Joint position of MedicalMountains GmbH and SPECTARIS:

Electronic Instructions for Use (eIFU) for Medical Devices

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Introduction

When Implementing Regulation (EU) 2021/2226[1] laying down detailed rules for the implementation of Regulation (EU) 2017/745[2] (MDR) with regard to electronic instructions for use (eIFUs) for medical devices was published in December 2021, disillusionment spread throughout the German medical technology industry. The hope was, that the revision of the regulation would be associated with an expanded scope for the use of eIFUs - making them the standard in the professional environment and only issuing a printed version on request. This was only the case for software in accordance with the MDR, where improvements have been made.

MedicalMountains and SPECTARIS have been working intensively on the topic of eIFU for a long time. Position papers on the intended revision of the scope of application were published in May 2019[3] and June 2020[4]. As little as the legal framework has changed, the core demands then and now remain very similar. Nevertheless, the climate within the industry has been continuously analyzed. The most recent activity in this area is a joint survey among medical device manufacturers, the results of which were presented in July 2023[5]. The Survey results supplement those of a survey among users from 2021[6]. The feedback collected from manufacturers and users has been incorporated into this position paper.

The benefits of the eIFU are still not sufficiently recognized at EU level. Manufacturers have already made significant progress in this area. Many offer digital versions on a voluntary basis in addition to the paper version. It is incomprehensible why the frequently propagated digitalization strategy is being slowed down in an area where it can have a comprehensive benefit.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R2226
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745
[3] https://www.spectaris.de/fileadmin/Infothek/Medizintechnik/Positionen/20190508_SPECTARIS_Positionspapier_eIFU_final.pdf
[4] https://medicalmountains.de/produkt/positionspapier-eifu-2020/
[5] MedicalMountains GmbH and SPECTARIS: „Elektronische Gebrauchsanweisungen für Medizinprodukte (eIFU) – Ergebnisse einer Umfrage unter Herstellern von Medizinprodukten“; July 2023
[6] MedicalMountains GmbH and SPECTARIS: „Elektronische Gebrauchsanweisungen für Medizinprodukte (eIFU) – Ergebnisse einer Umfrage unter Anwendern von Medizinprodukten“; October 2021

Arguments and approaches for urgently adapting the legal basis for eIFUs for medical devices

eIFUs contribute to resource and climate protection

Digitalized processes are state of the art in many areas of social life and industry and are playing an increasingly central role in terms of resource conservation. Paper production still interferes with the forest ecosystem and consumes significant amounts of energy. In 2022, the paper industry used around 79 % recycled paper and was thus able to reduce wood, water and primary energy consumption per ton of paper. Nevertheless, an increase in paper consumption puts the resulting efficiency gains into perspective[7]. According to the latest survey by MedicalMountains GmbH and SPECTARIS, a complete switch to eIFUs could save an average of around 500 tons of paper per company per year. For larger companies, this would already amount to over 6000 tons per year per company. Such figures have a massive impact on the CO2 footprint of a medical technology company. These paper savings are not yet possible - not because the companies are not willing to do otherwise, but because they are not allowed to.

The elimination of printed instructions for use also enables smaller packaging systems. Here, too, there is potential to reduce not only the amount of plastic or cardboard used, but also the overall weight. In particular for products that are produced in large quantities and need to be individually packaged with printed instructions for use - typically surgical instruments - even a small weight saving could add up to an annual amount that noticeably reduces energy consumption during transport. This is apart from the fact that one or a few instructions for use are usually sufficient, regardless of how many instruments are actually ordered. The surplus copies are thrown away unseen.

eIFUs keep information up to date in real time

When a medical device is launched on the market, it is equipped with the latest instructions for use at that time - for most products these are still in printed form. If a manufacturer makes changes, it becomes complicated to inform users. The route via dealers or even customers known by name is costly, time-consuming, and uncertain. Basically, users only find out about important warnings when they order a new, identical medical device. Mandatory use of eIFUs from the very first moment reduces this risk. Corresponding information chains could be implemented with little effort (e.g., through a one-off registration with the manufacturer) so that information on updated details can be communicated in real time and with pinpoint accuracy.

[7] https://www.umweltbundesamt.de/daten/ressourcen-abfall/verwertung-entsorgung-ausgewaehlter-abfallarten/altpapier

eIFUs are more easily available

Apart from stationary, permanently installed equipment, medical devices are on the move within a clinic. For example, they go through sterilization and preparation for reuse processes or switch between stations. It is highly unlikely that printed instructions for use will "move" with the product and always be located exactly where it is. The same applies to leafing through non-sterile folders during an operation. Such information is stored digitally and made available. This can be done using an eIFU before or independently upon delivery of a medical device. Portable devices or installed computers can be used to access electronic instructions for use provided online from almost anywhere – especially given that the users in question are professional in nature.

Nevertheless, a manufacturer uses a thorough risk analysis as part of its existing risk management system to assess the advantages and disadvantages of each individual medical device, as well as the associated potential risks, and decides how to develop the strategy. Emergency kits for paramedics can be cited as an example of the sensible use of printed instructions for use. Such areas of application are known to manufacturers and are taken into account accordingly. In addition, it will still be possible to print out the instructions for use or request them in printed form from the manufacturer even when using eIFUs.

eIFUs are more user-friendly

According to the manufacturer survey conducted by MedicalMountains GmbH and SPECTARIS, more than half of customers (53 %) would like electronic instructions for use. The direct user survey revealed an even higher figure of 80 %. One major advantage of an eIFU is that the digital version can be provided with features that give staff more benefits when using the products - whether as initial training or with assistance for advanced users. For example, explanatory videos can be integrated and called up as required. The visualization of various processes in conjunction with the spoken word provides a new depth of information transfer beyond the regulatory framework. The diversity of languages is also better accommodated. As a rule, instructions for use in healthcare facilities are only available in the national language. With the eIFU, the information can be made available in several languages with little effort and for convenient and accurate access by the user.

eIFUs make medical devices safer

Electronic instructions for use improve patient safety. Increasingly extensive paper instructions are not read by users and therefore have the opposite of the desired effect: they jeopardize patient safety. The eIFU, on the other hand, enables faster availability, more up-to-date and contextually searchable information, more user benefits in terms of content and languages, better hygiene, and integration into stable hospital referral processes - all of which are fundamental aspects of safe and progressive patient care. According to the survey conducted by MedicalMountains GmbH and SPECTARIS, the responding manufacturers are aware of this responsibility. 64 % in the EU offer an eIFU in addition to the paper version. They are taking on a

voluntary double burden. No product becomes less safe when electronic instructions for use are offered. The opposite is the case. In the course of safety corrective actions (FSCA) by the manufacturer, relevant information is immediately available to the user. An updated version of the eIFU can be finalized within a few weeks, whereas updating the paper version can take up to 6 months.

eIFUs contribute to successful MDR implementation

The use of electronic instructions for use ensures that companies can implement the requirements of Regulation (EU) 2017/745 (MDR) quickly and uniformly in all EU member states, thus improving the efficiency of the system. Frequent updates of MDR documents by manufacturers, such as the Periodic Safety Update Report (PSUR) and the Summary of Safety and Clinical Performance (SSCP), have a direct impact on the IFU. These must be updated with a new version of PSUR or SSCP. In the case of paper versions of the IFU, this can lead to significant delays in the supply chain. By using eIFU, such delays can be avoided. Changes can be made within a few weeks (usually up to 2 weeks). All necessary language versions in the individual EU member states can be updated simultaneously.

eIFUs meet the EU's objectives in terms of reducing bureaucracy, the Green Deal and digitalization

In October 2023, the European Commission adopted its work program for 2024. It places a particular focus on simplifying regulations for companies throughout the European Union and includes important initiatives to reduce bureaucracy - including the increased use of digitalization. The Commission is also deliberately calling for dialogue with SMEs and proposals for improvement.

eIFUs offer an immediate opportunity to simplify and improve antiquated processes without lowering security standards. They also contribute to the international harmonization of high patient safety standards.

Appeal to politicians

With regard to the important aspects of sustainability, resource and climate protection and the necessary digitalization for global competitiveness, maintaining and holding on to printed instructions for use is outdated and no longer appropriate. In addition, the widespread use of eIFUs increases the safety of medical devices and contributes to patient protection and the successful implementation of the MDR!

In this context, it is absolutely necessary to create a legal basis in the EU in the short-term that allows the general authorization of electronic instructions for use for medical devices for professional users.

The topic of eIFU for medical devices should be a high priority work item. Implementation both by the legislator and by companies can be carried out within a short timeframe and at a relatively low resource cost, thereby achieving extensive positive effects.

Legal Background

Article 2, §14 of Regulation (EU) 2017/745 (MDR) on medical devices refers to instructions for use as "the information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken". Annex I, Chapter III, Paragraph 23 specifies the "requirements regarding the information supplied with the device" for "label and instructions for use". This subsequently concerns the required information, but also the form in which instructions for use are provided. Paragraph 23.1, letter f states: "Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in Regulation (EU) No 207/2012 or in any subsequent implementing rules adopted pursuant to this Regulation."

Regulation (EU) 207/2012 on electronic instructions for use for medical devices has since been replaced by Implementing Regulation (EU) 2021/2226 to the MDR. This regulation elaborates conditions under which manufacturers may provide information in the instructions for use in electronic form instead of in paper form. According to Art. 3, this is generally possible for the following products or product groups:

- implantable and active implantable medical devices and their accessories;
- fixed installed medical devices and their accessories;
- medical devices and their accessories fitted with a built-in system visually displaying the instructions for use.

In each case, however, it must be ensured that use is only by professional users and can be "reasonably" excluded by other persons. For software in accordance with the MDR, manufacturers can provide eIFUs using the software itself.

As part of the transitional provisions, Regulation (EU) 207/2012 continues to apply to "legacy devices" in accordance with Art. 120, para. 3 MDR. The implementing regulation differs from the older regulation primarily with regard to "software". It has been removed from the concept of "professional users".