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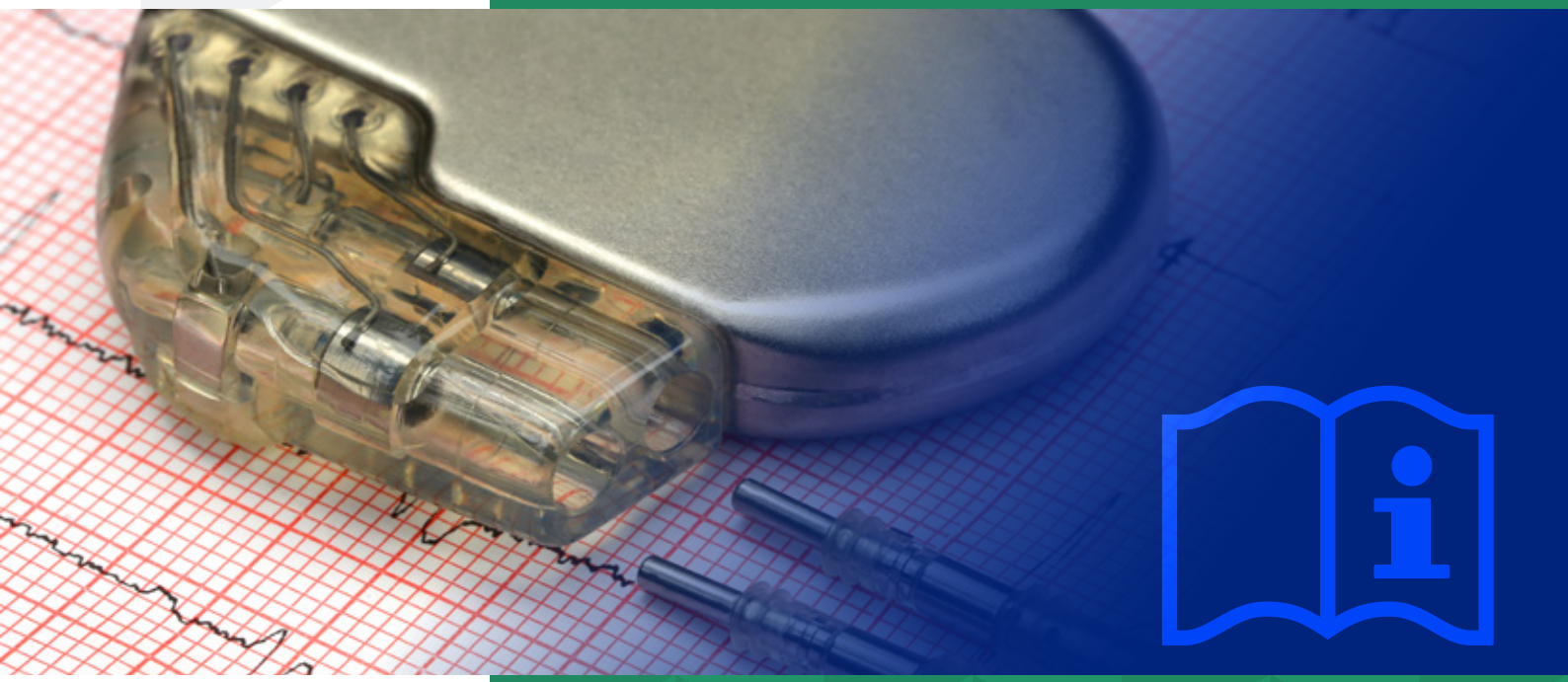
Labeling/eIFU Implementation Regulation Summary for EU MDR



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Labeling/eIFU: Implementation Regulation Summary for EU MDR

It is beneficial for some medical devices to be provided with instructions for use in electronic form (eIFU) instead of in paper form as it helps to reduce the environmental burden, maintains or improves the level of safety, can be accessed readily in all union languages and reduces costs for the medical device industry. To meet this requirement, the European Commission on December 14th, 2021 issued an **Implementing Regulation (EU) 2021/2226** with 11 Articles, laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices.

Regulation Overview

This Implementing Regulation establishes the conditions under which information in the instructions for use may be provided by manufacturers in electronic form, as referred to in **MDR Annex I**, Chapter III, point 23.1(f). The Regulation does not cover products listed in Annex XVI, EU MDR (devices without an intended medical purpose). The regulation repeals Commission Regulation (EU) No 207/2012, however Commission Regulation (EU) No 207/2012 continues to apply to devices placed on the market or put into service during the transitional period set out in MDR Article 120(3) until **26 May 2024**.

The obligations laid down in Articles 4 to 7 of this Regulation shall be reviewed by a notified body during the procedure applicable for conformity assessment as referred to in Article 52 of Regulation (EU) 2017/745.

Attention to further down device manufacturers

The instructions for use in electronic form instead of in paper form which manufacturers may provide for the below medical devices that are:

- Implantable and active implantable along with their accessories
- Fixed installed and their accessories
- With their accessories fitted with a built-in system visually displaying the instructions for use
- For software, manufacturers may provide eIFU by means of the software itself instead of in paper form

Key conditions to provide eIFU: Under the following conditions the manufacturers may provide IFU in electronic form instead of in paper form for the above listed devices

- The devices and accessories are intended for exclusive use by professional users.
- The use by other persons is not reasonably foreseeable.

Risk Assessment

The manufacturers shall undertake a documented risk assessment which shall cover at least the following elements:

- ✓ Knowledge and experience of the intended users mainly regarding use of the device and user needs

- ✓ Environmental characteristics
- ✓ Knowledge and experience of the intended user of hardware and software needed to display eIFU
- ✓ Access of the user to the reasonably foreseeable electronic resources needed at the time of use
- ✓ Performance of safeguards to ensure the data and content are protected from tampering
- ✓ Safety and back-up mechanisms in the event of hardware/ software fault
- ✓ Foreseeable medical emergency situations requiring the provision of information in paper form
- ✓ Impact caused by the temporary unavailability of the specific website as well as Safety measures
- ✓ Evaluation of the period within which the IFU shall be provided in paper form at the user's request
- ✓ Assessment of the website's compatibility displaying the eIFU with different devices which could be used to display those instructions
- ✓ Management of different versions of the IFUs

This documented risk assessment shall be updated based on the gained post-marketing experience

Information provided on label for eIFU

The manufacturers are advised to clearly indicate on the label that IFU of the device are supplied in electronic form instead of in paper form and it should be provided on each unit of packaging. For the fixed installed medical devices the information shall also be provided on the device itself.
In case of software, the information shall be provided at the location from where access to the software is granted.

How to access the IFU in electronic form

The manufacturer must provide information needed to access the IFU in electronic form by providing

- Any information needed to view the instructions for use
- The Basic UDI-DI and/or the UDI-DI of the device or any additional information for the identification of the device, including its name and if applicable the model
- Relevant manufacturer contact details e.g. manufacturer's name, address, email address or other means of online communication and website
- Details on where and how instructions for use in paper form can be requested and within which time they can be obtained at no additional cost
- For devices and accessories referred, a part of the IFU is intended to be provided to the patient, that part shall not be provided in electronic form
- The eIFU shall be available entirely as text, which may contain symbols and graphics, with at least the same information as the IFU in paper form. Video or audio files may be provided in addition to the text

Website requirements

If the manufacturer provides the IFU in electronic form on an electronic storage medium together with the device or if the device itself is fitted with a built-in system visually displaying the instructions for use then the eIFU shall also be made accessible to the users through a website.

- → The eIFU should be provided in a commonly used format that can be read with freely available software
- → It shall be protected against unauthorised access and tampering of content
- → It shall be provided in such a way that the server downtime and display errors are reduced as far as possible
- → It shall fulfill the requirements of General Data Protection Regulation (EU) 2016/679 (GDPR)
- → The internet address shall be stable and directly accessible
- → All issued historical electronic versions of the eIFU and their date of publication shall be available on the website

Key Points to be considered to provide eIFU

- The risk assessment shall demonstrate that providing eIFU maintains or improves the level of safety obtained by providing IFU in paper form
- Shall provide eIFU in all Member States ***in an official language*** where the product is made available or put into service unless justified in risk assessment
- Shall have a system in place to provide the IFU in paper form at ***no additional cost*** for the user within at least ***7 calendar days*** or as set out in risk assessment
- Shall provide information (on the device or a leaflet) on foreseeable medical emergency situations on how to start the device
- Shall ensure that displaying the instructions for use does not impede the safe use of the devices fitted with a built-in system
- Shall provide information on software and hardware requirements needed to display the IFU in their catalogue or other appropriate device information support
- Shall keep the eIFU available for users after the last device has been placed on the market
    - o For devices with ***a defined expiry date***, except implantable devices - for **10 years** and **at least 2 years** after the end of the expiry date of the last produced device
    - o For devices ***without a defined expiry date and implantable devices*** - for **15 years**
- Effective systems and procedures shall be in place to ensure that device users having downloaded IFU from the website can be informed in case of updates or corrective actions

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