Electronic Instructions for Use (eIFU) for Medical Devices – New Regulation released by the European Commission

Instructions for Use (IFU)

The provision of an IFU is one of the most important requirements of all directives related to MD, AIMD and IVD.
In addition of providing information about the safe and proper use of a device, its expected performances and the precautions to be taken, the IFU must be properly readable. This includes suitable font sizes and graphics, the understandability of texts or the quality of translations. The needs and abilities of potential users should also be taken into account.

E-Labeling for Professional Users Only

From March 1st, 2013, Regulation No. 207/2012 enables medical device manufacturers to provide an electronic IFU. A definition of the commonly called e-labeling is given as:
"(…) instructions for use in electronic form means instructions for use displayed in electronic form by the device, contained in portable electronic storage media supplied by the manufacturer together with the device, or instructions for use available through a website."

Applications and Limitations

E-labeling is applicable for

- active implantable medical devices and implantable medical devices including their accessories intended to be used exclusively for the implantation or programming of a defined active implantable medical device
- fixed installed medical devices
- medical devices and their accessories fitted with a built-in system visually displaying the instructions for use
- stand-alone software covered by the relevant directive

The regulation is only applicable if the devices and accessories are intended for exclusive use by professional users and if the use by other persons is not reasonably foreseeable.

Requirements for the Manufacturer

- Clear indication either on packaging or the device itself that the IFU is supplied electronically.
- Information on how to access the IFU in electronic form must be provided.
- The online access of an IFU for devices with a defined expiry date requires a stable and directly accessible internet address for at least **two years** after the end of the expiry date of the last produced device.
- For devices without a defined expiry date and for implantable devices, the instructions for use must be available in electronic form for a period of **15 years** after the last device has been manufactured.
- The paper form of the IFU must be available upon request at any time.

Involvement of the Notified Body

The fulfillment of the obligations shall be reviewed by a notified body during the procedure of conformity assessment as referred to in the applicable directives. Medical devices classified as class I devices are excluded from a review of a notified body.

For any question or inquiry, please do not hesitate to contact us!
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