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Short communication

eIFUs as a default option for medical devices used by professional users: regulatory developments and implications

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Introduction

Instructions for use (IFUs), as part of the documentation accompanying medical devices and containing the information provided by the manufacturer, shall comply with the requirements laid down in the applicable EU regulatory framework. The format enabling user access to this information represents a key element for ensuring the safe and effective use of medical devices.

In the context of ongoing digitalization, technological advancements across sectors, including healthcare, and increasing focus on environmental sustainability, the EU regulatory framework concerning IFUs for medical devices is evolving. Regulation (EU) 207/2012 was the first EU regulation addressing electronic instructions for use (eIFUs), allowing their use under very limited conditions.

It was later repealed by Implementing Regulation (EU) 2021/2226, which was subsequently amended by Implementing Regulation (EU) 2025/1234, significantly expanding the scope and conditions for the use of eIFUs Mecomed (2024), Regulation (EU) 2021/2226, MedTech Europe, eurom, and EuromContact (2025).

Benefits of the amending Regulation (EU) 2025/1234 compared to Regulation (EU) 2021/2226

Scope of devices and user population

According to Article 3 of Regulation (EU) 2021/2226, manufacturers were allowed to provide instructions for use in electronic form instead of paper form only for a limited group of medical devices covered by Regulation (EU) 2017/745. These included implantable and active implantable medical devices and their accessories, fixed installed devices and their accessories, and devices equipped with built-in systems displaying the instructions for use.

The replacement of paper IFUs with eIFUs was allowed only if the conditions set out in Article 3(2) were fulfilled, namely that the devices were intended exclusively for professional users and that use by other persons was not reasonably foreseeable.

The amendment introduced by Regulation (EU) 2025/1234 significantly expands this scope, allowing the provision of electronic instructions for use as a default option for all devices intended for professional users. This applies to devices covered by Regulation (EU) 2017/745, including medical devices, accessories, and products without an intended medical purpose, as well as legacy devices

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subject to transitional provisions under Article 120 of Regulation (EU) 2017/745.

Furthermore, the amended provision clarifies that where it is reasonably foreseeable that a device intended for professional use may also be used by lay persons, manufacturers shall provide paper instructions for use intended for lay users. Therefore, in such cases, eIFUs can be used in parallel, but do not replace the obligation to provide paper IFUs for lay users (Regulation (EU) 2021/2226, Regulation (EU) 2025/1234, Casus Consulting (2025), and Seib (2025).

Manufacturers' obligations

Although the use of eIFUs is permitted, manufacturers must fulfil specific obligations prior to their implementation in order to ensure the safe use of the devices.

A documented risk assessment must be performed, taking into account user competence, availability of electronic resources, emergency situations, cybersecurity aspects, and other requirements set out in Article 4.

In addition, Article 5 defines the conditions under which eIFUs may be provided instead of paper format, including the obligation to have a system in place for supplying paper IFUs upon user request.

Labelling requirements defined in Article 6 ensure that users are adequately informed about access to eIFUs and the conditions under which paper IFUs can be obtained.

When eIFUs are provided via a website, Article 7 establishes specific requirements for the website. With the amendment introduced by Regulation (EU) 2025/1234, some of these requirements have been revised.

In particular, the requirement to provide all previous versions of eIFUs on the website, including their publication dates, is no longer applicable. In contrast, the requirement related to the EUDAMED UDI database has been updated, requiring manufacturers to provide the internet address of the website containing eIFUs (Casus Consulting, 2025; Seib, 2025).

Conclusion

The latest regulatory developments concerning eIFUs, particularly the amendment introduced by Regulation (EU) 2025/1234, significantly expand their use in the EU, transitioning from a limited exception to a broadly accepted default option for devices intended for professional users.

These changes provide clear benefits for manufacturers, users, and environmental sustainability, including improved access to up-to-date information, enhanced usability, and increased efficiency in information distribution.

However, manufacturers must ensure full compliance with the applicable requirements for the implementation of eIFUs, in order to guarantee patient and user safety, appropriate device use, and reliable access to information equivalent to, or exceeding, that provided by traditional paper-based instructions (MedTech Europe, eurom, and EuromContact, 2025; Mecomed, 2024).

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