incorporate, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma as referred to in the first sub-paragraph of regulation 68(8), the manufacturer shall inform the notified body of the release of the batch of devices and send it the official certificate concerning the release of the batch of human blood or plasma derivative used in the device, issued by a laboratory designated for that purpose by an EU Member State in accordance with Article 114(2) of Directive 2001/83/EC or, where applicable, a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012(a).

Chapter 3

Administrative provisions

3.—(1) The manufacturer or, if the manufacturer is not established in the United Kingdom, the person placing the product on the market must, for a period ending no sooner than 10 years, and in the case of implantable devices no sooner than 15 years, after the last device has been placed on the market, keep at the disposal of the Secretary of State—

- (a) the EU declaration of conformity;
- (b) the documentation referred to in paragraph 1(2)(e) and in particular the data and records arising from the procedures referred to paragraph 1(4)(c);
- (c) information on the changes referred to in paragraph 1(6);
- (d) the documentation referred to in paragraph 2(2);
- (e) the decisions and reports from the notified body.

(2) The documentation in sub-paragraph (1) must be kept so that it is available to the Secretary of State throughout the relevant period specified in sub-paragraph (1) irrespective of the continued status (and whether the person continues trading or not) of the manufacturer or person placing the product on the market.

SCHEDULE 11

Regulation 1A

Conformity assessment based on type examination

1. In this Schedule a “type examination” is a procedure whereby a notified body ascertains and certifies that a device, including its technical documentation and relevant life cycle processes and a corresponding representative sample of the device production envisaged, fulfils the relevant provisions.

Application

2. The manufacturer must lodge an application for assessment based on type examination with a notified body and the application must—

- (a) include the name of the manufacturer and address of the registered place of business of the manufacturer and, if the application is lodged by the authorised

(a) 2012 c. 7.

representative, the name of the authorised representative and the address of its registered place of business;

- (b) include the technical documentation referred to in Schedules 4 and 5;
- (c) make available to the notified body a representative sample of the device production envisaged ('type') (and provide other samples if requested by the notified body);
- (d) make a written declaration that no application has been lodged with any other notified body for the same type, or information about any previous application for the same type that was refused by another notified body or was withdrawn by the manufacturer or its authorised representative before that other notified body made its final assessment.

Assessment

3. The assessment must be carried out by a notified body in accordance with the obligations placed on such a body by Section 3 of Annex X of Regulation (EU) 2017/745.

Certificates

4. The certificate must be completed by a notified body in accordance with Section 4 of Annex X of Regulation (EU) 2017/745.

Changes to type

5.—(1) The applicant must inform the notified body which issued the type-examination certificate of any planned change to the approved type or of its intended purpose and conditions of use.

(2) Changes to the approved device including limitations of its intended purpose and conditions of use must be further approved by the notified body which issued the EU type-examination certificate where such changes may affect conformity with the general safety and performance requirements or with the conditions prescribed for use of the product.

(3) The approval of any change to the approved type must take the form of a supplement to the type-examination certificate.

(4) Changes to the intended purpose and conditions of use of the approved device, with the exception of limitations of the intended purpose and conditions of use, require a new application for a conformity assessment.

Administrative provisions

6.—(1) The manufacturer or, if the manufacturer is not established in the United Kingdom, the person placing the product on the market must, for a period ending no sooner than 10 years, and in the case of implantable devices no sooner than 15 years, after the last device has been placed on the market, keep at the disposal of the Secretary of State—

- (a) the documentation referred to in paragraph 2(b);
- (b) information on changes referred to in paragraph 5;
- (c) copies of type-examination certificates, scientific opinions and reports (and any supplements or additions to those reports).

(2) The documentation in sub-paragraph (1) must be kept so that it is available to the Secretary of State throughout the relevant period specified in sub-paragraph (1) irrespective of the continued status (and whether the person continues trading or not) of the manufacturer or person placing the product on the market.

Conformity assessment based on the product conformity verification

1. A “conformity assessment based on product conformity verification” is a procedure the purpose of which is to ensure that devices conform to the type for which a type-examination certificate has been issued, and that they meet the provisions of Part VIII which apply to them.

2. Where a type-examination certificate mentioned in paragraph 4 of Schedule 11 has been issued, the manufacturer may either apply the procedure set out in Part A (production quality assurance) or the procedure set out in Part B (product verification) of this Schedule.

3. Manufacturers of Class IIa devices, may draw up the technical documentation set out in Schedules 3 and 4 and follow the conformity assessment procedure set out in this Schedule.

PART A

Production quality assurance

4. The manufacturer must ensure that the quality management system approved for the manufacture of the devices concerned is implemented, must carry out a final verification, as specified in paragraph 6, and must be subject to the surveillance referred to in paragraph 7.

5. Subject to paragraph 8, when the manufacturer fulfils the obligations laid down in paragraph 4, it must draw up and keep a declaration of conformity in accordance with regulation 86 and Schedule 6 for the device covered by the conformity assessment procedure and by issuing an EU declaration of conformity, the manufacturer is deemed to ensure and to declare that the device concerned conforms to the type described in the type-examination certificate and meets the requirements of Part VIII which apply to the device.

Quality management system

6.—(1) The manufacturer must lodge an application for assessment of its quality management system with a notified body and that application must include—

- (a) all elements listed in paragraph 1(2) of Schedule 10;
- (b) the technical documentation referred to in Schedules 4 and 5 for the types approved;
- (c) a copy of the type-examination certificates referred to in paragraph 4 of Schedule 11 but if the type-examination certificates have been issued by the same notified body with which the application is lodged, a reference to the technical documentation and its updates and the certificates issued shall also be included in the application.

(2) Implementation of the quality management system must be such as to ensure that there is compliance with the type described in the type-examination certificate and with the provisions of Part VIII which apply to the devices at each stage.

(3) All the elements, requirements and provisions adopted by the manufacturer for its quality management system must be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures, such as quality programmes, quality plans and quality records.

(4) The documentation in sub-paragraph (3) must, in particular, include an adequate description of all elements listed in paragraphs (a), (b), (d) and (e) of paragraph 1(4) of Schedule 10.

(5) The requirement in paragraph 1(6) of Schedule 10 applies.

(6) Upon completing the manufacture of each batch of devices that incorporate, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma referred to in regulation 68(8), the manufacturer shall inform the notified body of the release of the batch of devices and send it the official certificate concerning the release of the batch of human blood or plasma derivative used in the device, issued by a laboratory designated for that purpose by an EU Member State in accordance with Article 114(2) of Directive 2001/83/EC or, where applicable, a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012.

Administrative provisions

7.—(1) Subject to paragraph 8(3), the manufacturer or, if the manufacturer is not established in the United Kingdom, the person placing the product on the market must, for a period ending no sooner than 10 years, and in the case of implantable devices no sooner than 15 years, after the last device has been placed on the market, keep at the disposal of the Secretary of State—

- (a) the declaration of conformity;
- (b) the documentation referred to in paragraph (e) of paragraph 1(2) of Schedule 10;
- (c) the documentation referred to in paragraph (h) of paragraph 1(2) of Schedule 10, including the type examination certificate referred to in Schedule 11;
- (d) information on the changes referred to in paragraph 1(6) of Schedule 10;
- (e) the decisions and reports from the notified body.

(2) The documentation in paragraphs (a) to (e) of sub-paragraph (1) must be kept so that it is available to the Secretary of State throughout the relevant period specified in sub-paragraph (1) irrespective of the continued status (and whether the person continues trading or not) of the manufacturer or person placing the product on the market.

Application to Class IIa devices

8.—(1) For Class IIa devices, by making the declaration of conformity the manufacturer is deemed to ensure and declare that those devices are manufactured in conformity with the technical documentation referred to in Schedules 4 and 5.

(2) The manufacturer must follow the procedure set down in Section 10.2 to 10.4 of Annex XI of Regulation (EU) 2017/745 and obtain the certificate relevant to that Part of that Annex.

(3) The manufacturer or, if the manufacturer is not established in the United Kingdom, the person placing the product on the market must, for a period ending no sooner than 10 years after the last device has been placed on the market, keep at the disposal of the Secretary of State—

- (a) the declaration of conformity;
- (b) the technical documentation referred to in Schedules 4 and 5;
- (c) the certificate referred to in sub-paragraph (2).

(5) The documentation in sub-paragraph (3) must be kept so that it is available to the Secretary of State throughout the relevant period specified in sub-paragraph (3) irrespective of the continued status (and whether the person continues trading or not) of the manufacturer or person placing the product on the market.

PART B

Product Verification

9. “Product verification” means a procedure whereby, after examination of every manufactured device, the manufacturer, by issuing a declaration of conformity in accordance with regulation 84 is deemed to ensure and declare that the devices which have

been subject to the procedure set out in Sections 14 and 15 of Annex XI of Regulation (EU) 2017/745 conform to the type described in the type-examination certificate and meet the requirements of Part VIII which apply to them.

10.—(1) The manufacturer must take all the measures necessary to ensure that the manufacturing process produces devices which conform to the type described in the type-examination certificate and to the requirements of Part VIII which apply to them.

(2) Prior to the start of manufacture, the manufacturer must prepare documents defining the manufacturing process, in particular, and where applicable, as regards sterilisation, together with all routine, pre-established procedures to be implemented to ensure homogeneous production and, where appropriate, conformity of the devices with the type described in the type-examination certificate and with the requirements of Part VIII which apply to them.

(3) In addition, for devices placed on the market in a sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer must apply the provisions of paragraph 6 and comply with the surveillance obligations.

(4) The manufacturer must undertake to institute and keep up to date a post-market surveillance plan, including a PMCF plan, and the procedures ensuring compliance with the obligations of the manufacturer resulting from the provisions on vigilance and post-market surveillance system set out in regulations 122 to 125.

(5) Upon completing the manufacture of each batch of devices that incorporate, as an integral part, a medicinal substance which, if used separately, would be considered to be a medicinal product derived from human blood or human plasma referred to in the first subparagraph of regulation 68(8), the manufacturer shall inform the notified body of the release of the batch of devices and send it the official certificate concerning the release of the batch of human blood or plasma derivative used in the device, issued by a laboratory designated for that purpose by an EU Member State in accordance with Article 114(2) of Directive 2001/83/EC, or, where applicable, a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012.

Administrative provisions

11.—(1) Subject to paragraph 12, the manufacturer or, if the manufacturer is not established in the United Kingdom, the person placing the product on the market must, for a period ending no sooner than 10 years and, in the case of implantable devices, 15 years after the last device has been placed on the market, keep at the disposal of the Secretary of State—

- (a) the EU declaration of conformity;
- (b) the documentation referred to in paragraph (2);
- (c) the verification certificate referred to in Section 15.2 of Annex XI of Regulation (EU) 2017/745;
- (d) the type-examination certificate referred to in Schedule 11.

(2) The documentation in sub-paragraph (1) must be kept so that it is available to the Secretary of State throughout the relevant period specified in sub-paragraph (1) irrespective of the continued status (and whether the person continues trading or not) of the manufacturer or person placing the product on the market.

Application to Class IIa devices

12.—(1) By virtue of the declaration of conformity the manufacturer is deemed to ensure and to declare that the Class IIa devices in question are manufactured in conformity with the technical documentation referred to in Schedules 4 and 5 meet the requirements of Part VIII which apply to them.

(2) The manufacturer must obtain a certificate issued in pursuance of Part B of Annex XI of Regulation (EU) 2017/745.

(3) The manufacturer or, if the manufacturer is not established in the United Kingdom, the person placing the product on the market must, for a period ending no sooner than 10 years after the last device has been placed on the market, keep at the disposal of the Secretary of State—

- (a) the declaration of conformity;
- (b) the technical documentation referred to Schedules 4 and 5;
- (c) the certificate referred to in sub-paragraph (2).

(4) The documentation in sub-paragraph (3) must be kept so that it is available to the Secretary of State throughout the relevant period specified in sub-paragraph (3) irrespective of the continued status (and whether the person continues trading or not) of the manufacturer or person placing the product on the market.

SCHEDULE 13

Regulation 1A

Procedure for custom-made devices

1. For custom-made devices the manufacturer or its authorised representative must draw up a statement containing all of the following information—

- (a) the name and address of the manufacturer, and of all manufacturing sites;
- (b) if applicable, the name and address of the person placing the product on the market;
- (c) data allowing identification of the device in question;
- (d) a statement that the device is intended for exclusive use by a particular patient or user, identified by name, an acronym or a numerical code;
- (e) the name of the person who made out the prescription and, where applicable, the name of the health institution concerned;
- (f) the specific characteristics of the product as indicated by the prescription;
- (g) a statement that the device in question conforms to the general safety and performance requirements set out in Schedule 3 and, where applicable, indicating which general safety and performance requirements have not been fully met, together with the grounds;
- (h) where applicable, an indication that the device contains or incorporates a medicinal substance, including a human blood or plasma derivative, or tissues or cells of human origin, or of animal origin as referred to in Regulation (EU) No 722/2012.

2. The manufacturer must undertake to keep available for the Secretary of State documentation that indicates its manufacturing site or sites and allows an understanding to be formed of the design, manufacture and performance of the device, including the expected performance, so as to allow assessment of conformity with the requirements of Part VIII.

3. The manufacturer shall take all the measures necessary to ensure that the manufacturing process produces devices which are manufactured in accordance with the documentation referred to in paragraph 2.

4. The statement referred to in paragraph 1(g) must be kept for a period of at least 10 years after the device has been placed on the market and, in the case of implantable devices, the period must be at least 15 years.

5. The statement referred to in paragraph 4 must be kept so that it is available to the Secretary of State throughout the relevant period specified in paragraph 4 irrespective of the continued status (and whether the person continues trading or not) of the manufacturer or person placing the product on the market.

6. The manufacturer must—

- (a) review and document experience gained in the post-production phase, including from PMCF as referred to in Part B of Schedule 14;
- (b) implement appropriate means to apply any necessary corrective action;
- (c) report in accordance with regulation 125 to the Secretary of State any serious incidents or field safety corrective actions or both as soon as it learns of them.

SCHEDULE 14

Regulation 1A

Clinical evaluation and post market clinical follow-up

Part A

Clinical evaluation

1. Manufacturers must plan, continuously conduct and document a clinical evaluation and must—

- (a) establish and update a clinical evaluation plan, which must include at least—
 - (i) an identification of the general safety and performance requirements that require support from relevant clinical data;
 - (ii) a specification of the intended purpose of the device;
 - (iii) a clear specification of intended target groups with clear indications and contra-indications;
 - (iv) a detailed description of intended clinical benefits to patients with relevant and specified clinical outcome parameters;
 - (v) a specification of methods to be used for examination of qualitative and quantitative aspects of clinical safety with clear reference to the determination of residual risks and side-effects;
 - (vi) an indicative list and specification of parameters to be used to determine, based on the state of the art in medicine, the acceptability of the benefit-risk ratio for the various indications and for the intended purpose or purposes of the device;
 - (vii) an indication of how benefit-risk issues relating to specific components such as use of pharmaceutical, non- viable animal or human tissues, are to be addressed;
 - (viii) a clinical development plan indicating progression from exploratory investigations, such as first-in-man studies, feasibility and pilot studies, to confirmatory investigations, such as pivotal clinical investigations, and a PMCF as referred to in Part B of this Schedule with an indication of milestones and a description of potential acceptance criteria;
- (b) identify available clinical data relevant to the device and its intended purpose and any gaps in clinical evidence through a systematic scientific literature review;
- (c) appraise all relevant clinical data by evaluating their suitability for establishing the safety and performance of the device;
- (d) generate, through properly designed clinical investigations in accordance with the clinical development plan, any new or additional clinical data necessary to address outstanding issues;
- (e) analyse all relevant clinical data in order to reach conclusions about the safety and clinical performance of the device including its clinical benefits.

2. The clinical evaluation must—

- (a) be thorough and objective, and take into account both favourable and unfavourable data;
- (b) be proportionate and appropriate (in terms of depth and extent) to the nature, classification, intended purpose and risks of the device in question, as well as to the manufacturer's claims in respect of the device.

3.—(1) A clinical evaluation may be based on clinical data relating to a device for which equivalence to the device in question can be demonstrated.

(2) The following characteristics must be taken into consideration for the demonstration of equivalence—

- (a) technical characteristics where the device—
 - (i) is of similar design;
 - (ii) is used under similar conditions of use;
 - (iii) has similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms;
 - (iv) where relevant, uses similar deployment methods;
 - (v) has similar principles of operation and critical performance requirements;
- (b) biological characteristics where the device uses the same materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables;
- (c) clinical characteristics where the device—
 - (i) is used for the same clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology;
 - (ii) has the same kind of user;
 - (iii) has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.

(3) The characteristics listed in the sub-paragraph (2) must—

- (a) be similar to the extent that there would be no clinically significant difference in the safety and clinical performance of the device;
- (b) be based on proper scientific justification;
- (c) be clearly demonstrated that manufacturers have sufficient levels of access to the data relating to devices with which they are claiming equivalence in order to justify their claims of equivalence.

(4) The results of the clinical evaluation and the clinical evidence on which it is based must be documented in a clinical evaluation report which—

- (a) must support the assessment of the conformity of the device;
- (b) must include any non-clinical data generated from non-clinical testing and other relevant documentation which must allow the manufacturer to demonstrate conformity with the general safety and performance requirements and which must be part of the technical documentation for the device in question;
- (c) must include as part of the technical documentation favourable and unfavourable data considered in the clinical evaluation.

PART B

Post –market clinical follow-up (PMCF)

4.—(1) PMCF must be addressed in the manufacturer’s post-market surveillance plan.

(2) When conducting PMCF, the manufacturer must proactively collect and evaluate clinical data from the use in or on humans of a device which bears the CE marking and is placed on the market or put into service within its intended purpose as referred to in the relevant conformity assessment procedure, with the aim of confirming the safety and performance throughout the expected lifetime of the device, of ensuring the continued acceptability of identified risks and of detecting emerging risks on the basis of factual evidence.

5.—(1) PMCF must be performed pursuant to a documented method laid down in a PMCF plan.

(2) The PMCF plan must specify the methods and procedures for proactively collecting and evaluating clinical data with the aim of—

- (a) confirming the safety and performance of the device throughout its expected lifetime;
- (b) identifying previously unknown side-effects and monitoring the identified side-effects and contraindications;
- (c) identifying and analysing emergent risks on the basis of factual evidence;
- (d) ensuring the continued acceptability of the benefit-risk ratio referred to in paragraph 1 and 9 of Schedule 3;
- (e) identifying possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose is correct.

(3) The PMCF plan must include at least—

- (a) the general methods and procedures of the PMCF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of clinical data;
- (b) the specific methods and procedures of PMCF to be applied, such as evaluation of suitable registers or PMCF studies;
- (c) a rationale for the appropriateness of the methods and procedures referred to in paragraphs (3)(a) and (b);
- (d) a reference to the relevant parts of the clinical evaluation report referred to in paragraph 3(4) and to the risk management referred to in paragraph 3 of Schedule 3;
- (e) the specific objectives to be addressed by the PMCF;
- (f) an evaluation of the clinical data relating to equivalent or similar devices;
- (g) reference to any relevant standards when used by the manufacturer, and relevant guidance on PMCF;
- (h) a detailed and adequately justified time schedule for PMCF activities (e.g. analysis of PMCF data and reporting) to be undertaken by the manufacturer.

6. The manufacturer must analyse the findings of the PMCF and document the results in a PMCF evaluation report that must be part of the clinical evaluation report and the technical documentation.

7.—(1) The conclusions of the PMCF evaluation report must be taken into account —

- (i) for the clinical evaluation referred to in regulation 102 and Part A of this Schedule;
- (ii) in the risk management referred to in paragraph 3 of Schedule 3;

(2) If, through the PMCF, the need for preventive or corrective measures has been identified, the manufacturer must implement them.

SCHEDULE 15

Regulation 1A

Clinical investigations

Chapter I

General requirements

Ethical principles

1. Each step in a clinical investigation, from the initial consideration of the need for and justification of the study, to the publication of the results, must be carried out in accordance with recognised ethical principles.

Methods

2.—(1) Clinical investigations must—

- (a) be performed on the basis of an appropriate plan of investigation reflecting the latest scientific and technical knowledge and defined in such a way as to confirm or refute the manufacturer's claims regarding the safety, performance and aspects relating to benefit-risk of devices as referred to in regulation 103(1);
- (b) include an adequate number of observations to guarantee the scientific validity of the conclusions;
- (c) be presented as described in paragraph 3(2)(i) of Chapter II of this Schedule with the rationale for the design and chosen statistical methodology.

(2) The procedures used to perform the clinical investigation must be appropriate to the device under investigation.

(3) The research methodologies used to perform the clinical investigation must be appropriate to the device under investigation.

(4) Clinical investigations must—

- (a) be performed in accordance with the clinical investigation plan by a sufficient number of intended users and in a clinical environment that is representative of the intended normal conditions of use of the device in the target patient population;
- (b) be in line with the clinical evaluation plan as referred to in Part A of Schedule 14.

(5) All the appropriate technical and functional features of the device must be appropriately addressed in the investigational design, in particular—

- (a) those features involving safety and performance, and their expected clinical outcomes;
- (b) a list of the technical and functional features of the device and the related expected clinical outcomes must be provided.

(6) The endpoints of the clinical investigation—

- (a) must address the intended purpose, clinical benefits, performance and safety of the device;
- (b) be determined and assessed using scientifically valid methodologies;
- (c) must be appropriate to the device and clinically relevant.

(7) The following apply in relation to those involved in the clinical investigation—

- (a) investigators must have access to the technical and clinical data regarding the device;

- (b) personnel involved in the conduct of an investigation must be adequately instructed and trained in the proper use of the investigational device;
- (c) this training must be verified and where necessary arranged by the sponsor and documented appropriately.

(8) The clinical investigation report, signed by the investigator, must contain a critical evaluation of all the data collected during the clinical investigation, and must include any negative findings.

Chapter II

Documentation regarding the application for clinical investigation

For investigational devices covered by regulation 103, the sponsor must draw up and submit the application in accordance with regulation 110 accompanied by the following documents—

Application form

1. An application form, duly filled in, containing the following information—
 - (a) name, address and contact details of the sponsor and, the name, address and contact details of its contact person or legal representative in accordance with regulation 103;
 - (b) if different from those in paragraph (a), name, address and contact details of the manufacturer of the device intended for clinical investigation and, if applicable, of its authorised representative;
 - (c) title of the clinical investigation;
 - (d) status of the clinical investigation application (that is, whether it is the first submission, resubmission, significant amendment);
 - (e) details or reference to the clinical evaluation plan;
 - (f) if the application is a resubmission with regard to a device for which an application has been already submitted—
 - (i) the date and reference number of the earlier application or in the case of significant amendment, reference to the original application;
 - (ii) information from the sponsor regarding all of the changes from the previous application together with a rationale for those changes, in particular, whether any changes have been made to address conclusions of previous reviews;
 - (g) if the application is submitted in parallel with an application for a clinical trial on a medicinal product for human use, reference to the official registration number of the clinical trial;
 - (h) identification of the countries in which the clinical investigation is to be conducted as part of a multicentre or multinational study at the time of application;
 - (i) a brief description of the investigational device, its classification and other information necessary for the identification of the device and device type;
 - (j) information as to whether the device incorporates a medicinal substance, including a human blood or plasma derivative or whether it is manufactured utilising non-viable tissues or cells of human or animal origin, or their derivatives;
 - (k) summary of the clinical investigation plan including the objective or objectives of the clinical investigation, the number and gender of subjects, criteria for subject selection, whether there are subjects under 18 years of age, design of the investigation such as controlled or randomised studies, planned dates of commencement and of completion of the clinical investigation;

- (l) if applicable, information regarding a comparator device, its classification and other information necessary for the identification of the comparator device;
- (m) evidence from the sponsor that the clinical investigator and the investigational site are capable of conducting the clinical investigation in accordance with the clinical investigation plan;
- (n) details of the anticipated start date and duration of the investigation;
- (o) details to identify the notified body, if already involved at the stage of application for a clinical investigation;
- (p) confirmation that the sponsor is aware that the Secretary of State may contact the ethics committee that is assessing or has assessed the application;
- (q) the statement referred to in paragraph 4(1).

Investigator's brochure

2.—(1) An investigator's brochure (IB) must contain the clinical and non-clinical information on the investigational device that is relevant for the investigation and available at the time of application.

(2) Any updates to the IB or other relevant information that is newly available must be brought to the attention of the investigators in a timely manner.

(3) The IB must be clearly identified and contain in particular the following information—

- (a) identification and description of the device, including information on the intended purpose, the risk classification and applicable classification rule pursuant to Schedule 9, design and manufacturing of the device and reference to previous and similar generations of the device;
- (b) the manufacturer's—
 - (i) instructions for installation, maintenance, maintaining hygiene standards and for use, including storage and handling requirements, as well as, to the extent that such information is available, information to be placed on the label;
 - (ii) instructions for use to be provided with the device when placed on the market; and
 - (iii) information relating to any relevant training required.
- (c) pre-clinical evaluation based on relevant pre-clinical testing and experimental data, in particular regarding in-design calculations, in vitro tests, ex vivo tests, animal tests, mechanical or electrical tests, reliability tests, sterilisation validation, software verification and validation, performance tests, evaluation of biocompatibility and biological safety, as applicable.
- (d) existing clinical data, in particular—
 - (i) from relevant scientific literature available relating to the safety, performance, clinical benefits to patients, design characteristics and intended purpose of the device or of equivalent or similar devices;
 - (ii) other relevant clinical data available relating to the safety, performance, clinical benefits to patients, design characteristics and intended purpose of equivalent or similar devices of the same manufacturer, including length of time on the market and a review of performance, clinical benefit and safety-related issues and any corrective actions taken;
- (e) a summary of the benefit-risk analysis and the risk management, including information regarding known or foreseeable risks, any undesirable effects, contraindications and warnings;
- (f) in the case of devices that incorporate a medicinal substance, including a human blood or plasma derivative or devices manufactured utilising non-viable tissues or cells of human or animal origin, or their derivatives, detailed information on the

medicinal substance or on the tissues, cells or their derivatives, and on the compliance with the relevant general safety and performance requirements and the specific risk management in relation to the substance or tissues, cells or their derivatives, as well as evidence for the added value of incorporation of such constituents in relation to the clinical benefit or safety of the device;

- (g) a list detailing the fulfilment of the relevant general safety and performance requirements set out in Schedule 3, including the standards applied, in full or in part, as well as a description of the solutions for fulfilling the relevant general safety and performance requirements, in so far as those standards have not or have only been partly fulfilled or are lacking;
- (h) a detailed description of the clinical procedures and diagnostic tests used in the course of the clinical investigation and in particular information on any deviation from normal clinical practice.

Clinical investigation plan

3.—(1) The clinical investigation plan (CIP) must—

- (a) set out the rationale, objectives, design methodology, monitoring, conduct, record-keeping and the method of analysis for the clinical investigation;
- (b) contain in particular the information as laid down in this Schedule and if part of this information is submitted in a separate document, it must be referenced in the CIP.

General information

(2) The general information to be provided is as follows—

- (a) identification of the sponsor—
 - (i) name, address and contact details of the sponsor;
 - (ii) where applicable, the name, address and contact details of the sponsor's contact person or legal representative in accordance with regulation 103(3);
- (b) information on the principal investigator at each investigational site, the coordinating investigator for the investigation, the address details for each investigational site, the emergency contact details for the principal investigator at each site and the roles, responsibilities and qualifications of the various kinds of investigators;
- (c) a brief description of how the clinical investigation is financed and a brief description of the agreement between the sponsor and the site;
- (d) an overall synopsis in English of the clinical investigation;
- (e) an identification and description of the device, including its intended purpose, its manufacturer, its traceability, the target population, materials coming into contact with the human body, the medical or surgical procedures involved in its use and the necessary training and experience for its use, background literature review, the current state of the art in clinical care in the relevant field of application and the proposed benefits of the new device;
- (f) the risks and clinical benefits of the device to be examined, with justification of the corresponding expected clinical outcomes in the clinical investigation plan;
- (g) a description of the relevance of the clinical investigation in the context of the state of the art of clinical practice;
- (h) the objectives and hypotheses of the clinical investigation;
- (i) design of the clinical investigation with evidence of its scientific robustness and validity and including—
 - (i) general information such as type of investigation with rationale for choosing it, for its endpoints and for its variables as set out in the clinical evaluation plan;

- (ii) information on the investigational device, on any comparator and on any other device or medication to be used in the clinical investigation;
- (iii) information on subjects, selection criteria, size of investigation population, representativeness of investigation population in relation to target population and, if applicable, information on vulnerable subjects involved such as children, pregnant women, immuno-compromised or, elderly subjects;
- (iv) details of measures to be taken to minimise bias, such as randomisation, and management of potential confounding factors;
- (v) description of the clinical procedures and diagnostic methods relating to the clinical investigation and in particular highlighting any deviation from normal clinical practice;
- (j) the monitoring plan;
- (k) statistical considerations, with justification, including a power calculation for the sample size, if applicable;
- (l) data management;
- (m) the information about any amendments to the CIP;
- (n) the policy regarding follow-up and management of any deviations from the CIP at the investigational site and clear prohibition of use of waivers from the CIP;
- (o) accountability regarding the device, in particular control of access to the device, follow-up in relation to the device used in the clinical investigation and the return of unused, expired or malfunctioning devices;
- (p) a statement of compliance with the recognised ethical principles for medical research involving humans, and the principles of good clinical practice in the field of clinical investigations of devices, as well as with the applicable regulatory requirements;
- (q) a description of the informed consent process;
- (r) safety reporting, including definitions of adverse events and serious adverse events, device deficiencies, procedures and timelines for reporting;
- (s) criteria and procedures for follow-up of subjects following the end, temporary halt or early termination of an investigation, for follow-up of subjects who have withdrawn their consent and procedures for subjects lost to follow-up and such procedures must, for implantable devices, cover as a minimum traceability;
- (t) a description of the arrangements for taking care of the subjects after their participation in the clinical investigation has ended, where such additional care is necessary because of the subjects' participation in the clinical investigation and where it differs from that normally expected for the medical condition in question;
- (u) the policy as regards the establishment of the clinical investigation report and publication of results in accordance with the legal requirements and the ethical principles referred to in paragraph 1 of Chapter I;
- (v) a list of the technical and functional features of the device, with specific mention of those covered by the investigation;
- (w) bibliography.

Other information

The other information required is as follows.

4.—(1) A signed statement by the person responsible for the manufacture of the investigational device that the device in question conforms to the general safety and performance requirements apart from the aspects covered by the clinical investigation and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the subject.

(2) Where available a copy of the opinion or opinions of the ethics committee or committees concerned.

(3) Proof of insurance cover or indemnification of subjects in case of injury, pursuant to regulation 109.

(4) Documents to be used to obtain informed consent, including the patient information sheet and the informed consent document.

(5) Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data, in particular—

(a) organisational and technical arrangements that will be implemented to avoid unauthorised access, disclosure, dissemination, alteration or loss of information and personal data processed;

(b) a description of measures that will be implemented to ensure confidentiality of records and personal data of subjects;

(c) a description of measures that will be implemented in case of a data security breach in order to mitigate the possible adverse effects.

(6) Full details of the available technical documentation, for example detailed risk analysis and management documentation or specific test reports, must upon request, be submitted to the Secretary of State.

Chapter III

Other obligations of the sponsor

5. The sponsor must undertake to keep available for the Secretary of State any documentation necessary to provide evidence for the documentation referred to in Chapter II of this Annex, but if the sponsor is not the person responsible for the manufacture of the investigational device, that obligation may be fulfilled by that person on behalf of the sponsor.

6. The Sponsor must have an agreement in place to ensure that any serious adverse events or any other event as referred to in regulation 119(2) are reported by the investigator or investigators to the sponsor in a timely manner.

7.—(1) The documentation mentioned in this Schedule must be kept for a period of at least 10 years after the clinical investigation with the device in question has ended, or, in the event that the device is subsequently placed on the market, at least 10 years after the last device has been placed on the market and in the case of implantable devices, the period shall be at least 15 years.

(2) The documentation in sub-paragraph (1) must be kept at the disposal of the Secretary of State for the period referred to in sub-paragraph (1) in case the sponsor, or its contact person or legal representative as referred to in regulation 103(2), irrespective of the status (and whether the person continues trading or not) of that person.

8. The Sponsor must appoint a monitor that is independent from the investigational site to ensure that the investigation is conducted in accordance with the CIP, the principles of good clinical practice and Part VIII.

9. The Sponsor must complete the follow-up of investigation subjects.

10. The Sponsor must provide evidence that the investigation is being conducted in line with good clinical practice, for instance through internal or external inspection.

11. The Sponsor must prepare a clinical investigation report which includes at least the following—

(a) cover or introductory page indicating the title of the investigation, the investigational device, the single identification number, the CIP number and the

details with signatures of the coordinating investigators and the principal investigators from each investigational site;

- (b) details of the author and date of the report;
- (c) a summary of the investigation covering the title, purpose of the investigation, description of the investigation, investigational design and methods used, the results of the investigation and conclusion of the investigation;
- (d) the completion date of the investigation, and in particular details of early termination, temporary halts or suspensions of investigations;
- (e) investigational device description, in particular clearly defined intended purpose;
- (f) a summary of the clinical investigation plan covering objectives, design, ethical aspects, monitoring and quality measures, selection criteria, target patient populations, sample size, treatment schedules, follow-up duration, concomitant treatments, statistical plan, including hypothesis, sample size calculation and analysis methods, as well as a justification;
- (g) results of the clinical investigation covering, with rationale and justification, subject demographics, analysis of results related to chosen endpoints, details of subgroup analysis, as well as compliance with the CIP, and covering follow-up of missing data and of patients withdrawing from the clinical investigation, or lost to follow-up;
- (h) summary of serious adverse events, adverse device effects, device deficiencies and any relevant corrective actions;
- (i) discussion and overall conclusions covering safety and performance results, assessment of risks and clinical benefits, discussion of clinical relevance in accordance with clinical state of the art, any specific precautions for specific patient populations, implications for the investigational device, limitations of the investigation.

SCHEDULE 16

Regulation 1A

List of groups of products without an intended medical purpose referred to in regulation 68(2)(b)

- 1.** Contact lenses or other items intended to be introduced into or onto the eye.
- 2.** Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.
- 3.** Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.
- 4.** Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.
- 5.** High intensity electromagnetic radiation (for example infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.
- 6.** Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

General safety and performance requirements- in vitro diagnostic medical devices

PART 1

General requirements for in vitro diagnostic medical devices

1. Devices must—

- (a) achieve the performance intended by their manufacturer;
- (b) be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose;
- (c) be safe and effective;
- (d) not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.

2. The requirement in this Schedule to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.

3.—(1) Manufacturers must establish, implement, document and maintain a risk management system.

(2) Risk management must be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating and in carrying out risk management manufacturers must—

- (a) establish and document a risk management plan for each device;
- (b) identify and analyse the known and foreseeable hazards associated with each device;
- (c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;
- (d) eliminate or control the risks referred to in sub-paragraph (c) in accordance with the requirements of paragraph 4;
- (e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, the benefit-risk ratio and risk acceptability;
- (f) based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of paragraph 4.

4.—(1) Risk control measures adopted by manufacturers for the design and manufacture of the devices must conform to safety principles, taking account of the generally acknowledged state of the art.

(2) To reduce risks, the manufacturers must manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable.

(3) In selecting the most appropriate solutions, manufacturers must, in the following order of priority—

- (a) eliminate or reduce risks as far as possible through safe design and manufacture;
- (b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated;

- (c) provide information for safety (warnings, precautions, contra-indications) and, where appropriate, training to users;
- (d) inform users of any residual risks.

5. In eliminating or reducing risks related to use error, the manufacturer must—

- (a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety);
- (b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

6. The characteristics and performance of a device must not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.

7. Devices must be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.

8. All known and foreseeable risks, and any undesirable effects must be minimised and be acceptable when weighed against the evaluated potential benefits to the patients or the user arising from the intended performance of the device during normal conditions of use.

PART 2

Requirements regarding design and manufacture of in vitro diagnostic medical devices

Performance characteristics

9.—(1) Devices must—

- (a) be designed and manufactured in such a way that they are suitable for one or more of the purposes listed in the definition of “in vitro diagnostic medical device” in regulation 137, as specified by the manufacturer, and suitable with regard to the performance they are intended to achieve, taking account of the generally acknowledged state of the art;
- (b) achieve the performances, as stated by the manufacturer and in particular, where applicable—
 - (i) the analytical performance, such as, analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and quantitation, measuring range, linearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known relevant endogenous and exogenous interference, cross- reactions;
 - (ii) the clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations.

(2) The performance characteristics of the device must be maintained during the lifetime of the device as indicated by the manufacturer.

(3) Where the performance of devices depends on the use of calibrators or control materials—

- (a) the metrological traceability of values assigned to calibrators or control materials must be assured through suitable reference measurement procedures or suitable reference materials of a higher metrological order;
 - (b) where available, metrological traceability of values assigned to calibrators and control materials must be assured to certified reference materials or reference measurement procedures.
- (4) The characteristics and performances of the device must be specifically checked in the event that they may be affected when the device is used for the intended use under normal conditions—
- (a) for devices for self-testing, performances obtained by laypersons;
 - (b) for devices for near-patient testing, performances obtained in relevant environments (for example, patient home, emergency units, ambulances).

Chemical physical and biological properties

10.—(1) Devices must be designed and manufactured in such a way as to ensure that the characteristics and performance requirements referred to in Part 1 are fulfilled and, in this regard, particular attention must be paid to the possibility of impairment of analytical performance due to physical or chemical incompatibility between the materials used and the specimens, analyte or marker to be detected (such as biological tissues, cells, body fluids and micro-organisms), taking account of the intended purpose of the device.

(2) As regards substances or particles that may be released from the device—

- (a) devices must be designed and manufactured in such a way as to reduce to a level as low as reasonably practicable the risks posed by these substances or particles, including wear debris, degradation products and processing residues;
- (b) special attention must be given to substances—
 - (i) which are carcinogenic, mutagenic or toxic to reproduction ('CMR') and on the UK mandatory classification and labelling list established and maintained in accordance with Article 38A of Regulation (EC) No 1272/2008 of the European Parliament and of the Council; and
 - (ii) with endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council.

(3) Devices must be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress of substances into the device, taking into account the device and the nature of the environment in which it is intended to be used.

Infection and microbial contamination

11.—(1) Devices and their manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or, where applicable, other persons and the design must—

- (a) allow easy and safe handling;
- (b) reduce, as far as possible, any microbial leakage from the device or microbial exposure during use;
- (c) where necessary, prevent microbial contamination of the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen.

(2) Devices labelled either as sterile or as having a specific microbial state must be designed, manufactured and packaged to ensure that their sterile condition or microbial state is maintained under the transport and storage conditions specified by the manufacturer until that packaging is opened at the point of use, unless the packaging which maintains their sterile condition or microbial state is damaged.

(3) Devices labelled as sterile must be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.

(4) Devices intended to be sterilised must be manufactured and packaged in appropriate and controlled conditions and facilities.

(5) Packaging systems for non-sterile devices must—

- (a) maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination;
- (b) be suitable taking account of the method of sterilisation indicated by the manufacturer.

(6) The labelling of the device must distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition additional to the symbol used to indicate that devices are sterile.

Devices incorporating materials of a biological origin

12. Where devices include tissues, cells and substances of animal, human or microbial origin—

- (a) the selection of sources, the processing, preservation, testing and handling of tissues, cells and substances of such origin and control procedures must be carried out so as to provide safety for users or other persons;
- (b) safety with regard to microbial and other transmissible agents must be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process but this requirement would not apply to devices if the activity of the microbial and other transmissible agent are integral to the intended purpose of the device or when such elimination or inactivation process would compromise the performance of the device.

Construction of devices and interaction with the environment

13.—(1) If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, must be safe and must not impair the specified performances of the devices and any restrictions on use applying to such combinations must be indicated on the label and in the instructions for use.

(2) Devices must be designed and manufactured in such a way as to remove or reduce as far as possible—

- (a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;
- (b) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;
- (c) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;
- (d) the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;
- (e) the risks of accidental ingress of substances into the device;
- (f) the risk of incorrect identification of specimens and the risk of erroneous results due to, for example, confusing colour or numeric or character codings on specimen receptacles, removable parts or accessories used with devices in order to perform the test or assay as intended;
- (g) the risks of any foreseeable interference with other devices.

(3) Devices must be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition and, in this regard, particular attention must be paid to devices the intended use of which includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.

(4) Devices must be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively.

(5) Devices that are intended to be operated together with other devices or products must be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.

(6) Devices must be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of related waste substances by users, or other persons and, in doing so manufacturers must—

- (a) identify and test procedures and measures as a result of which their devices can be safely disposed after use;
- (b) ensure that such test procedures are described in the instructions for use.

(7) The measuring, monitoring or display scale (including colour change and other visual indicators) must be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the devices are intended to be used.

Devices with a measuring function

14.—(1) Devices having a primary analytical measuring function must be designed and manufactured in such a way as to provide appropriate analytical performance in accordance with paragraph 9(1), taking into account the intended purpose of the device.

(2) The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of the Units of Measurement Regulations 1986.

Protection against radiation

15.—(1) Devices must be designed, manufactured and packaged in such a way that exposure of users or other persons to radiation (intended, unintended, stray or scattered) is reduced as far as possible and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for diagnostic purposes.

(2) When devices are intended to emit hazardous, or potentially hazardous, ionizing or non-ionizing radiation, they must as far as possible be—

- (a) designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled or adjusted;
- (b) fitted with visual displays or audible warnings of such emissions.

(3) The operating instructions for devices emitting hazardous or potentially hazardous radiation must contain—

- (a) detailed information as to the nature of the emitted radiation, the means of protecting the user, and on ways of avoiding misuse and of reducing the risks inherent to installation as far as possible and appropriate;
- (b) information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure.

Electronic programmable systems- devices that incorporate programmable systems and software that are devices in themselves

16.—(1) Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, must—

- (a) be designed to ensure repeatability, reliability and performance in line with their intended use;

- (b) in the event of a single fault condition, appropriate means must be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.

(2) For devices that incorporate software or for software that is a device in itself, the software must be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.

(3) Software referred to in this paragraph that is intended to be used in combination with mobile computing platforms must be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards level of light or noise).

(4) Manufacturers must set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

Devices connected to or equipped with an energy source

17.—(1) For devices connected to or equipped with an energy source, in the event of a single fault condition, appropriate means must be adopted to eliminate or reduce as far as possible consequent risks.

(2) Devices where the safety of the patient depends on an internal power supply must be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical and if necessary, such warning or indication shall be given prior to the power supply becoming critical.

(3) Devices must be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of the device in question or other devices or equipment in the intended environment.

(4) Devices must be designed and manufactured in such a way as to provide a level of intrinsic immunity to electromagnetic interference such that is adequate to enable them to operate as intended.

(5) Devices must be designed and manufactured in such a way as to avoid as far as possible the risk of accidental electric shocks to the user, or other person both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.

Protection against mechanical and thermal risks

18.—(1) Devices must be designed and manufactured in such a way as to protect users and other persons against mechanical risks.

(2) Devices must—

- (a) be sufficiently stable under the foreseen operating conditions;
- (b) be suitable to withstand stresses inherent to the foreseen working environment, and to retain this resistance during the expected lifetime of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer.

(3) Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means must be incorporated.

(4) Any guards or other means included with the device to provide protection, in particular against moving parts, must be secure and must not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.

(5) Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of

technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.

(6) Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.

(7) Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle, must be designed and constructed in such a way as to minimise all possible risks.

(8) Errors likely to be made when fitting or refitting certain parts which could be a source of risk must be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves or their housings.

(9) Information must be given on moving parts or their housings where the direction of movement needs to be known in order to avoid a risk.

(10) Accessible parts of devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal conditions of use.

Protection against the risks posed by devices intended for self-testing or near-patient testing

19.—(1) Devices intended for self-testing or near-patient testing—

- (a) must be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to the intended user and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment;
- (b) the information and instructions provided by the manufacturer must be easy for the intended user to understand and apply in order to correctly interpret the result provided by the device and to avoid misleading information;
- (c) in the case of near-patient testing, the information and the instructions provided by the manufacturer must make clear the level of training, qualifications or experience required by the user.

(2) Devices intended for self-testing or near-patient testing must be designed and manufactured in such a way as to—

- (a) ensure that the device can be used safely and accurately by the intended user at all stages of the procedure if necessary after appropriate training or information;
- (b) reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen, and also in the interpretation of the results.

(3) Devices intended for self-testing and near-patient testing must, where feasible, include a procedure by which the intended user—

- (a) can verify that, at the time of use, the device will perform as intended by the manufacturer;
- (b) be warned if the device has failed to provide a valid result.

PART 3

Requirements regarding information supplied with the device

Labels and instructions for use

General requirements regarding the information supplied by the manufacturer

20.—(1) Each device must be accompanied—

- (a) by the information needed to identify the device and its manufacturer;

- (b) by any safety and performance information relevant to the user or any other person, as appropriate.

(2) The information in paragraph (1) may appear on the device itself, on the packaging or in the instructions for use, and must, if the manufacturer has a website, be made available and kept up to date on the website, taking into account the following—

- (a) the medium, format, content, legibility, and location of the label and instructions for use must be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user and, in particular, instructions for use must be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams;
- (b) the information required on the label must be provided on the device itself or if this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit and, if individual full labelling of each unit is not practicable, the information must be set out on the packaging of multiple devices;
- (c) labels must be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification or bar codes;
- (d) instructions for use must be provided together with devices but, in duly justified and exceptional cases, instructions for use are not required, or may be abbreviated, if the device can be used safely and as intended by the manufacturer without any such instructions for use;
- (e) where multiple devices, with the exception of devices intended for self-testing or near-patient testing, are supplied to a single user or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided free of charge;
- (f) when the device is intended for professional use only, instructions for use may be provided to the user in non-paper format (e.g. electronic), except when the device is intended for near-patient testing;
- (g) residual risks which are required to be communicated to the user or other person shall be included as limitations, contra-indications, precautions or warnings in the information supplied by the manufacturer;
- (h) where appropriate, the information supplied by the manufacturer—
 - (i) must take the form of internationally recognised symbols, taking into account the intended users;
 - (ii) must conform, in terms of any symbols or identification colour used, to the designated standards or CS;
 - (iii) in areas for which no designated standards or CS exist, the symbols and colours must be described in the documentation supplied with the device;
- (i) in the case of devices containing a substance or a mixture which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present—
 - (i) relevant hazard pictograms and labelling requirements of Regulation (EC) No 1272/2008 apply; or
 - (ii) where there is insufficient space to put all the information on the device itself or on its label, the relevant hazard pictograms must be put on the label and the other information required by Regulation (EC) No 1272/2008 must be given in the instructions for use;
- (j) the provisions of Regulation (EC) No 1907/2006 on the safety data sheet must apply, unless all relevant information, as appropriate, is already made available in the instructions for use.

Information on the label

(3) The label must bear all of the following particulars—

- (a) the name or trade name of the device;
 - (b) the details strictly necessary for a user to identify the device and, where it is not obvious for the user, the intended purpose of the device;
 - (c) the name, registered trade name or registered trade mark of the manufacturer and the address of its registered place of business;
 - (d) if the manufacturer has its registered place of business outside the United Kingdom, the name and address of the person placing the device on the market;
 - (e) an indication that the device is an in vitro diagnostic medical device, or if the device is a 'device for performance study', an indication of that fact;
 - (f) the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate;
 - (g) the UDI carrier as referred to in regulation 157 and Part C of Schedule 22;
 - (h) an unambiguous indication of the time limit for using the device safely, without degradation of performance, expressed at least in terms of year and month and, where relevant, the day, in that order;
 - (i) where there is no indication of the date until when it may be used safely, the date of manufacture and this date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable;
 - (j) where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of thereof, or other terms which accurately reflect the contents of the package;
 - (k) an indication of any special storage or handling condition that applies;
 - (l) where appropriate, an indication of the sterile state of the device and the sterilisation method, or a statement indicating any special microbial state or state of cleanliness;
 - (m) warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device or to any other person (this information may be kept to a minimum in which case more detailed information must appear in the instructions for use, taking into account the intended users);
 - (n) if the instructions for use are not provided in paper form in accordance with paragraph 20(2)(f), a reference to their accessibility (or availability), and where applicable the website address where they can be consulted;
 - (o) where applicable, any particular operating instructions;
 - (p) if the device is intended for single use, an indication of that fact;
 - (q) if the device is intended for self-testing or near-patient testing, an indication of that fact;
 - (r) where rapid assays are not intended for self-testing or near-patient testing, the explicit exclusion thereof;
- (4) The following additional labelling requirements apply to these specific devices—
- (a) for device kits which include individual reagents and articles that are made available as separate devices, the labelling requirements contained in subparagraph (3) and requirements of Part IX apply to each device;
 - (b) devices and separate components must be identified, where applicable in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components and, as far as practicable and appropriate, the information must be set out on the device itself and, where appropriate, on the sales packaging;
 - (c) the label for devices for self-testing must bear the following particulars—
 - (i) the type of specimens required to perform the test (for example blood, urine or saliva);

- (ii) the need for additional materials for the test to function properly;
- (iii) contact details for further advice and assistance;
- (d) the name of devices for self-testing must not reflect an intended purpose other than that specified by the manufacturer.

Information on the packaging which maintains the sterile condition of a device ('sterile packaging')

- (5) The following particulars must appear on the sterile packaging—
- (a) an indication permitting the sterile packaging to be recognised as such;
 - (b) a declaration that the device is in a sterile condition;
 - (c) the method of sterilisation;
 - (d) the name and address of the manufacturer;
 - (e) description of the device;
 - (f) the month and year of manufacture;
 - (g) an unambiguous indication of the time limit for using the device safely, expressed at least in terms of year and month and, where relevant, the day, in that order.

Information in the instructions for use

- (6) The instructions for use must contain all of the following particulars—
- (a) the name or trade name of the device;
 - (b) the details strictly necessary for the user to uniquely identify the device;
 - (c) the device's intended purpose in terms of—
 - (i) what is detected or measured;
 - (ii) its function (for example screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic);
 - (iii) the specific information that is intended to be provided in the context of—
 - (aa) a physiological or pathological state;
 - (bb) congenital physical or mental impairments;
 - (cc) the predisposition to a medical condition or a disease;
 - (dd) the determination of the safety and compatibility with potential recipients;
 - (ee) the prediction of treatment response or reactions;
 - (ff) the definition or monitoring of therapeutic measures;
 - (iv) whether it is automated or not;
 - (v) whether it is qualitative, semi-quantitative or quantitative;
 - (vi) the type of specimens required;
 - (vii) where applicable, the testing population;
 - (viii) for companion diagnostics, the International Non-proprietary Name (INN) of the associated medicinal product for which it is a companion test;
 - (d) an indication that the device is an in vitro diagnostic medical device, or, if the device is a 'device for performance study', an indication of that fact;
 - (e) the intended user, as appropriate (for example self-testing, near patient and laboratory professional use, healthcare professionals);
 - (f) the test principle;
 - (g) a description of the calibrators and controls and any limitation upon their use (for example suitable for a dedicated instrument only);
 - (h) a description of the reagents and any limitation upon their use (for example suitable for a dedicated instrument only) and the composition of the reagent product by nature and amount or concentration of the active ingredient of the

- reagent or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;
- (i) a list of materials provided and a list of special materials required but not provided;
 - (j) for devices intended for use in combination with or installed with or connected to other devices or general purpose equipment—
 - (i) information to identify such devices or equipment, in order to obtain a validated and safe combination, including key performance characteristics;
 - (ii) information on any known restrictions to combinations of devices and equipment;
 - (k) an indication of any special storage (for example temperature, light, humidity, etc.) or handling conditions which apply;
 - (l) in-use stability which may include the storage conditions, and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant;
 - (m) if the device is supplied as sterile, an indication of its sterile state, the sterilisation method and instructions in the event of the sterile packaging being damaged before use;
 - (n) information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device, that information must, where appropriate, cover—
 - (i) warnings, precautions or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance;
 - (ii) warnings, precautions or measures to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature,
 - (iii) warnings, precautions or measures to be taken as regards the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or other procedures such as electromagnetic interference emitted by the device affecting other equipment;
 - (iv) precautions related to materials incorporated into the device that contain or consist of CMR substances, or endocrine disrupting substances or that could result in sensitisation or an allergic reaction by the patient or user;
 - (v) if the device is intended for single use, an indication of that fact;
 - (vi) if the device is reusable—
 - (aa) information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging and, where appropriate, the validated method of re-sterilisation,
 - (bb) information on when the device should no longer be used such as signs of material degradation or the maximum number of allowable reuses;
 - (o) any warnings or precautions related to potentially infectious material that is included in the device;
 - (p) where relevant, requirements for special facilities, such as a clean room environment, or special training, such as on radiation safety, or particular qualifications of the intended user;
 - (q) conditions for collection, handling, and preparation of the specimen;

- (r) details of any preparatory treatment or handling of the device before it is ready for use, such as sterilisation, final assembly, calibration, etc., for the device to be used as intended by the manufacturer;
- (s) the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant—
 - (i) details of the nature, and frequency, of preventive and regular maintenance, including cleaning and disinfection;
 - (ii) identification of any consumable components and how to replace them;
 - (iii) information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime;
 - (iv) methods for mitigating the risks encountered by persons involved in installing, calibrating or servicing devices;
- (t) where applicable, recommendations for quality control procedures;
- (u) the metrological traceability of values assigned to calibrators and control materials, including identification of applied reference materials or reference measurement procedures of higher order and information regarding maximum (self-allowed) batch to batch variation provided with relevant figures and units of measure;
- (v) assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing is to be considered;
- (w) where applicable, the instructions for use shall be accompanied by information regarding batch to batch variation provided with relevant figures and units of measure;
- (x) analytical performance characteristics, such as analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and measurement range, (information needed for the control of known relevant interferences, cross-reactions and limitations of the method), measuring range, linearity and information about the use of available reference measurement procedures and materials by the user;
- (y) clinical performance characteristics as defined in paragraph 9(1) of this Schedule;
- (z) the mathematical approach upon which the calculation of the analytical result is made;
- (aa) where relevant, clinical performance characteristics, such as threshold value, diagnostic sensitivity and diagnostic specificity, positive and negative predictive value;
- (bb) where relevant, reference intervals in normal and affected populations;
- (cc) information on interfering substances or limitations (for example visual evidence of hyperlipidaemia or haemolysis, age of specimen) that may affect the performance of the device;
- (dd) warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories, and the consumables used with it, if any which, where appropriate, must cover—
 - (i) infection or microbial hazards, such as consumables contaminated with potentially infectious substances of human origin;
 - (ii) environmental hazards such as batteries or materials that emit potentially hazardous levels of radiation);
 - (iii) physical hazards such as explosion;
- (ee) the name, registered trade name or registered trade mark of the manufacturer and the address of their registered place of business at which they can be contacted and

their location be established, together with a telephone number or fax number or website address to obtain technical assistance;

(ff) date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use, with a clear indication of the introduced modifications;

(gg) a notice to the user that any serious incident that has occurred in relation to the device must be reported to the manufacturer and to the Secretary of State;

(7) The following additional requirements relating to the instructions for use apply to these specific devices—

(a) for device kits which include individual reagents and articles that may be made available as separate devices, each of these devices must comply with the instructions for use requirements contained in this sub-paragraph (6) and with the requirements of Part IX;

(b) for devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

(c) the instructions for use for devices intended for self-testing must comply with all of the following principles—

(i) details of the test procedure shall be given, including any reagent preparation, specimen collection or preparation and information on how to run the test and interpret the results;

(ii) specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the results produced by the device;

(iii) the device's intended purpose must provide sufficient information to enable the user to understand the medical context and to allow the intended user to make a correct interpretation of the results;

(iv) the results must be expressed and presented in a way that is readily understood by the intended user;

(v) information—

(aa) must be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result), on the test limitations and on the possibility of false positive or false negative result;

(bb) must also be provided as to any factors that can affect the test result such as age, gender, menstruation, infection, exercise, fasting, diet or medication;

(vi) the information provided must include a statement clearly directing that the user should not take any decision of medical relevance without first consulting the appropriate healthcare professional, information on disease effects and prevalence, and, where available, information on where a user can obtain further advice such as helplines, websites;

(d) for devices intended for self-testing used for the monitoring of a previously diagnosed existing disease or condition, the information must specify that the patient should only adapt the treatment if he has received the appropriate training to do so.

Technical documentation- in vitro diagnostic medical devices

1. The technical documentation and, if applicable, the summary thereof to be drawn up by the manufacturer must be presented in a clear, organised, readily searchable and unambiguous manner and must include in particular the elements listed in this Schedule.

Device description and specification, including variants and accessories

Device description and specification

- 2.—(1) The description and specification of the device must contain the following—
- (a) product or trade name and a general description of the device including its intended purpose and intended users;
 - (b) the Basic UDI-DI as referred to in Part C of Schedule 22 assigned by the manufacturer to the device in question, as soon as identification of this device becomes based on a UDI system, or otherwise a clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;
 - (c) the intended purpose of the device which may include information on—
 - (i) what is to be detected or measured;
 - (ii) its function such as screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic;
 - (iii) the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;
 - (iv) whether it is automated or not;
 - (v) whether it is qualitative, semi-quantitative or quantitative;
 - (vi) the type of specimen required;
 - (vii) where applicable, the testing population;
 - (viii) the intended user;
 - (ix) in addition, for companion diagnostics, the relevant target population and the associated medicinal products;
 - (d) the description of the principle of the assay method or the principles of operation of the instrument;
 - (e) the rationale for the qualification of the product as a device;
 - (f) the risk class of the device and the justification for the classification rules applied in accordance with Schedule 23;
 - (g) the description of the components and where appropriate, the description of the reactive ingredients of relevant components such as antibodies, antigens, nucleic acid primers;
 - (h) where applicable, the description of the specimen collection and transport materials provided with the device or descriptions of specifications recommended for use;
 - (i) where applicable, for instruments of automated assays, the description of the appropriate assay characteristics or dedicated assays;
 - (j) where applicable, for automated assays, a description of the appropriate instrumentation characteristics or dedicated instrumentation;
 - (k) where applicable, a description of any software to be used with the device;
 - (l) where applicable, a description or complete list of the various configurations or variants of the device that are intended to be made available on the market;

- (m) where applicable, a description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with the device.

Reference to previous and similar generations of the device

(2) Where applicable the technical documentation must contain—

- (a) an overview of the previous generation or generations of the device produced by the manufacturer, where such devices exist;
- (b) an overview of identified similar devices available on international markets, where such devices exist.

Information to be supplied by the manufacturer

3. The manufacturer must supply a complete set of—

- (a) the label or labels on the device and on its packaging, such as single unit packaging, sales packaging, transport packaging in the case of specific management conditions, in English;
- (b) the instructions for use in English.

Design and manufacturing information

Design information

4.—(1) Information to allow the design stages applied to the device to be understood must include—

- (a) a description of the critical ingredients of the device such as antibodies, antigens, enzymes and nucleic acid primers provided or recommended for use with the device;
- (b) for instruments, a description of major subsystems, analytical technology such as operating principles and control mechanisms, dedicated computer hardware and software;
- (c) for instruments and software, an overview of the entire system;
- (d) for software, a description of the data interpretation methodology, namely the algorithm;
- (e) for devices intended for self-testing or near-patient testing, a description of the design aspects that make them suitable for self-testing or near-patient testing.

Manufacturing information

(2) Manufacturing information must include—

- (a) information to allow the manufacturing processes such as production, assembly, final product testing, and packaging of the finished device to be understood (more detailed information must be provided for the audit of the quality management system or other applicable conformity assessment procedures);
- (b) identification of all sites, including suppliers and sub-contractors, where manufacturing activities are performed.

General safety and performance requirements

5.—(1) The documentation must contain information for the demonstration of conformity with the general safety and performance requirements set out in Schedule 17 that are applicable to the device taking into account its intended purpose, and must include a justification, validation and verification of the solutions adopted to meet those requirements.

(2) The demonstration of conformity must also include—

- (a) the general safety and performance requirements that apply to the device and an explanation as to why others do not apply;
- (b) the method or methods used to demonstrate conformity with each applicable general safety and performance requirement;

- (c) the designated standards, CS or other solutions applied;
- (d) the precise identity of the controlled documents offering evidence of conformity with each designated standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements.
- (e) the information referred to in paragraph (d) must incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.

Benefit-risk analysis and risk management

6. The documentation must contain information on—

- (a) the benefit-risk analysis referred to in paragraphs 1 and 8 of Schedule 17,
- (b) the solutions adopted and the results of the risk management referred to in paragraph 3 of Schedule 17.

Product verification and validation

7. The documentation must contain the results and critical analyses of all verifications and validation tests or studies undertaken to demonstrate conformity of the device with the requirements Part IX and Schedules 17 to 28 and in particular the applicable general safety and performance requirements in Schedule 17.

Performance of the device

8.—(1) The documentation must include the information on the performance of the device listed in sub-paragraphs (2) and (3).

(2) The specimen type which must describe the different specimen types that can be analysed, including their stability such as storage, where applicable specimen transport conditions and, with a view to time-critical analysis methods, information on the timeframe between taking the specimen and its analysis and storage conditions such as duration, temperature limits and freeze/thaw cycles;

(3) The accuracy of the measurement consisting of—

- (a) the trueness of the measurement which must provide information on the trueness of the measurement procedure and summarise the data in sufficient detail to allow an assessment of the adequacy of the means selected to establish the trueness whilst noting that trueness measures apply to both quantitative and qualitative assays only when a certified reference material or certified reference method is available;
- (b) the precision of the measurement which must describe the repeatability and reproducibility studies;
- (c) the analytical sensitivity which must include—
 - (i) information about the study design and results;
 - (ii) a description of specimen type and preparation including matrix, analyte levels, and how levels were established;
 - (ii) the number of replicates tested at each concentration must also be provided as well as a description of the calculation used to determine assay sensitivity;
- (d) analytical specificity which must include—
 - (i) a description of interference and cross reactivity studies performed to determine the analytical specificity in the presence of other substances/agents in the specimen;
 - (ii) information on the evaluation of potentially interfering and cross-reacting substances or agents on the assay, on the tested substance or agent type and its concentration, specimen type, analyte test concentration, and results;

- (iii) information on interferences and cross-reacting substances or agents, which vary greatly depending on the assay type and design and could derive from exogenous or endogenous sources such as—
 - (aa) substances used for patient treatment such as medicinal products;
 - (bb) substances ingested by the patient such as alcohol, foods;
 - (cc) substances added during specimen preparation such as preservatives, stabilisers;
 - (dd) substances encountered in specific specimen types such as haemoglobin, lipids, bilirubin, proteins;
 - (ee) analytes of similar structure such as precursors, metabolites or medical conditions unrelated to the test condition including specimens negative for the assay but positive for a condition that can mimic the test condition;
- (iv) the metrological traceability of calibrator and control material values;
- (v) the measuring range of the assay which must include information—
- (vi) on the measuring range regardless of whether the measuring systems are linear or non-linear, including the limit of detection and describe information on how the range and detection limit were established;
- (vii) including a description of specimen type, number of specimens, number of replicates, and specimen preparation including information on the matrix, analyte levels and how levels were established;
- (viii) applicable, a description of any high dose hook effect and the data supporting the mitigation such as dilution steps shall be added;
- (ix) a definition of the assay cut-off including—
- (x) a summary of analytical data with a description of the study design including methods for determining the assay cut-off, such as—
 - (aa) the populations studied including demographics, selection, inclusion and exclusion criteria, number of individuals included;
 - (bb) the method or mode of characterisation of specimens;
 - (cc) statistical methods such as Receiver Operator Characteristic (ROC) to generate results and if applicable, define grey-zone/equivocal zone;
- (xi) the analytical performance report referred to in Schedule 27.

Performance evaluation report

9. The documentation—

- (a) must contain the performance evaluation report, which includes the reports on the scientific validity, the analytical and the clinical performance, as referred to in Schedule 27, together with an assessment of those reports;
- (b) must include, or fully reference, the clinical performance study documents referred to in paragraph 2 of Part A of Schedule 27.

Shelf life, in-use stability and shipping stability studies

10. The documentation must describe claimed shelf life, in use stability and shipping stability studies.

11. For claimed shelf life the documentation must—

- (a) provide information on stability testing studies to support the shelf life that is claimed for the device;
- (b) confirm that testing has been performed on at least 3 different (but not necessarily consecutive) lots manufactured under conditions that are essentially equivalent to routine production conditions;

- (c) describe whether accelerated studies or extrapolated data from real time data are used for initial shelf life claims and that these studies will be followed up with real time stability studies;
- (d) include the detailed information in paragraphs (b) to (c) which must include—
 - (i) the study report including the protocol, number of lots, acceptance criteria and testing intervals;
 - (ii) where accelerated studies have been performed in anticipation of the real time studies, the method used for accelerated studies must be described;
 - (iii) the conclusions and claimed shelf life.

12. For in-use stability the documentation must—

- (a) provide information on in-use stability studies for one lot reflecting actual routine use of the device, regardless of whether real or simulated which may include open vial stability or, for automated instruments, on board stability;
- (b) provide supporting data in cases of automated instrumentation where calibration stability is claimed;
- (c) include—
 - (i) the study report (including the protocol, acceptance criteria and testing intervals);
 - (ii) the conclusions and claimed in-use stability.

13. For shipping stability the documentation must—

- (a) provide information on shipping stability studies for one lot of devices to evaluate the tolerance of devices to the anticipated shipping conditions;
- (b) provide information on whether the shipping studies were done under real or simulated conditions and must include variable shipping conditions such as extreme heat and/or cold;
- (c) include—
 - (i) the study report (including the protocol, acceptance criteria);
 - (ii) the method used for simulated conditions;
 - (iii) conclusion and recommended shipping conditions.

Software verification and validation

14. The documentation must—

- (a) contain evidence of the validation of the software, as it is used in the finished device;
- (b) typically include the summary results of all verification, validation and testing performed in-house and applicable in an actual user environment prior to final release;
- (c) also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.

Additional information required in specific cases

15. The additional information required in specific cases is as follows—

- (a) in the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps;
- (b) in the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with regard to packaging, sterilisation and maintenance of sterility and the validation report must address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues;

- (c) in the case of devices containing tissues, cells and substances of animal, human or microbial origin, information on the origin of such material and on the conditions in which it was collected;
- (d) in the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications;
- (e) if the device is to be connected to other equipment in order to operate as intended, a description of the resulting combination including proof that it conforms to the general safety and performance requirements set out in Schedule 17 when connected to any such equipment having regard to the characteristics specified by the manufacturer.

SCHEDULE 19

Regulation 1A

Technical documentation on post-market surveillance for in vitro diagnostic medical devices

1. The technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with regulations 186 to 189 must be presented in a clear, organised, readily searchable and unambiguous manner and must include in particular the elements described in this Schedule.

2. In the post market surveillance plan drawn up in accordance with regulation 187 the manufacturer must prove that the plan complies with the obligation in regulation 186.

3. The post-market surveillance plan must address the collection and utilisation of available information, in particular—

- (a) information concerning serious incidents, including information from PSURs, and field safety corrective actions;
- (b) records referring to non-serious incidents and data on any undesirable side-effects,
- (c) information from trend reporting;
- (d) relevant specialist or technical literature, databases and/or registers;
- (e) information, including feedbacks and complaints, provided by users, distributors and importers;
- (f) publicly-available information about similar medical devices.

4. The post-market surveillance plan must cover at least—

- (a) a proactive and systematic process to collect any information referred to in paragraph 3 which must allow a correct characterisation of the performance of the devices and must also allow a comparison to be made between the device and similar products available on the market;
- (b) effective and appropriate methods and processes to assess the collected data;
- (c) suitable indicators and threshold values that must be used in the continuous reassessment of the benefit-risk analysis and of the risk management as referred to in paragraph 3 of Schedule 3;
- (d) effective and appropriate methods and tools to investigate complaints and analyse market-related experience collected in the field;
- (e) methods and protocols to manage the events subject to the trend report as provided for in regulation 191, including the methods and protocols to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period;

- (f) methods and protocols to communicate effectively with the Secretary of State, notified bodies, economic operators and users;
- (g) reference to procedures to fulfil the manufacturers obligations laid down in regulations 186, 187 and 189;
- (h) systematic procedures to identify and initiate appropriate measures including corrective actions;
- (i) effective tools to trace and identify devices for which corrective actions might be necessary; and
- (j) PMPF plan as referred to in Part B of Schedule 27 or a justification as to why a PMPF is not applicable.

5. The PSUR referred to in Article 81 and the post-market surveillance report referred to in Article 80.

SCHEDULE 20

Regulation 1A

Declaration of conformity for in vitro diagnostic medical devices

The declaration of conformity must contain the following information—

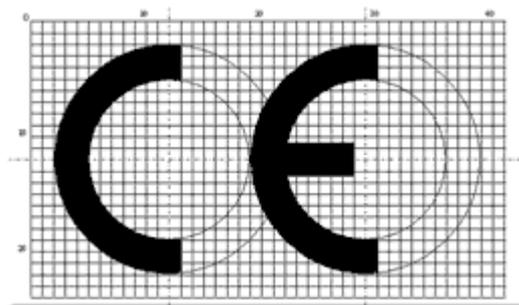
- (a) name, registered trade name or registered trade mark and, if applicable, the authorised representative, and the address of their registered place of business where they can be contacted and their location be established;
- (b) a statement that the declaration of conformity is issued under the sole responsibility of the manufacturer;
- (c) the Basic UDI-DI as referred to in Part C of Schedule 22;
- (d) the product or trade name along with—
 - (i) the product code;
 - (ii) the catalogue number; or
 - (iii) other unambiguous reference allowing identification and traceability of the device covered by the declaration of conformity, such as a photograph; and
 - (iv) the product's intended purpose;
 but, except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI referred to in paragraph (c);
- (e) the risk class of the device in accordance with the rules set out in Schedule 23;
- (f) a statement that the device, covered by the present declaration is in conformity with Part IX or Regulation (EU) 2017/746 and, if applicable, with any other relevant legislation that provides for the issuing of a declaration of conformity;
- (g) references to any CS used and in relation to which conformity is declared;
- (h) where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate or certificates issued;
- (i) where applicable, additional information;
- (j) the place and date of issue of the declaration, the name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed;
- (k) signature.

SCHEDULE 21

Regulation 1A

CE marking of conformity

1. The CE marking must consist of the initials 'CE' taking the following form—



2. If the CE marking is reduced or enlarged the proportions given in the above graduated drawing shall be respected.
3. The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm but this minimum dimension may be waived for small-scale devices.

SCHEDULE 22

Regulation 1A

Information to be submitted upon registration of in vitro diagnostic medical devices and economic operators in accordance with regulations (1) and 160, core data elements to be provided to the UDI database together with the UDI-DI in accordance with regulations

Part A

Information to be submitted upon the registration of devices and economic operators in accordance with regulations (1) and 160

1. The information relating to the economic operator is as follows—
 - (a) type of economic operator (manufacturer, authorised representative, UK responsible person or importer);
 - (b) name, address and contact details of the economic operator;
 - (c) where submission of information is carried out by another person on behalf of any of the economic operators mentioned in paragraph (a), the name, address and contact details of that person.
2. The information relating to the device is as follows—
 - (a) basic UDI;
 - (b) type, number and expiry date of the certificate issued by the notified body and the name or identification number of that notified body and the link to the information that appears on the certificate;
 - (c) if the device has been placed on the market of a state other than the United Kingdom before being placed on the United Kingdom market, the name of that state;

- (d) in the case of Class B, Class C or Class D devices, the name of the state other than the United Kingdom, where the device is or is to be made available;
- (e) presence of tissues, cells, or their derivatives of human origin;
- (f) presence of tissues, cells or their derivatives of animal origin;
- (g) presence of cells or substances of microbial origin;
- (h) risk class of the device;
- (i) where applicable, the single identification number of the performance study;
- (j) in the case of devices designed and manufactured by another legal or natural person as referred in regulation 145(22), the name, address and contact details of that legal or natural person;
- (k) in the case of Class C or D devices, the summary of safety and performance;
- (l) status of the device (whether it is on the market, no longer placed on the market, recalled, field safety corrective Action initiated);
- (m) indication as to whether the device is a “new device” and a device is to be considered “new device” if—
 - (i) there has been no such device continuously available on the United Kingdom or European Union market during the previous 3 years for the relevant analyte or other parameter; or
 - (ii) the procedure involves analytical technology not continuously used in connection with a given analyte or other parameter on the United Kingdom market or European Union market during the previous 3 years;
- (n) indication as to whether the device is intended for self-testing or near-patient testing.

PART B

Core data elements to be provided to the UDI database together with the UDI-DI in accordance with regulations (1) and (1)

- 3.** The person placing the product on the market must provide to the UDI database the UDI-DI and the following information relating to the manufacturer and the device—
- (a) quantity per package configuration;
 - (b) the Basic UDI-DI as referred to in regulation 157(6) and any additional UDI-DIs;
 - (c) the manner in which production of the device is controlled (expiry date or manufacturing date, lot number, serial number);
 - (d) if applicable, the ‘unit of use’ UDI-DI (where a UDI is not labelled on the device at the level of its ‘unit of use’, a ‘unit of use’ UDI-DI shall be assigned so as to associate the use of a device with a patient);
 - (e) name and address of the manufacturer, as indicated on the label;
 - (f) if applicable, name and address of the authorised representative (as indicated on the label);
 - (g) the medical device nomenclature code as provided for in regulation 156;
 - (h) risk class of the device;
 - (i) if applicable, name or trade name;
 - (j) if applicable, device model, reference, or catalogue number;
 - (k) any additional product description;
 - (l) if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use);

- (m) if applicable, additional trade names of the device;
- (n) whether the device is, and is labelled as, a single use device;
- (o) if applicable, the maximum number of reuses;
- (p) device labelled sterile;
- (q) URL for additional information, such as electronic instructions for use (optional);
- (r) if applicable, critical warnings or contra-indications;
- (s) status of the device (on the market, no longer placed on the market, recalled, field safety action initiated).

PART C

The UDI System

Definitions

4. In this Part of this Schedule—

“automated identification and data capture” or “AIDC” means a technology used to automatically capture data for example bar codes, smart cards, biometrics and RFID;

“Basic UDI” is—

- (a) the primary identifier of a device model which is assigned at the level of the device unit of use;
- (b) the main key for records in the UDI database;
- (c) referenced in relevant certificates and EU declarations of conformity;

“unit of Use DI” means a device identifier used to associate the use of a device with a patient in instances in which a UDI is not labelled on the individual device at the level of its unit of use, for example in the event of several units of the same device being packaged together;

“configurable device” means a device that consists of several components which can be assembled by the manufacturer in multiple configurations and those individual components may be devices in themselves;

“configuration” means a combination of items of equipment, as specified by the manufacturer, that operate together as a device to achieve an intended purpose and which may be modified, adjusted or customised to meet specific needs;

“UDI-DI” means unique numeric or alphanumeric code specific to a model of device and that is also used as the ‘access key’ to information stored in a UDI database;

“Human readable interpretation” or “HRI” is a legible interpretation of the data characters encoded in the UDI carrier;

“packaging levels” means the various levels of device packaging that contain a fixed quantity of devices, such as a carton or case;

“product identifier” or “UDI-PI” means a numeric or alphanumeric code that identifies the unit of device production examples of which include serial number, lot number, software identification and manufacturing or expiry date or both types of date;

“Radio Frequency Identification” or “RFID” means a technology that uses communication through the use of radio waves to exchange data between a reader and an electronic tag attached to an object, for the purpose of identification;

“shipping container” means a container in relation to which traceability is controlled by a process specific to logistics systems;

“unique device identifier” or “UDI”, which is comprised of the UDI-DI and the UDI-PI, means a series of numeric or alphanumeric characters that is created through a

globally accepted device identification and coding standard and which allows the unambiguous identification of a specific device on the market;

“UDI carrier” means the method of conveying (by for example ID/linear bar code, 2D/Matrix bar code or RFID) the UDI by using AIDC, and if applicable, its HRI.

General requirements

5.—(1) The affixing of the UDI does not replace any other marking or labelling requirements laid down in Schedule 17 to these regulations.

(2) The manufacturer must assign and maintain unique UDIs for its devices.

(3) Only the manufacturer may place the UDI on the device or its packaging.

(4) Only coding standards provided by issuing entities may be used.

The UDI

6.—(1) A UDI must be assigned to the device itself or its packaging and higher levels of packaging must have their own UDI.

(2) Shipping containers must be exempted from the requirement in sub-paragraph (1), for example, a UDI is not be required on a logistics unit so that where a healthcare provider orders multiple devices using the UDI or model number of individual devices and the manufacturer places those devices in a container for shipping or to protect the individually packaged devices, the container (logistics unit) is not be subject to UDI requirements.

(3) The UDI must contain two parts, a UDI-DI and a UDI-PI.

(4) The UDI-DI must be unique at each level of device packaging.

(5) Where on the label there is—

(a) a lot number, serial number, software identification or expiry date, it must be part of the UDI-PI; or

(b) only a manufacturing date, this must be used as the UDI-PI;

but where there is both a lot number, serial number, software identification or expiry date and a manufacturing date, the manufacturing date does not need to be included in the UDI-PI.

(6) Each component that is considered to be a device and is commercially available on its own must be assigned a separate UDI unless the components are part of a configurable device that is marked with its own UDI.

(7) Kits shall be assigned and bear their own UDI.

(8) The manufacturer must assign the UDI to a device following the relevant coding standard.

(9) A new UDI-DI is required whenever there is a change that could lead to misidentification of the device or ambiguity in its traceability and in particular, any change of one of the following UDI database data elements requires a new UDI-DI—

(a) name or trade name;

(b) device version or model;

(c) labelled as single use;

(d) packaged sterile;

(e) need for sterilization before use;

(f) quantity of devices provided in a package;

(g) critical warnings or contra-indications.

(10) Manufacturers that repackage or relabel devices with their own label must retain a record of the original device manufacturer’s UDI.

UDI carrier

7.—(1) The UDI carrier (AIDC and HRI representation of the UDI) must be placed on the label and on all higher levels of device packaging other than shipping containers.

(2) Where there are significant space constraints on the unit of use packaging the UDI carrier may be placed on the next higher packaging level.

(3) Subject to sub-paragraph (4) for single use Class A and Class B devices packaged and labelled individually, the UDI carrier is not be required to appear on the packaging but it must appear on a higher level of packaging, for example a carton containing several packages.

(4) However, when the healthcare provider is not expected to have access, in cases such as in home healthcare settings, to the higher level of device packaging, the UDI must be placed on the packaging.

(5) For devices exclusively intended for retail point of sale, the UDI-PIs in AIDC is not be required to appear on the point of sale packaging.

(6) When AIDC carriers, other than the UDI carrier, are part of the product labelling, the UDI carrier must be readily identifiable.

(7) If linear bar codes are used, the UDI-DI and UDI-PI may be concatenated or non-concatenated in two or more bar codes but all parts and elements of the linear bar code must be distinguishable and identifiable.

(8) Subject to sub-paragraph (9), there are significant constraints limiting the use of both AIDC and HRI on the label, only the AIDC format is be required to appear on the label.

(9) For devices intended to be used outside healthcare facilities, such as devices for home care, the HRI must appear on the label even if this results in there being no space for the AIDC.

(10) The HRI format must follow the rules of the UDI code-issuing entity.

(11) If the manufacturer is using RFID technology, a linear or 2D bar code in line with the standard provided by the issuing entities must also be provided on the label.

(12) Devices that are reusable—

(a) must bear a UDI carrier on the device itself;

(b) for reusable devices that require disinfection, sterilisation or refurbishing between patient uses, the UDI carrier must be permanent and readable after each process performed to make the device ready for the subsequent use throughout the intended lifetime of the device.

(13) The UDI carrier must be readable during normal use and throughout the intended lifetime of the device.

(14) If the UDI carrier is readily readable or scannable through the device's packaging, the placing of the UDI carrier on the packaging is not required.

(15) In the case of single finished devices made up of multiple parts that must be assembled before first use, it shall be sufficient to place the UDI carrier on only one part of each device.

(16) The UDI carrier must be placed in a manner such that the AIDC can be accessed during normal operation or storage.

(17) Bar code carriers that include both a UDI-DI and a UDI-PI may also include essential data for the device to operate or other data.

General principles of the UDI database

8.—(1) The UDI database must support the use of all core UDI database data elements referred to in Part B of this Schedule.

(2) Manufacturers must be responsible for the initial submission and updates of the identifying information and other device data elements in the UDI database.

(3) Appropriate methods or procedures for validation of the data provided must be implemented.

(4) Manufacturers must periodically verify the correctness of all of the data relevant to devices they have placed on the market, except for devices that are no longer available on the market.

(5) The presence of the device UDI-DI in the UDI database must not be assumed to mean that the device is in conformity with Part IX.

(6) The database must allow for the linking of all the packaging levels of the device.

(7) The data for new UDI-DIs must be available at the time the device is placed on the market.

(8) Manufacturers must update the relevant UDI database record within 30 days of a change being made to an element, which does not require a new UDI-DI.

(9) Internationally accepted standards for data submission and updates must, wherever possible, be used by the UDI database.

(10) The user interface of the UDI database must be available in English.

Rules for specific device types

Reusable devices that are part of kits and that require cleaning, sterilisation or refurbishing between uses

9.—(1) For reusable devices that are part of kits and that require cleaning, sterilisation or refurbishing between uses—

- (a) the UDI must be placed on the device and must be readable after each procedure to make the device ready for the next use;
- (b) the UDI-PI characteristics such as the lot or serial number must be defined by the manufacturer.

Device software

(2) The UDI assignment criteria for device software are—

- (a) the UDI must be assigned at the system level of the software but only software which is commercially available on its own and software which constitutes a device in itself is subject to that requirement;
- (b) the software identification must be considered to be the manufacturing control mechanism and must be displayed in the UDI-PI.

(3) A new UDI-DI is required whenever there is a modification that changes—

- (a) the original performance;
- (b) the safety or the intended use of the software;
- (c) interpretation of data;

and such modifications include new or modified algorithms, database structures, operating platform, architecture or new user interfaces or new channels for interoperability.

(4) Minor software revisions—

- (a) require a new UDI-PI and not a new UDI-DI;
- (b) are generally associated with bug fixes, usability enhancements that are not for safety purposes, security patches or operating efficiency;
- (c) must be identified by a manufacturer-specific form of identification.

UDI placement criteria for software

(5) The UDI placement criteria for software are as follows—

- (a) where the software is delivered on a physical medium, for example via a CD or DVD, each packaging level must bear the human readable and AIDC representation of the complete UDI and the UDI that is applied to the physical medium containing the software and its packaging must be identical to the UDI assigned to the system level software;

- (b) the UDI must be provided on a readily accessible screen for the user in an easily-readable plain-text format such as an 'about' file, or included on the start-up screen;
- (c) software lacking a user interface such as middleware for image conversion, must be capable of transmitting the UDI through an application programming interface (API);
- (d) only the human readable portion of the UDI is required in electronic displays of the software and the marking of UDI using AIDC is not required in the electronic displays such as 'about' menu, splash screen (a window consisting of an image or logo typically used to notify the user that a programme is in the process of loading);
- (e) the human readable format of the UDI for the software must include the application identifiers (AI) for the standard used by the issuing entities, so as to assist the user in identifying the UDI and determining which standard is being used to create the UDI.

SCHEDULE 23

Regulation 1A

Classification Rules for in vitro diagnostic medical devices

Implementation rules

1.—(1) Application of the classification rules must be governed by the intended purpose of the devices.

(2) If the device in question is intended to be used in combination with another device, the classification rules must apply separately to each of the devices.

(3) Accessories for an in vitro diagnostic medical device must be classified in their own right separately from the device with which they are used.

(4) Software which—

(a) drives a device or influences the use of a device, must fall within the same class as the device;

(b) is independent of any other device, must be classified in its own right.

(5) Calibrators intended to be used with a device must be classified in the same class as the device.

(6) Control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes must be classified in the same class as the device.

(7) The manufacturer must take into consideration all classification and implementation rules in order to establish the proper classification for the device.

(8) Where a manufacturer states multiple intended purposes for a device, and as a result the device falls into more than one class, it must be classified in the higher class.

(9) If several classification rules apply to the same device, the rule resulting in the higher classification must apply.

(10) Each of the classification rules must apply to first line assays, confirmatory assays and supplemental assays.

Classification rules

Rule 1

2.—(1) Devices intended to be used for the following purposes are classified as Class D—

- (a) detection of the presence of, or exposure to, a transmissible agent in blood, blood components, cells, tissues or organs, or in any of their derivatives, in order to assess their suitability for transfusion, transplantation or cell administration;

- (b) detection of the presence of, or exposure to, a transmissible agent that causes a life-threatening disease with a high or suspected high risk of propagation;
- (c) determining the infectious load of a life-threatening disease where monitoring is critical in the process of patient management.

Rule 2

(2) Devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration, are classified as class C, except when intended to determine any of the following markers—

- (a) ABO system [A (ABO1), B (ABO2), AB (ABO3)];
 - (b) Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)];
 - (c) Kell system [Kell1 (K)];
 - (d) Kidd system [JK1 (Jka), JK2 (Jkb)];
 - (e) Duffy system [FY1 (Fya), FY2 (Fyb)];
- in which case they are classified as Class D.

Rule 3

(3) Devices are classified as Class C if they are intended—

- (a) for detecting the presence of, or exposure to, a sexually transmitted agent;
- (b) for detecting the presence in cerebrospinal fluid or blood of an infectious agent without a high or suspected high risk of propagation;
- (c) for detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual, foetus or embryo being tested, or to the individual's offspring;
- (d) for pre-natal screening of women in order to determine their immune status towards transmissible agents;
- (e) for determining infective disease status or immune status, where there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;
- (f) to be used as companion diagnostics;
- (g) to be used for disease staging, where there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;
- (h) to be used in screening, diagnosis, or staging of cancer;
- (i) for human genetic testing;
- (j) for monitoring of levels of medicinal products, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;
- (k) for management of patients suffering from a life-threatening disease or condition;
- (l) for screening for congenital disorders in the embryo or foetus;
- (m) for screening for congenital disorders in new-born babies where failure to detect and treat such disorders could lead to life-threatening situations or severe disabilities.

Rule 4

(4) Devices intended for self-testing are classified as Class C, except for devices testing the following which are classified in Class D—

- (a) the detection of pregnancy;
- (b) fertility testing;

- (c) for determining cholesterol level;
 - (d) for the detection of glucose, *erythrocytes*, *leucocytes* and bacteria in urine.
- (5) Devices intended for near-patient testing are classified in their own right.

Rule 5

- (6) The following devices are classified as Class A—
- (a) products for general laboratory use, accessories which possess no critical characteristics, buffer solutions, washing solutions, and general culture media and histological stains, intended by the manufacturer to make them suitable for in vitro diagnostic procedures relating to a specific examination;
 - (b) instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures;
 - (c) specimen receptacles.

Rule 6

Devices not covered by the above-mentioned classification rules are classified as Class B.

Rule 7

Devices which are controls without a quantitative or qualitative assigned value are classified as Class B.

SCHEDULE 24

Regulation 1A

Conformity assessment based on quality management system and on assessment of technical documentation- in vitro diagnostic medical devices

PART 1

Quality management system

- 1.—(1) The manufacturer must—
- (a) establish, document and implement a quality management system as described in regulation 145(12);
 - (b) maintain its effectiveness throughout the life cycle of the devices concerned;
 - (c) ensure the application of the quality management system as specified in sub-paragraph (2);
 - (d) comply with the surveillance requirements as specified in sub-paragraph (7).

Quality management system assessment

- (2) The manufacturer must lodge an application for assessment of its quality management system with a notified body and the application must include—
- (a) the name of the manufacturer and address of its registered place of business and any additional manufacturing site covered by the quality management system, and, if the manufacturer's application is lodged by its authorised representative the name of the authorised representative and the address of the authorised representative's registered place of business;
 - (b) all relevant information on the device or group of devices covered by the quality management system;
 - (c) a written declaration that no application has been lodged with any other notified body for the same device-related quality management system, or information about any previous application for the same device-related quality management system;

- (d) a draft of a declaration of conformity for the device model covered by the conformity assessment procedure;
- (e) the documentation on the manufacturer's quality management system,
- (f) a documented description of the procedures in place to fulfil the obligations arising from the quality management system and required under Part IX and of the undertaking by the manufacturer in question to apply those procedures;
- (g) a description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures;
- (h) the documentation on the manufacturer's post-market surveillance system, and, where applicable, on the PMPF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in regulations 190 to 194;
- (i) a description of the procedures in place to keep up to date the post-market surveillance system and, where applicable, the PMPF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in regulations 190 to 194, as well as the undertaking by the manufacturer to apply those procedures;
- (j) documentation on the performance evaluation plan;
- (k) a description of the procedures in place to keep up to date the performance evaluation plan, taking into account the state of the art.

(3) Implementation of the quality management system must ensure compliance with Part IX and all the elements, requirements and provisions adopted by the manufacturer for its quality management system must be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures, such as quality programmes, quality plans and quality records.

(4) The documentation to be submitted for the assessment of the quality management system must include an adequate description of, in particular—

- (a) the manufacturer's quality objectives;
- (b) the organisation of the business and in particular—
 - (i) the organisational structures with the assignment of staff responsibilities in relation to critical procedures, the responsibilities of the managerial staff and their organisational authority;
 - (ii) the methods of monitoring whether the operation of the quality management system is efficient and in particular the ability of that system to achieve the desired design and device quality, including control of devices which fail to conform;
 - (iii) where the design, manufacture, or final verification and testing of the devices, or parts of any of those processes, is carried out by another party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party;
 - (iv) where applicable, the draft mandate for the designation of an authorised representative and a letter of intention from the authorised representative to accept the mandate;
- (c) the procedures and techniques for monitoring, verifying, validating and controlling the design of the devices, and the corresponding documentation as well as the data and records arising from those procedures and techniques and those procedures and techniques must specifically cover—
 - (i) the strategy for regulatory compliance, including processes for identification of relevant legal requirements, qualification, classification, handling of equivalence, choice of, and compliance with, conformity assessment procedures;

- (ii) identification of applicable general safety and performance requirements and solutions to fulfil those requirements, taking applicable CS into account and, where opted for, designated standards;
 - (iii) risk management as referred to in paragraph 3 of Schedule 17;
 - (iv) the performance evaluation, pursuant to regulation 167 and Schedule 27, including PMPF;
 - (v) solutions for fulfilling the applicable specific requirements regarding design and construction, including appropriate pre-clinical evaluation, in particular the requirements of Part 2 of Schedule 17;
 - (vi) solutions for fulfilling the applicable specific requirements regarding the information to be supplied with the device, in particular the requirements of Part 3 of Schedule 17;
 - (vii) the device identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture; and
 - (viii) management of design or quality management system changes;
- (d) the verification and quality assurance techniques at the manufacturing stage and in particular the processes and procedures which are to be used, particularly as regards sterilisation, and the relevant documents;
- (e) the appropriate tests and trials which are to be carried out before, during and after manufacture, the frequency with which they are to take place, and the test equipment to be used and it must be possible to trace back adequately the calibration of that test equipment.
- (5) The manufacturer must grant the notified body access to the technical documentation referred to in Schedules 18 and 19.

(6) The manufacturer must inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system, or the device-range covered and the approval of any substantive change to the quality management system or the device-range covered must take the form of a supplement to the quality management system certificate.

Surveillance applicable to Class C and Class D devices

(7) The manufacturer of Class C and D devices must give authorisation to the notified body to carry out all the necessary audits, including on-site audits, and supply it with all relevant information, in particular—

- (a) the documentation on its quality management system;
- (b) the documentation on any findings and conclusions resulting from the application of the post-market surveillance plan, including the PMPF plan, for a representative sample of devices, and of the provisions on vigilance set out in regulations 190 to 194;
- (c) the data stipulated in the part of the quality management system relating to design, such as the results of analyses, calculations, tests and the solutions adopted regarding the risk-management as referred to in paragraph 4 of Schedule 17;
- (d) the data stipulated in the part of the quality management system relating to manufacture, such as quality control reports and test data, calibration data, and records on the qualifications of the personnel concerned.

PART 2

Assessment of technical documentation

Assessment of the technical documentation of class B, C and D devices and batch verification applicable to class D devices

2.—(1) In addition, to the obligation laid down in paragraph 1, the manufacturer of Class B, C and D devices must lodge with the notified body an application for the assessment of the technical documentation relating to the device which it plans to place on the market or put into service and which is covered by the quality management system referred to in paragraph 1.

(2) The application must describe the design, manufacture and performance of the device in question and must include the technical documentation as referred to in Schedules 18 and 19.

(3) In the case of devices for self-testing or near-patient testing, the application must also include the aspects referred to in paragraph 3(b).

Assessment of technical documentation of specific types of devices

3. For Class B, C and D devices for self-testing and near-patient testing the assessment of the technical documentation must be carried out as follows—

- (a) the manufacturer of Class B, C and D devices for self-testing and near-patient testing must lodge with the notified body an application for the assessment of the technical documentation;
- (b) the application must enable the design of the device characteristics and performance to be understood and must enable conformity with the design-related requirements of this Part to be assessed and must include—
 - (i) test reports, including results of studies carried out with intended users;
 - (ii) where practicable, an example of the device and, if required, the device must be returned on completion of the technical documentation assessment;
 - (iii) data showing the suitability of the device in view of its intended purpose for self-testing or near patient- testing;
 - (iv) the information to be provided with the device on its label and its instructions for use.

Assessment of the technical documentation of companion diagnostics

4.—(1) The manufacturer of a companion diagnostic must lodge with the notified body an application for the assessment of the technical documentation and the notified body will assess that application in accordance with the procedure laid down in Sections 4.1 to 4.8 of this Annex IX to Regulation (EU) 2017/746.

(2) The application must enable the characteristics and performance of the device to be understood, and must enable conformity with the design-related requirements of this Part to be assessed, in particular, with regard to the suitability of the device in relation to the medicinal product concerned.

PART 3

Administrative Provisions

5. The manufacturer or, where the manufacturer does not have a registered place of business in the United Kingdom, the person placing the product on the market must, for a period ending no sooner than 10 years after the last device has been placed on the market, keep at the disposal of the Secretary of State—

- (a) the declaration of conformity;

- (b) the documentation referred to in the fifth indent of paragraph 1(2) and, in particular, the data and records arising from the procedures referred to in paragraph 1(4)(c);
- (c) information on the changes referred to in paragraph 1(6);
- (d) the documentation referred to in paragraph 2(2) and paragraph 3(b); and
- (e) the decisions and reports from the notified body.

6. The documentation in paragraph 5 must be kept available to the Secretary of State throughout the 10 year period specified in paragraph 5 irrespective of the continued status (and whether the person continues trading or not) of the manufacturer or person placing the product on the market.

SCHEDULE 25

Regulation 1A

Conformity assessment based on the type-examination

1. In this Schedule a “type-examination” is the procedure whereby a notified body ascertains and certifies that a device, including its technical documentation and relevant life cycle processes and a corresponding representative sample of the device production envisaged, fulfils the relevant provisions.

Application

2. The manufacturer must lodge an application for assessment with a notified body and the application must—

- (a) include the name of the manufacturer and the address of its registered place of business and, if the application is lodged by the authorised representative, the name of the authorised representative and the address of its registered place of business;
- (b) include the technical documentation referred to in Schedules 18 and 19;
- (c) provide to or make available, a representative sample of the device production envisaged (‘type’), to the notified body (the notified body may request other samples as necessary);
- (d) in the case of devices for self-testing or near-patient testing, provide test reports, including results of studies carried out with intended users, and data showing the handling suitability of the device in relation to its intended purpose for self-testing or near patient-testing;
- (e) where practicable, provide an example of the device which, if required, must be returned on completion of the technical documentation assessment;
- (f) include data showing the suitability of the device in relation to its intended purpose for self-testing or near-patient testing;
- (g) the information to be provided with the device on its label and its instructions for use; and
- (h) a written declaration that no application has been lodged with any other notified body for the same type, or information about any previous application for the same type that was refused by another notified body or was withdrawn by the manufacturer or its authorised representative before that other notified body made its final assessment.

Assessment

3. The assessment must be carried out by a notified body in accordance with the obligations placed on such a body by Section 3 of Annex X to Regulation (EU) 2017/746.

Changes to the type

4.—(1) The applicant must inform the notified body which issued the type-examination certificate of any planned change to the approved type or of its intended purpose and conditions of use.

(2) Changes to the approved device including limitations of its intended purpose and conditions of use must be further approved by the notified body which issued the type-examination certificate where such changes may affect conformity with the general safety and performance requirements or with the conditions prescribed for use of the product.

(3) The approval of any change to the approved type must take the form of a supplement to the type-examination certificate.

(4) Changes to the intended purpose and conditions of use of the approved device, with the exception of limitations of the intended purpose and conditions of use, require a new application for a conformity assessment.

Administrative provisions

5.—(1) The manufacturer or, where the manufacturer does not have a registered place of business in a United Kingdom, the person placing the product on the market must, for a period ending no sooner than 10 years, after the last device has been placed on the market, keep at the disposal of the Secretary of State—

- (a) the documentation referred to in paragraph 2(b);
- (b) information on the changes referred to in paragraph 4;
- (c) copies of type-examination certificates, scientific opinions and reports and their additions/supplements.

(2) The documentation in sub-paragraph (1) must be kept available to the Secretary of State throughout the period specified in sub-paragraph (1) irrespective of the continued status (and whether the person continues trading or not) of the person placing the product on the market.

SCHEDULE 26

Regulation 1A

Conformity assessment based on production quality assurance

1.—(1) The manufacturer must—

- (a) ensure that the quality management system approved for the manufacture of the devices concerned is implemented;
- (b) carry out final verification, as specified in paragraph 2(3);
- (c) be subject to the surveillance referred to in paragraph 4.

(2) When the manufacturer fulfils the obligations laid down in sub-paragraph (1), the manufacturer must draw up and keep a declaration of conformity in accordance with regulation 151 for the device covered by the conformity assessment procedure.

(3) By issuing a declaration of conformity, the manufacturer must be deemed to ensure, and to declare, that the device concerned meets the requirements of this Part which apply to the device, and in the case of Class C and Class D devices that undergo a type examination, conforms to the type described in the type-examination certificate.

Quality management system

2.—(1) The manufacturer must lodge an application for assessment of its quality management system with a notified body.

(2) The application in sub-paragraph (1) must include—

- (a) all elements listed in paragraph 1(2) of Schedule 24;

- (b) the technical documentation referred to in Schedules 18 and 19 for the types approved;
- (c) a copy of the type-examination certificates and, if the type-examination certificates have been issued by the same notified body with which the application is lodged, a reference to the technical documentation and its updates and the certificates issued must also be included in the application.

(3) Implementation of the quality management system must be such as to ensure that there is compliance with the type described in the type-examination certificate and with the provisions of this Part which apply to the devices at each stage.

(4) All the elements, requirements and provisions adopted by the manufacturer for its quality management system must be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures, such as quality programmes, quality plans and quality records and that documentation must, in particular, include an adequate description of all elements listed in paragraphs (a), (b), (d) and (e) of paragraph 1(4).

(5) The manufacturer must inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system, or the device-range covered and the approval of any substantial change to the quality management system or device-range covered must take the form of a supplement to the quality management system certificate.

Surveillance

3. The manufacturer of Class C and D devices must give authorisation to the notified body to carry out all the necessary audits, including on-site audits, and supply it with all relevant information, in particular—

- (a) the documentation on its quality management system;
- (b) the documentation on any findings and conclusions resulting from the application of the post-market surveillance plan, including the PMPF plan, for a representative sample of devices, and of the provisions on vigilance set out in regulations 190 to 194;
- (c) the data stipulated in the part of the quality management system relating to design, such as the results of analyses, calculations, tests and the solutions adopted regarding the risk-management as referred to in paragraph 4 of Schedule 17;
- (d) the data stipulated in the part of the quality management system relating to manufacture, such as quality control reports and test data, calibration data, and records on the qualifications of the personnel concerned.

Verification of manufactured Class D devices

4.—(1) In the case of Class D devices, the manufacturer must carry out tests on each manufactured batch of devices.

(2) After the conclusion of the controls and tests, the manufacturer must forward to the notified body without delay the relevant reports on those tests.

(3) The manufacturer must make samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and detailed arrangements.

(4) The manufacturer may place the devices on the market, unless the notified body communicates to the manufacturer within the agreed timeframe, but not later than 30 days after reception of the samples, any other decision, including in particular any condition of validity of delivered certificates.

Administrative provisions

5.—(1) The manufacturer or, where the manufacturer does not have a registered place of business in the United Kingdom, the person placing the product on the market must, for a

period ending no sooner than 10 years after the last device has been placed on the market, keep at the disposal of the Secretary of State—

- (a) the declaration of conformity;
- (b) the documentation referred to in the paragraph 1(2)(e) of Schedule 24;
- (c) the documentation referred to in paragraph 1(2)(i) of Schedule 24, including the type- examination certificate referred to in Schedule 25;
- (d) information on the changes referred to in paragraph 1(6) of Schedule 24;
- (e) the decisions and reports from the notified body.

(2) The documentation listed in sub-paragraph (1) must be kept available to the Secretary of State throughout the period specified in sub-paragraph (1) irrespective of the continued status (and whether the person continues trading or not) of the manufacturer or person placing the product on the market.

SCHEDULE 27

Regulation 1A

Performance evaluation, performance studies and post-market performance follow-up

PART A

Performance evaluation and performance studies

Performance evaluation

1.—(1) Performance evaluation of a device is a continuous process by which data are assessed and analysed to demonstrate the scientific validity, analytical performance and clinical performance of that device for its intended purpose as stated by the manufacturer.

(2) The performance evaluation must—

- (a) be thorough and objective, considering both favourable and unfavourable data;
- (b) be proportionate in terms of its depth and extent and appropriate to the characteristics of the device including the risks, risk class, performance and its intended purpose.

(3) To plan, continuously conduct and document a performance evaluation, the manufacturer must establish and update a performance evaluation plan which must specify the characteristics and the performance of the device and the process and criteria applied to generate the necessary clinical evidence.

Performance evaluation plan

(4) As a general rule the performance evaluation plan must include at least—

- (a) a specification of the intended purpose of the device;
- (b) a specification of the characteristics of the device as described in paragraph 9 of Part 2 of Schedule 17 and in paragraph 20(6)(c) of Part 3 of Schedule 17;
- (c) a specification of the analyte or marker to be determined by the device;
- (d) a specification of the intended use of the device;
- (e) identification of certified reference materials or reference measurement procedures to allow for metrological traceability;
- (f) a clear identification of specified target patient groups with clear indications, limitations and contra-indications;
- (g) an identification of the general safety and performance requirements as laid down in paragraphs 1 to 9 of Schedule 17 that require support from relevant scientific validity and analytical and clinical performance data;

- (h) a specification of methods, including the appropriate statistical tools, used for the examination of the analytical and clinical performance of the device and of the limitations of the device and information provided by it;
- (i) a description of the state of the art, including an identification of existing relevant standards, CS, guidance or best practices documents;
- (j) an indication and specification of parameters to be used to determine, based on the state of the art in medicine, the acceptability of the benefit-risk ratio for the intended purpose or purposes and for the analytical and clinical performance of the device;
- (k) for software qualified as a device, an identification and specification of reference databases and other sources of data used as the basis for its decision making;
- (l) an outline of the different development phases including the sequence and means of determination of the scientific validity, the analytical and clinical performance, including an indication of milestones and a description of potential acceptance criteria;
- (m) the PMPF planning as referred to in Part B of this Schedule.

(5) Where any of the elements set out in sub-paragraph (4) are not deemed appropriate in the performance evaluation plan due to the specific device characteristics a justification must be provided in the plan.

Demonstration of the scientific validity and the analytical and clinical performance

- (6) As a general methodological principle the manufacturer must—
- (a) identify through a systematic scientific literature review the available data relevant to the device and its intended purpose and identify any remaining unaddressed issues or gaps in the data;
 - (b) appraise all relevant data by evaluating their suitability for establishing the safety and performance of the device;
 - (c) generate any new or additional data necessary to address outstanding issues.

Demonstration of scientific validity

(7) The manufacturer must demonstrate the scientific validity based on one or a combination of the following sources—

- (a) relevant information on the scientific validity of devices measuring the same analyte or marker;
- (b) scientific (peer-reviewed) literature;
- (c) consensus expert opinions/positions from relevant professional associations;
- (d) results from proof of concept studies;
- (e) results from clinical performance studies.

(8) The scientific validity of the analyte or marker must be demonstrated and documented in the scientific validity report.

Demonstration of the analytical performance

(9) The manufacturer must demonstrate the analytical performance of the device in relation to all the parameters described in paragraph 9(b)(i) of Schedule 17, unless any omission can be justified as not applicable.

(10) As a general rule, the analytical performance shall always be demonstrated on the basis of analytical performance studies.

(11) For novel markers or other markers without available certified reference materials or reference measurement procedures where it is not possible to demonstrate trueness and where there are no comparable methods—

- (a) different approaches may be used if demonstrated to be appropriate, such as comparison to some other well-documented methods or the composite reference standard;

- (b) in the absence of such approaches, a clinical performance study comparing performance of the novel device to the current clinical standard practice is required.

(12) Analytical performance must be demonstrated and documented in the analytical performance report.

Demonstration of the clinical performance

(13) The manufacturer shall demonstrate the clinical performance of the device in relation to all the parameters described in paragraph 9(b)(ii) of Schedule 17, unless any omission can be justified as not applicable.

(14) Demonstration of the clinical performance of a device must be based on one or a combination of the following sources—

- (a) clinical performance studies;
- (b) scientific peer-reviewed literature;
- (c) published experience gained by routine diagnostic testing.

(15) Clinical performance studies must be performed unless due justification is provided for relying on other sources of clinical performance data.

(16) Clinical performance must be demonstrated and documented in the clinical performance report.

Clinical evidence and performance evaluation report

(17) The manufacturer must assess all relevant scientific validity, analytical and clinical performance data to verify the conformity of its device with the general safety and performance requirements as referred to in Schedule 17.

(18) The amount and quality of that data must allow the manufacturer to make a qualified assessment whether the device will achieve the intended clinical benefit or benefits and safety, when used as intended by the manufacturer.

(19) The data and conclusions drawn from this assessment constitute the clinical evidence for the device.

(20) The clinical evidence must scientifically demonstrate that the intended clinical benefit or benefits and safety will be achieved according to the state of the art in medicine.

Performance evaluation report

(21) The clinical evidence must be documented in a performance evaluation report and this report must include the scientific validity report, the analytical performance report, the clinical performance report and an assessment of those reports allowing demonstration of the clinical evidence.

(22) The performance evaluation report shall in particular include—

- (a) the justification for the approach taken to gather the clinical evidence;
- (b) the literature search methodology and the literature search protocol and literature search report of a literature review;
- (c) the technology on which the device is based, the intended purpose of the device and any claims made about the device's performance or safety;
- (d) the nature and extent of the scientific validity and the analytical and clinical performance data that has been evaluated;
- (e) the clinical evidence as the acceptable performances against the state of the art in medicine;
- (f) any new conclusions derived from PMPF reports in accordance with Part B of this Schedule.

(23) The clinical evidence and its assessment in the performance evaluation report must be updated throughout the life cycle of the device concerned with data obtained from the implementation of the manufacturer's PMPF plan in accordance with Part B of this

Schedule, as part of the performance evaluation and the post-market surveillance system referred to in regulation 145(14).

(24) The performance evaluation report must be part of the technical documentation and both favourable and unfavourable data considered in the performance evaluation must be included in the technical documentation.

Clinical performance studies

Purpose of clinical performance studies

2.—(1) The purpose of clinical performance studies is to establish or confirm aspects of device performance which cannot be determined by analytical performance studies, literature or previous experience gained by routine diagnostic testing.

(2) This information from a clinical performance study is used to demonstrate compliance with the relevant general safety and performance requirements with respect to clinical performance.

(3) When clinical performance studies are conducted, the data obtained must be used in the performance evaluation process and be part of the clinical evidence for the device.

Ethical considerations for clinical performance studies

(4) Each step in the clinical performance study, from the initial consideration of the need for and justification of the study to the publication of the results, must be carried out in accordance with recognised ethical principles.

Methods for clinical performance studies

(5) Clinical performance studies must be designed in such a way as to maximize the relevance of the data while minimising potential bias.

(6) Clinical performance studies must be performed on the basis of a clinical performance study plan (CPSP).

(7) The CPSP must define the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical performance study and must contain in particular the following information—

- (a) identification of the sponsor, including the name, address of the registered place of business and contact details of the sponsor and, if applicable, the name, address of the registered place of business and contact details of its contact person or legal representative pursuant regulation 169(5);
- (b) information on the investigator or investigators, namely principal, coordinating or other investigator; qualifications, contact details, and investigation site or sites, such as number, qualification, contact details and, in the case of devices for self-testing, the location and number of lay persons involved;
- (c) the starting date and scheduled duration for the clinical performance study;
- (d) identification and description of the device, its intended purpose, the analyte or analytes or marker or markers, the metrological traceability, and the manufacturer;
- (e) information about the type of specimens under investigation;
- (f) overall synopsis of the clinical performance study, its design type, such as observational, interventional, together with the objectives and hypotheses of the study, reference to the current state of the art in diagnosis or medicine;
- (g) a description of the expected risks and benefits of the device and of the clinical performance study in the context of the state of the art in clinical practice, and with the exception of studies using left-over samples, the medical procedures involved and patient management;
- (h) the instructions for use of the device or test protocol, the necessary training and experience of the user, the appropriate calibration procedures and means of control, the indication of any other devices, medical devices, medicinal product or other articles to be included or excluded and the specifications on any comparator or comparative method used as reference;

- (i) a description of and justification for the design of the clinical performance study, its scientific robustness and validity, including the statistical design, and details of measures to be taken to minimise bias, such as randomisation, and management of potential confounding factors;
 - (j) the analytical performance in accordance with paragraph 9(b)(i) of Schedule 17 with justification for any omission;
 - (k) parameters of clinical performance in accordance with paragraph 9(b)(ii) of Schedule 17 to be determined, with justification for any omission and with the exception of studies using left-over samples the specified clinical outcomes/endpoints (primary/secondary) used with a justification and the potential implications for individual health or public health management decisions;
 - (l) information on the performance study population: specifications of the subjects, selection criteria, size of performance study population, representativity of target population and, if applicable, information on vulnerable subjects involved, such as children, pregnant women, immuno-compromised or elderly subjects;
 - (m) information on use of data out of left over specimens banks, genetic or tissue banks, patient or disease registries etc. with description of reliability and representativity and statistical analysis approach; assurance of relevant method for determining the true clinical status of patient specimens;
 - (n) the monitoring plan;
 - (o) data management;
 - (p) decision algorithms;
 - (q) policy regarding any amendments, including those in accordance with regulation 182, to or deviations from the CPSP, with a clear prohibition of use of waivers from the CPSP;
 - (r) accountability regarding the device, in particular control of access to the device, follow-up in relation to the device used in the clinical performance study and the return of unused, expired or malfunctioning devices;
 - (s) statement of compliance with the recognised ethical principles for medical research involving humans and the principles of good clinical practice in the field of clinical performance studies as well as with the applicable regulatory requirements;
 - (t) description of the informed consent process, including a copy of the patient information sheet and consent forms;
 - (u) procedures for safety recording and reporting, including definitions of recordable and reportable events, and procedures and timelines for reporting;
 - (v) criteria and procedures for suspension or early termination of the clinical performance study;
 - (w) criteria and procedures for follow up of subjects following completion of a performance study, procedures for follow up of subjects in the case of suspension or early termination, procedures for follow up of subjects who have withdrawn their consent and procedures for subjects lost to follow up;
 - (x) procedures for communication of test results outside the study, including communication of test results to the performance study subjects;
 - (y) policy as regards the establishment of the clinical performance study report and publication of results in accordance with the legal requirements and the ethical principles referred to in sub-paragraph (4);
 - (z) list of the technical and functional features of the device indicating those that are covered by the performance study;
 - (aa) bibliography.
- (8) Sub-paragraph (7) applies subject to the following—

- (a) if part of the information referred to in sub-paragraph (7) is submitted in a separate document, it must be referenced in the CPSP;
- (b) for studies using left-over samples, paragraphs (u), (x), (y) and (z) do not apply.

(9) Where any of the elements referred to in the second paragraph are not deemed appropriate for inclusion in the CPSP due to the specific study design chosen, such as use of left-over samples versus interventional clinical performance studies, a justification must be provided.

Clinical performance study report

(10) A clinical performance study report, signed by a medical practitioner or any other authorised person responsible, must contain documented information on the clinical performance study protocol plan, results and conclusions of the clinical performance study, including negative findings.

(11) The results and conclusions of the clinical performance study must be transparent, free from bias and clinically relevant.

(12) The clinical performance study report must—

- (a) contain sufficient information to enable it to be understood by an independent party without reference to other documents;
- (b) include as appropriate any protocol amendments or deviations, and data exclusions with the appropriate rationale.

Other performance studies

3. The performance study plan and the performance study report must be documented for performance studies other than clinical performance studies.

PART B

Post-market performance follow-up (PMPF)

4.—(1) PMPF must be specifically addressed in the manufacturer's post-market surveillance plan.

(2) When conducting PMPF, the manufacturer must proactively collect and evaluate performance and relevant scientific data from the use of a device which bears the CE marking and is placed on the market or put into service within its intended purpose as referred to in the relevant conformity assessment procedure, with the aim of confirming the safety, performance and scientific validity throughout the expected lifetime of the device, of ensuring the continued acceptability of the benefit-risk ratio and of detecting emerging risks on the basis of factual evidence.

5.—(1) PMPF shall be performed pursuant to a documented method laid down in a PMPF plan.

(2) The PMPF plan must specify the methods and procedures for proactively collecting and evaluating safety, performance and scientific data with the aim of—

- (a) confirming the safety and performance of the device throughout its expected lifetime;
- (b) identifying previously unknown risks or limits to performance and contraindications;
- (c) identifying and analysing emergent risks on the basis of factual evidence;
- (d) ensuring the continued acceptability of the clinical evidence and of the benefit-risk ratio referred to in paragraphs 1 and 8 of Part 1 of Schedule 17; and
- (e) identifying possible systematic misuse.

(3) The PMPF plan shall include at least—

- (a) the general methods and procedures of the PMPF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of performance or scientific data;
- (b) the specific methods and procedures of PMPF to be applied, such as ring trials and other quality assurance activities, epidemiological studies, evaluation of suitable patient or disease registers, genetic databanks or post-market clinical performance studies;
- (c) rationale for the appropriateness of the methods and procedures referred to in paragraphs (a) and (b);
- (d) reference to the relevant parts of the performance evaluation report referred to in sub-paragraphs (17) to (20) of paragraph 1 of this Schedule and to the risk management referred to in paragraph 3 of Schedule 17;
- (e) the specific objectives to be addressed by the PMPF;
- (f) an evaluation of the performance data relating to equivalent or similar devices, and the current state of the art;
- (g) reference to any relevant CS, designated standards when used by the manufacturer, and relevant guidance on PMPF;
- (h) a detailed and adequately justified time schedule for PMPF activities, such as analysis of PMPF data and reporting, to be undertaken by the manufacturer.

6. The manufacturer must analyse the findings of the PMPF and document the results in a PMPF evaluation report that shall update the performance evaluation report and be part of the technical documentation.

7. The conclusions of the PMPF evaluation report must be taken into account for the performance evaluation referred to in regulation 167 and Part A of this Schedule and in the risk management referred to in paragraph 3 of Schedule 17 and if, through the PMPF, the need for preventive or corrective measures has been identified, the manufacturer must implement them.

8. If PMPF is not deemed appropriate for a specific device then a justification shall be provided and documented within the performance evaluation report.

SCHEDULE 28

Regulation 1A

Interventional clinical performance studies and certain other performance studies

PART 1

Documentation regarding the application for interventional clinical performance studies and other performance studies involving risks for the subjects of the studies

Application form

1. For devices intended to be used in the context of interventional clinical performance studies or other performance studies involving risks for the subjects of the studies, the sponsor must draw up and submit the application in accordance with regulation 169 accompanied by the following documents—

- (a) The application form, filled in and containing the following information—
 - (i) name, address and contact details of the sponsor and, if applicable, name, address and contact details of its contact person or legal representative in accordance with regulation 169(5) established in the United Kingdom;

- (ii) if different from those in sub-paragraph (i), name, address and contact details of the manufacturer of the device intended for performance evaluation and, if applicable, of the manufacturer's authorised representative;
- (iii) the title of the performance study;
- (iv) status of the performance study, such as the first submission, resubmission, significant amendment;
- (v) details or reference to the performance study plan, such as including details of the design phase of the performance study;
- (vi) if the application is a resubmission with regard to a device for which an application has been already submitted—
 - (aa) the date or dates and reference number or numbers of the earlier application or in the case of significant amendment, reference to the original application;
 - (bb) all of the changes from the previous application together with a rationale for those changes, in particular, whether any changes have been made to address conclusions of previous Secretary of State or ethics committee reviews;
- (vii) if the application is submitted in parallel with an application for a clinical trial in accordance with Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16th April 2014 on clinical trials on medicinal products for human use^(a) as it applies in European Union law, reference to the official registration number of the clinical trial;
- (viii) identification of the other countries outside the United Kingdom in which the clinical performance study is to be conducted as part of a multicentre or multinational study at the time of application;
- (ix) brief description of the device for performance study, its classification and other information necessary for the identification of the device and device type;
- (x) summary of the performance study plan;
- (xi) if applicable, information regarding a comparator device, its classification and other information necessary for the identification of the comparator device;
- (xii) evidence from the sponsor that the clinical investigator and the investigational site are capable of conducting the clinical performance study in accordance with the performance study plan;
- (xiii) details of the anticipated start date and duration of the performance study;
- (xiv) details to identify the notified body, if already involved at the stage of application for the performance study;
- (xv) confirmation that the sponsor is aware that the Secretary of State may contact the ethics committee that is assessing or has assessed the application;
- (xvi) the statement referred to in paragraph 3(a).

Investigator's brochure

2.—(1) The following requirements apply to the investigator's brochure (IB)—

- (a) The IB must contain the information on the device for performance study that is relevant for the study and available at the time of application;
- (b) any updates to the IB or other relevant information that is newly available must be brought to the attention of the investigators in a timely manner.

(a) OJ No. L 158, 27.5.2014, p.1.

(2) The IB must be clearly identified and contain in particular the following information—

- (a) identification and description of the device, including information on the intended purpose, the risk classification and applicable classification rule pursuant to Schedule 23, design and manufacturing of the device and reference to previous and similar generations of the device;
- (b) manufacturer's instructions for installation, maintenance, maintaining hygiene standards and for use, including storage and handling requirements, as well as, to the extent that such information is available, information to be placed the label, and instructions for use to be provided with the device when placed on the market;
- (c) information relating to any relevant training required;
- (d) analytical performance;
- (e) existing clinical data, in particular—
 - (i) from relevant peer-reviewed scientific literature and available consensus expert opinions or positions from relevant professional associations relating to the safety, performance, clinical benefits to patients, design characteristics, scientific validity, clinical performance and intended purpose of the device and/or of equivalent or similar devices;
 - (ii) other relevant clinical data available relating to the safety, scientific validity, clinical performance, clinical benefits to patients, design characteristics and intended purpose of similar devices, including details of their similarities and differences with the device in question;
- (f) summary of the benefit-risk analysis and the risk management, including information regarding known or foreseeable risks and warnings;
- (g) in the case of devices that include tissues, cells and substances of human, animal or microbial origins detailed information on the tissues, cells and substances, and on the compliance with the relevant general safety and performance requirements and the specific risk management in relation to those tissues, cells and substances;
- (h) a list detailing the fulfilment of the relevant general safety and performance requirements set out in Schedule 17, including the standards and CS applied, in full or in part, as well as a description of the solutions for fulfilling the relevant general safety and performance requirements, in so far as those standards and CS have not or have only been partly fulfilled or are lacking;
- (i) a detailed description of the clinical procedures and diagnostic tests used in the course of the performance study and in particular information on any deviation from normal clinical practice.
- (j) the Performance study plan as referred to in paragraphs 2 and 3 of Schedule 27.

Other information

3. The following other information consisting of—

- (a) a signed statement by the person responsible for the manufacture of the device for performance study that the device in question conforms to the general safety and performance requirements laid down in Schedule 17 apart from the aspects covered by the clinical performance study and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the subject;
- (b) where applicable, a copy of the opinion or opinions of the ethics committee or committees concerned;
- (c) proof of insurance cover or indemnification of subjects in case of injury, pursuant to regulation 175;
- (d) documents to be used to obtain informed consent, including the patient information sheet and the informed consent document;

- (e) documents to be used to obtain informed consent, including the patient information sheet and the informed consent document;
- (f) description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data, in particular—
 - (i) organisational and technical arrangements that will be implemented to avoid unauthorised access, disclosure, dissemination, alteration or loss of information and personal data processed;
 - (ii) a description of measures that will be implemented to ensure confidentiality of records and personal data of subjects;
 - (iii) a description of measures that will be implemented in case of a data security breach in order to mitigate the possible adverse effects;
- (g) full details of the available technical documentation, for example detailed risk analysis/management documentation or specific test reports must be submitted to the Secretary of State reviewing an application upon request.

PART 2

Other obligations of the sponsor

4.—(1) The sponsor must undertake to keep available for the Secretary of State any documentation necessary to provide evidence for the documentation referred to in Part 1 of this Schedule but, if the sponsor is not the person responsible for the manufacture of the device intended for performance study, that obligation may be fulfilled by that person on behalf of the sponsor.

(2) The sponsor must have an agreement in place to ensure that any serious adverse events or any other event as referred to in regulation 185(2) are reported by the investigator or investigators to the sponsor in a timely manner.

(3) The documentation mentioned in this Schedule must be kept for a period of time of at least 10 years after the clinical performance study with the device in question has ended, or, in the event that the device is subsequently placed on the market, for at least 10 years after the last device has been placed on the market.

(4) The documentation referred to in this Schedule must be kept at the disposal of the Secretary of State for the period indicated in sub-paragraph (3) irrespective of the continued status (and whether the person continues trading or not) of the sponsor or the sponsor's legal representative.

(5) The sponsor must appoint a monitor that is independent of the investigation site to ensure that the clinical performance study is conducted in accordance with the Clinical Performance Study Plan, the principles of good clinical practice and Part IX of these Regulations.”

Signed by the authority of the Secretary of State for Health and Social Care

Name
Minister of State
Department of Health and Social Care

Address
Date

Name
Two of the Lords Commissioners of Her Majesty's Treasury
Her Majesty's Treasury

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by section 8(1) of , paragraph 7(2) of Schedule 4 and paragraph 21 of Schedule 7 to the European Union (Withdrawal) Act 2018

(c. 16) (“the Withdrawal Act”) in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a) of the Withdrawal Act) arising from the withdrawal of the UK from the European Union

These Regulations make amendments to legislation in the field of medical devices.

Part 1 amends the existing Medical Devices Regulations 2002 (“the 2002 Regulations”) which implemented three European Union Directives which aimed to ensure the safety and quality of general medical devices, active implantable medical devices and in vitro diagnostic medical devices (“the three Directives”). Part I also makes certain transitional and savings provisions which seek to mirror the transitional and savings provisions which exist as part of current EU law in the two EU Regulations (see below). Part 1 also amends EU tertiary legislation which relates to the regime implemented by the 2002 Regulations and revokes certain tertiary legislation along with the two EU Regulations insofar as they are retained EU law.

Parts 2 and 3 restate (by inserting restated new provisions into the 2002 Regulations) the provisions of two EU Regulations: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5th April 2017 on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5th April 2017 on in vitro diagnostic medical devices (the two EU Regulations). Rights, powers, liabilities, obligations restrictions, remedies and procedures contained in the two Regulations were retained by virtue Section 4 of the Withdrawal Act and limited provisions were retained by virtue of section 3 of that Act.

Part 4 inserts new Schedules into the 2002 Regulations which reproduce the procedures in the Annexes to the two EU Regulations.

An explanatory memorandum is published alongside this instrument on www.legislation.gov.uk.

An impact assessment of the effect that this instrument will have on the costs to business, the voluntary sector and the public sector is available from the Medicines and Healthcare Products Regulatory Agency, 10 South Colonnade, Canary Wharf, London, E14 4PU and is published alongside this instrument www.legislation.gov.uk.