The following is a high level summary of the content of [The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019](https://www.legislation.gov.uk/uksi/2019/791/contents/made). These are the UK’s domestic regulations on medical devices and in vitro diagnostics post-EU membership.

The reader should keep in mind two points: First, that these regulations were initially prepared for 2018 in preparation for the “Exit day” in 2019. The 2018 Withdrawal act was subsequently amended by the final Brexit legislation, the European Union (Withdrawal Agreement) Act of 2020, which changed “Exit day” to “Implementation period completion day”, 31 December 2020. Second, considering again their origin in 2018, the first priority of these regulations was to establish the AIMDD, MDD and IVDD as UK domestic regulations for the intervening period until 2020/2022. This is the reason for the multiple changes to the UK’s already exiting medical device and IVD registration system.

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

**Regulation 1** specifies that these regulations come into force on “Exit day”. New registration requirements, fees and definitions associated with registration will come into force four months after Exit day. New medical device requirements ***(Regulation 10****)* come into force on 26 May 2020, and new IVD requirements *(****Regulation 11****)* come into force on 26 May 2022.

**Regulation 2** clarifies that this 2019 Act is an amending act to the 2002 Medical Devices Regulations. The 2002 act was the legislation that originally implemented the European medical device directives into UK law. *Note: This means that the 2019 regulation is not a stand-alone regulation and, at least at the time of writing this commentary, neither is there a consolidated version. One has for the time being to read the 2002 Regulation, together with the 2019 amendments, in order to understand the UK’s new medical device regulations.*

**Regulation 3** amends Part I of the 2002 Regulations, the provisions applicable to all medical devices. These amendments are quite wide ranging and include the following:

* Adds 26 new “Schedules” *(a UK specific term equivalent of the EU’s Annexes)* to the 2002 Regulations (See **Regulation 12**).
	+ The first Schedule (No. 2) lists those countries with MRAs on conformity assessment bodies *(presumable to support MDSAP)*, while the remainder *(Nos. 3-28)* are Annexes from the MDR and IVDR.
* Revises the definition of “Authorised representative” to being a person/entity outside the UK but inside the EEA.
* Limits the old EU Directives *(AIMDD/MDD/IVDD)* to being applicable until Brexit day.
* Removes references to the Medicines and Machinery Directives and replaces them with references to the UK’s own equivalent legislation.
* Removes EC *(European Community)* from references to Conformity Assessment Body *(CAB)*.
* Limits the definition of “Clinical investigations” to those performed in the UK
* Amends the definitions of “Placing on the market” and “Putting into service” by replacing “Community market” with the “United Kingdom”
* Removes the term “Harmonised Standard” from UK legislation and introduces a new UK specific term of “Designated Standard” for Standards that are accepted by the UK authorities.
	+ Introduces another UK specific term “UK Responsible Person” *(equivalent of the EU’s Authorised Representative) Note: Do not confuse this term with “Person Responsible for Regulatory Compliance”. They are quite different.*
* Amends the definition of mutual recognition agreements and reference the new Schedule *(Annex)* No. 2 listing the countries with a mutual recognition agreement.
* Bringing together several of the EUMDR/EUIVDR’s mentions of confidentiality into one place.
* Allowing medical devices to comply with the new regulations before May 2020 and IVDs before May 2022.
* Allows for transitional registration requirements for legacy AIMDD/MDD/IVDD devices.
* Allowing for transitional arrangement on registration data requirements should the new database not be available in time.
* Allowing legacy AIMDs, MDs and IVDs to be registered until 2025.
* Revoking a number of Commission Decisions and EU Regulations and aligning definitions across other UK legislation that mentions medical devices.

**Regulation 4** amends Part II of the 2002 Regulations on general medical devices.

* The amendment updates the UK’s rules for placing “general medical devices” on the market. *(i.e. the MDD legislation)*
* They update the registration obligations for legacy (MDD) general medical devices to cover the transitional period 2020-2025. *Note: It’s a half-way house between the limited registration requirements of the MDD and the full MDR registration requirements.*
* The person registering must have an address in the UK and fulfil many of the obligations found in Article 11 on Authorised Representatives of the EU MDR.

**Regulation 5** amends Part III of the 2002 Regulations on active implantable medical devices.

* The amendments update the UK’s rules for placing “active implantable medical devices” on the market. *(i.e. the AIMDD legislation)*
* They update the registration obligations for legacy (AIMDD) active implantable medical devices to cover the transitional period 2020-2025. *Note: It’s a half-way house between the limited registration requirements of the AIMDD and the full MDR registration requirements.*
* The person registering must have an address in the UK and fulfil many of the obligations found in Article 11 on Authorised Representatives of the EU MDR.

**Regulation 6** amends Part IV of the 2002 Regulations on in vitro diagnostic medical devices.

* The amendments update the UK’s rules for placing “in vitro diagnostic medical devices” on the market. *(i.e. the IVDD legislation)*
* They update the registration obligations for legacy (IVDD) in vitro diagnostic medical devices to cover the transitional period 2022-2025. *Note: It’s a half-way house between the limited registration requirements of the IVDD and the full MDR registration requirements*.
* The person registering must have an address in the UK and fulfil many of the obligations found in Article 11 on Authorised Representatives of the EU IVDR.

**Regulation 7** amends Part V of the 2002 Regulations on Notified and Conformity Assessment bodies.

* The amendments limit the UK regulations to applying to UK notified bodies *(not EC notified bodies)*,
* Recognises Conformity Assessment Bodies from additional countries who have a mutual recognition agreement with the UK.

**Regulation 8** amends Part VI of the 2002 Regulations on fees payable.

* Minor amendments only maintaining consistency with changes to wording made in the other amendments. *For example, on mutual recognition agreements.*

**Regulation 9** amends Part VII of the 2002 Regulations on general, enforcement and miscellaneous items.

* Minor amendments maintaining consistency with changes to wording made in the other amendments. *For example, “UK person responsible” in place of “Authorised representative”.*
* Adds “Schedule 2 Mutual Recognition Agreement countries”
	+ Australia, New Zealand, Canada, The United States of America, The Swiss Confederation.

**Regulation 10** amends and extends the original 2002 Regulations by introducing a new Part VIII, the medical device regulations.

* The new Part VIII introduces 68 new regulations (Nos 68 to 135). *Essentially equivalent to the EU MDR Articles 1 to 100, excluding Articles 3, 12, 24, 33, 34, 35-50, 54-58, 78, 79, 81, 91, 96, 99 100. i.e. excluded are the Articles on Notified Bodies and Articles which describe collaboration with the EU Commission or between Member States.*

**Regulation 11** amends and extends the original 2002 Regulations by introducing a new Part IX, the in vitro medical device regulations.

* The new Part IX introduces 63 new regulations, Nos 136 to 198. *Essentially equivalent to the EU IVDR Articles 1 to 116.*

**Regulation 12** amends and extends the 2002 Regulations original two Schedules, adding another 26 Schedules as follows:

* Schedule 2A modifies the existing Annexes of the AIMDD, MDD and IVDD
* Schedules 3 to 16. *Essentially equivalent to the EUMDR Annexes I to VI, VIII to XI, XIII to XVI – what are not adopted are the two Annexes on Notified Bodies and their certificates and the Correlation table.*
* Schedules 17 to 28. *Essentially equivalent to the EUIVDR Annexes I to VI, VIII to XI, XIII to XIV – again, what are not adopted are the two Annexes on Notified Bodies and their certificates and the Correlation table.*