

Digitalization Instructions for Use EU Issues Updated Framework for eIFUs of Medical Devices

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The European Commission recently published its [proposal](#) to revise the decade-old framework for electronic instructions for use (e-IFUs) of medical devices (Draft Regulation). The Draft Regulation aims to update the current rules applicable to e-IFUs in light of the [Medical Devices Regulation](#) (MDR) that will apply from May 26, 2021. The Draft Regulation is relevant for manufacturers of medical devices that wish to provide e-IFUs for their medical devices.

The Draft Regulation was subject to a public consultation between April 27, 2021 and May 25, 2021. Relevant stakeholders have provided their comments on the draft Regulation (see comments provided [here](#)). The European Commission plans to adopt the final version of the Regulation in the second quarter of 2021.

The Draft Regulation will replace the currently applicable rules, dating back to 2012, set out in [Commission Regulation \(EU\) 207/2012](#). That Regulation established the conditions for the use of e-IFUs of medical devices subject to the [Medical Devices Directive](#) and the [Active Implantable Medical Devices Directive](#).

The current Draft Regulation expands the use of e-IFUs to a larger group of medical devices and introduces new requirements and conditions applicable to e-IFUs for devices covered by the MDR.

E-IFUs allowed for a larger group of medical devices

Under the Draft Regulation, the use of e-IFUs is still limited to certain medical devices and accessories. In particular, manufacturers will be able to provide e-IFUs only where the instructions relate to the following devices covered by the MDR:

- implantable and active implantable medical devices and their accessories;
- fixed installed medical devices, that is, they cannot be moved from their installed location without using tools or apparatus; and/or
- medical devices and their accessories fitted where a built-in system visually displays the IFU.

To benefit from the opportunity to provide e-IFUs, devices falling within scope must also still be intended exclusively for use by professional users, and use of the medical devices by nonprofessional users must not be reasonably foreseeable.

Software covered by the MDR

The currently applicable regulation permits the use of e-IFU for stand-alone software covered by the Medical Devices Directive. Stand-alone software is software not incorporated in a medical device at the time of its placing on the market. However, the use of e-IFU is subject to similar limitations and requirements as those mentioned above.

The Draft Regulation expands the exception to use e-IFU to all software falling within scope of the MDR.

Moreover, the Draft Regulation opens the possibility for manufacturers of software to also provide e-IFUs when these are not exclusively intended for professional users. Manufacturers of software (e.g., apps) that fall within scope of the MDR and are intended for use by patients or other nonprofessional users will now also be able to provide e-IFUs.

According to the Draft Regulation, these e-IFUs must be provided at the location from which access to the software is granted.

Medical devices without an intended medical purpose

The Draft Regulation will not apply to products that do not have an intended medical purpose (i.e., those listed in Annex XVI to the MDR). These products include, for example, equipment for liposuction or laser equipment for tattoo removal.

Other new requirements for e-IFUs

Manufacturers that wish to use e-IFUs must still perform a documented risk assessment. However, the Draft Regulation introduces two new elements manufacturers must take into account when performing such risk assessment: (1) the assessment of the e-IFU's compatibility with different devices that could be used to display the instructions and (2) the management of different versions of the e-IFU, where applicable.

The Draft Regulation also provides that manufacturers using the e-IFU option must meet the following requirements:

- For medical devices (other than implantable devices) with a defined expiration date, the e-IFU must be kept available for users in electronic form for 10 years after the last device has been placed on the market and at least two years after the end of the expiration date of the last produced device. This 10-year retention is a new requirement under the Draft Regulation.
- For medical devices without a defined expiration date and implantable devices, the e-IFU shall be available for the users in electronic form for 15 years after the last device has been placed on the market.

- The e-IFU shall be available on the website in an official language of the European Union determined by the member state in which the medical device is made available.
- Effective systems and procedures shall be in place to ensure that users who have downloaded the e-IFU are informed in case of updates or corrective actions related to that e-IFU.
- All issued historical versions of the e-IFU must be available on the website.

Data privacy and cybersecurity considerations

Importantly, the Draft Regulation makes explicit reference to the EU General Data Protection Regulation (GDPR). In particular, the Draft Regulation requires that websites containing instructions for the use of a medical device should fulfill the transparency requirements under the GDPR. In turn, manufacturers should ensure that all necessary fair processing information (e.g., as it relates to the purposes and legal bases for processing, the retention of the personal data, and any international transfers of personal data) are provided on the website most likely in the form of an online privacy policy. To the extent consent is being obtained for the processing of the personal data, this consent will need to be GDPR-compliant (including as it relates to the use of any nonessential cookies on the website).

Transition provisions

The current regulation will continue to apply until May 26, 2024, to medical devices that were placed on the market under the Medical Devices Directive and the Active Implantable Medical Devices Directive and in accordance with the transitional provisions of the MDR. The Draft Regulation, once adopted, will apply to medical devices, including software, covered by the MDR.

The Draft Regulation provides an opportunity for manufacturers of medical devices, including software covered by the MDR, to go “paper free.” Manufacturers should carefully review the Draft Regulation and consider whether they meet the conditions to provide e-IFU for their medical devices.

CONTACTS

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