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Medical Devices - Electronic IFUs

E-update - 27th February 2013

Background

Commission Regulation (EU) No 207/2012 on electronic instructions for use (EIFU) of medical devices was published on 9 March 2012 and comes into effect from 1 March 2013. The Regulation is directly applicable in all EU Member States without a transition period and establishes the conditions under which the instructions for use of the following medical devices covered under Directive 90/385/EEC and Directive 93/42/EEC may be provided in electronic form:

- Active implantable medical devices and their accessories covered by Directive 90/385/EEC intended to be used exclusively for the implantation or programming of a defined active implantable medical device.
- Implantable medical devices and their accessories covered by Directive 93/42/EEC intended to be used exclusively for the implantation of a defined implantable medical device.
- Fixed installed medical devices covered by Directive 93/42/EEC.
- Medical devices and their accessories covered by Directives 90/385/EEC and 93/42/EEC fitted with a built-in system visually displaying the instructions for use.
- Stand-alone software covered by Directive 93/42/EEC.

Manufacturers can provide EIFUs for the above devices when they are intended for exclusive use by professional users and the use by other persons is not reasonably foreseeable. The Regulation allows EIFUs to be provided both in addition to and as an alternative to instructions for use in paper form with specific requirements identified for each scenario.

In Vitro Diagnostic (IVD) medical devices covered by the Directive 98/79/EC are not included in this Regulation and guidance on providing EIFUs for IVD devices can be found in MEDDEV 2.14/3.

Regulation Requirements

The Regulation identifies specific requirements related to EIFU contents, risk assessments, manufacturer obligations, verification and validation, EIFU access and websites providing the [illegible]. Manufacturers are referred to the EIFU Regulation for full details. Notified Bodies are

required to review the EIFUs as a part of the conformity assessment procedures based on a specific sampling method adapted to the device classification and the complexity of the product.

BSI Assessment of Electronic Instructions for Use

Manufacturers who intend to provide EIFUs should notify their BSI Scheme Manager in order to determine the subsequent steps required for review of the EIFUs by the Notified Body. It is expected that any website(s) providing the EIFUs are functional prior to BSI Review of the EIFUs. As per the Regulation requirements of NB assessment of EIFUs, BSI will be taking the following approach towards reviewing EIFUs.

Class III Devices & AIMD Devices

EIFUs of all Class III devices and AIMD devices will require a review and approval by the Notified Body. For new CE applications, the quality system aspects of the EIFUs will be assessed during the BSI QMS audits and the EIFUs themselves will be assessed from a technical perspective as part of the Design Dossier review.

The introduction of EIFUs for approved CE-marked devices will be considered a substantial change requiring review and approval prior to implementation. Manufacturers are required to submit the EIFUs and associated documentation for NB review and the normal procedures for review of changes to class III devices will be followed. At the conclusion of the BSI Review, the associated Design Exam Certificates will be reissued with the History Page identifying compliance to (EU) No 207/2012. The QMS aspects of the EIFU provision will be assessed during subsequent BSI QMS audits.

Class IIb, IIa Devices

For new CE applications, the quality system aspects of the EIFUs will be assessed during the BSI QMS audits and the EIFUs themselves will be assessed as a part of the Technical File reviews. Manufacturers intending to provide EIFUs for approved CE-marked devices can start doing so only afteradvising BSI of their intent and providing statements of compliance with the applicable requirements ofEIFU Regulation. EIFUs for IIa and IIb devices will be assessed from a technical perspective during Technical File Reviews as per the Technical File Sampling Plan in place for the Manufacturer. BSIScheme Managers will work with the Manufacturers and if required, amend the Technical File Sampling Plans in order to expedite the reviews of EIFUs. The QMS aspects of the EIFU provision will be assessed during subsequent BSI QMS audits.

EIFUs for Medical Devices Outside the Scope of (EU) No 207/2012

It is unclear if EIFUs may be provided for devices outside the scope of this Regulation. BSI may consider EIFUs for these devices on a case-by-case basis and as per the requirements of the medical device directive. Manufacturers interested in providing EIFUs for devices that fall outside the scope of (EU) No 207/2012 are requested to contact their BSI Scheme Manager for further discussion.

Final Comments

It is expected that the Medical Device Industry will take advantage of the EIFU Regulation to provide EIFUs in order to reduce costs while maintaining a high level of safety for the patients. Currently, there is a general lack of guidance on the EIFU Regulation and its implications on the Manufacturers and Notified Body Assessments. BSI has taken a pragmatic and risk-based approach to reviewing EIFUs based on the Regulatory Requirements and may have to revise its policy in the future based on the experience gained and any other future EU level guidance.

Manufacturers are requested to contact their BSI Scheme Managers for any questions they may have on EIFUs and the implications of the EIFU Regulation on their devices.

References

Commission Regulation
(EU) No 207/2012
of March 9, 2012 on electronic instructions for use of medical devices.

MHRA Guidance
on EU Commission Regulation (EU) No 207/2012.

MEDDEV 2.14/3
- Supply of Instructions For Use (IFU) and other information for In-vitro Diagnostic (IVD) Medical Devices.

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