Electronic Instructions for use (eIFU) for certain medical devices intended for lay users

Position paper

MedTech Europe
from diagnosis to cure

EUROMCONTACT

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1. Introduction

Recently, the electronic instructions for use (eIFU) Regulation (EU Regulation 2021/2226) has been updated by EU Regulation 2025/1234, which expands the possibility of eIFU to all professional use devices. The medical technology industry welcomed this initiative as it marks a crucial moment in the digitalisation of healthcare information. In addition, worldwide initiatives related to the digitalisation of healthcare information abound, and some of these can be found in Annex II of this paper.

In this context, MedTech Europe, the European Federation of Precision Mechanical and Optical Industries (eurom) and the European Association of the contact lens and lens care industry (EuromContact) underline that ongoing digitalisation efforts in the medical technology sector should be pursued in Europe, e.g. the introduction of eIFU for another group of devices. Such a step has the power to contribute significantly to supporting the European Green Deal's overarching goals of climate neutrality, sustainability, and resource efficiency. In addition, with rapid digitalisation becoming more of a norm in every part of life, access to online information is becoming more ubiquitous and expected, including in healthcare.

MedTech Europe, eurom and EuromContact hereby call on the Medical Devices Coordination Group (MDCG) to establish a dedicated workstream under the MDCG New Technologies working group to address further expansion of eIFU to certain medical devices intended for lay users.
We propose expanding the possibility of having electronic instructions for use (eIFU) for certain medical devices used by a lay user when **the following applies**:

- **Professional guidance during initial use**: Providing an explanation or training from a healthcare professional at the outset ensures that users understand how to use the device correctly from the beginning.
- **Recurrent use fostering familiarity**: Repeated use of a device helps users become more comfortable and proficient through practice, leveraging the repetitive nature of their application.

Examples of such devices include contact lenses, urinary catheters, and diabetes management devices, which are used repeatedly, often on a daily basis. These have been mapped in detail in Annex I of this paper.

2. Accessibility

We believe that accessibility of health-related information is essential. Increasingly, this information may be accessed through digital means. According to Eurostat, 93% of EU households had internet access in 2023, and between 82-89% of individuals used a mobile device to access the internet in 2023. [1] Evolving acceptance of delivery of information in a digital format can also be seen among patients. According to a recent European

[1] Eurostat regional yearbook, 2024 edition

Patients' Forum survey, 58% of respondents are open to receiving device use instructions or other information exclusively in digital form, while 38% prefer a combination of digital and paper format. [2]

It should be noted that eIFU:

- makes healthcare information more accessible for individuals with visual or cognitive impairments, such as persons with disabilities, elderly etc., via use of dynamic instructional content (i.e. the ability to shift from written to video/ audible material)
- provides access to the most up-to-date information, available in all languages and enhances user experience through adjustable formats, language preferences and localisation.

Unlike eIFU, paper instructions may pose challenges for the elderly and users with visual impairment. Small font sizes, limited space for visuals (e.g., pictures), and potential physical degradation over time or loss make them less usable. Also, updated paper IFUs are usually not distributed to the lay user - eIFU is the only way a user would always get the most up-to-date information. In addition, the user should always be able to request a paper copy of the IFU, as is currently the case for professional use medical devices under the eIFU Regulation EU 2021/2226 Art.5 (3).

3. Further impacts

Use of eIFU, instead of paper IFU, reduces environmental impact by:

- eliminating paper required for a traditional IFU and decreasing waste, in alignment with the objective of the Packaging and Packaging Waste Regulation 2025/40;
- reducing packaging size because the paper IFU is no longer required in the device package;
- reducing Ethylene Oxide emissions during sterilisation;
- reducing carbon emissions associated with printing and transportation.

Ultimately, a digitally transformed healthcare sector not only improves health outcomes but also aligns with the EU's broader vision for a green, modern, and efficient economy. Advancing on eIFU for certain medical devices for lay users also supports the European Commission's recent agenda on simplification and reduction of administrative burden in order to foster a more competitive and innovative business environment[3]. MedTech Europe has already identified eIFU for certain lay use medical devices in its administrative burden report[4] as a topic where digitalisation would minimise delays and maximise patient access.

4. Conclusion

As outlined in this paper, further expansion of eIFU is aligned with the European Commission's green agenda as well as with its efforts to support competitiveness through simplification and reduction of administrative burden. In addition, eIFU enhances accessibility for lay users and ensures users always have the most up-to-date safety information.

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[2] European Patients Forum (EPF). Patients Perspectives on Implementation challenges of the EU Medical Devices Regulations: EPF Survey Findings. November 2024. Available at: 101176367_deliverable-3.1_patient-perspectives-on-mdrf-implementation.pdf

[3] European Commission. Simplification and Implementation. Available at: https://commission.europa.eu/law/law-making-process/better-regulation/simplification-and-implementation_en?utm_source=chatgpt.com (Accessed: September 2025)

[4] MedTech Europe. Report on Administrative Burden under IVDR and MDR. MedTech Europe's Proposal for IVDR/MDR Targeted Evaluation. March 2025. Available at: https://www.medtecheurope.org/wp-content/uploads/2025/03/250318_mte-report-on-admin-burden-ivdr_mdr_final.pdf

It should also be underlined that the established risk assessment procedures (Art. 4 of EU Regulation 2021/2226) continue to apply to each device applying the eIFU framework.[5]

MedTech Europe, eurom and EuromContact, therefore, re-iterate their call for this topic to be included in the MDCG New Technologies work plan for 2026. We stand ready to collaborate with all relevant stakeholders and actively support the progress of this initiative.

[5] This includes cybersecurity risks

Annexes

Annex I: Medical devices for lay users accompanied by IFU where initial information is provided by a professional*

*professional refers to a Healthcare professional (HCP)

Note: this overview is based on input from MedTech Europe members and may not be exhaustive

Device type	**Recurrent use and lay user receives initial information from HCP**	**Comments**
Contact lenses	yes	Class IIa and IIb Data available from EUROMCONTACT
Devices specifically used for disinfecting, cleaning, rinsing or, where appropriate, hydrating contact lenses	yes	Class IIb Rule 16
Intermittent urinary catheters and accessories; urine bags, fixation bands, hangers, urine collectors, stoppers, clamps etc.	yes	Class Is
External catheters (for men), uridome, sheaths	yes	Class I
Catheter valve in case of indwelling catheters	yes	Class I and class Is
Devices supporting diabetes home management: Glucose monitoring systems, Insulin Pumps & accessories; cartridge, infusion/insertion set, main pump unit, filling device, extra inserter (for some patch pumps) Pen needles/injectors (with or without insulin)	yes	Sensors and infusion sets are consumables, All Class IIb in EU, unless pump uses a closed-loop glucose control algorithm – then pump is class III Some parts/accessories can come with their own IFU. But lay user would also be trained on this by HCP. Pen needles class IIa
Reservoir / syringe for infusion pump (not for insulin)	yes	Class IIa: sterile single-use reservoir

Devices supporting home management of neurostimulation implantable devices: Infusion pump, External neurostimulators (for trial stimulation), Patient programming system / patient therapy application software, Recharger for implantable neurostimulators	yes	Generally all Class III in EU except when: External neurostimulators (for trial stimulation) Class IIb in EU for Pelvic Health therapy Patient programming system / patient therapy application software Class IIb in EU for trialing of Pelvic Health therapy only
Devices supporting the home management of cardiac rhythm management: Patient assistant, Patient monitor / Home communicator, Patient Magnet	yes	All Class III in EU
Orthopaedic external fixation	yes	Class IIb
Negative pressure wound care treatment	yes	Class IIb Machine (hence not the same as wound dressings)
Wound care devices, e.g dressings, irrigation solutions, gels	yes	Class IIa, IIb & III single use devices used for a period of time
External prostheses including components and accessories (e.g, shoulder, elbow, wrist, hand, hip, knee, foot, cosmetic cover, liner…)	yes	Class I medical device
Physical therapy transcutaneous neuromuscular electrical stimulation system, external functional electrical stimulation system and accessories	yes	Class IIa medical device
Peritoneal Dialysis System, Home Hemodialysis Systems	yes	Class IIb
Ostomy products incl. accessories, e.g. belts, paste, powder, etc.	yes	Class I, Class I(s)

No-sting barrier film (spray, applicator, etc.)	yes	Class I – and some class Is
Adhesive remover	yes	Class I
Compression, retention or mobilising medical device (e.g, compression stocking, socks, band, garments…) and accessories, e.g. gloves and other items used for help	yes	Class I
Winged infusion set	yes	Class IIa in EU, consumable (for haemophilia patients
Needles with active safety feature	yes	Class IIa in EU; consumable,
Syringe for hormones	yes	Class IIa in EU, consumable,
Orthoses (e.g, ankle, knee, hand, finger, hand wrist, elbow, shoulder, cervical collar, belt…)	yes	Class I medical device
Mobility aids such as crutches, rollators and wheelchairs	yes	Class I medical device
Devices for enteral nutrition such as nasogastric tubes, gastric replacement tubes, enteral feeding pumps, feedings sets, ENFit-syringes and accessories	yes	Class I, Is, IIa, IIb
CPAP (continuous positive airway pressure) /BPAP (Bilevel Positive Airway Pressure devices) and their associated accessories, such as masks, tubing, humidifiers, filters, converters/adapters, and bags	yes	CPAP and masks Class IIa BPAP Class IIa or IIb Other accessories either Class I or IIa

Long-term Implantable surgical devices for the treatment of incontinence such as artificial sphincters	yes	Class IIb
Long-term Implantable surgical devices for the treatment of erectile dysfunction, such as inflatable penile prosthesis	yes	Class IIb & III
Home care infusion pump for drug delivery (ie Parkinson disease)	Yes	Class IIb
Home care medical beds	yes	Class I (in large majority)
Dialyse filters	yes	Class IIb
Oxygen stationary concentrators, oxygen portable concentrators, liquid oxygen tanks (Devices and their associated disposables and accessories, such as tubing, external batteries and power cords)	yes	Class IIa
Suction units (tracheal mucosity aspirators) for homecare (Devices and their associated disposables and accessories, such as tubing and power cords)	yes	Class IIa or IIb(depending on duration of use)
Pulse oxymeter	Yes	Class IIa
Cough assist (secretion management device)	yes	Class IIa
IIPB (IPPB= Intermittent Positive Pressure Breathing) device	yes	Class IIa
Systems for humidification and nebulisation for homecare	yes	Class IIa

Laryngectomy and neck stoma care (e.g., heat moisture exchangers, adhesives, cleaning accessories, laryngectomy tubes, tracheoesophageal voice prosthesis)	Yes	Class I, Class IIa, Class IIb

Annex II: Developments & acceptance of eIFU for lay users worldwide

Australia: considering lay use expansion, TGA recent survey on expansion of eIFU to lay users https://www.tga.gov.au/resources/consultation/consultation-availability-instructions-use-ifu-more-flexible-formats

Belgium: the new government has included 'partial digital labelling' in their government agreement, to be transposed into law. Regeerakkoord-Bart_De_Wever_nl.pdf, page 57

Canada: Health Canada is actively working on modernising the regulation of over-the-counter (OTC) products and medical devices, which may include aspects related to electronic instructions for use (eIFU). Health Canada's approach is to ensure the safety, effectiveness, and quality of health products, and they are exploring ways to align with international best practices and improve transparency. Reference: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices.html

India: The Ministry of Health and Family Welfare allows eIFU, as the primary form of IFU for all medical devices and IVDs without restriction. Reference: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzIwNQ==

Vietnam, Thailand, South Korea: eIFU for lay users also allowed based on: https://apacmed.org/wp-content/uploads/2024/09/Towards-MedTech-Efficiency-and-Sustainability-through-eLabel-and-eIFU_Digital-Spread.pdf

Malaysia: MDA is planning to implement eIFU for consumers. A draft regulation is expected by the end of Q3 2025.

About us:

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.
www.medtecheurope.org.

eurom, founded in 1958 as an umbrella organization, eurom represents the interests of high-tech industry manufacturers across Europe. The current membership reflects a tradition of small and medium-sized enterprises with precision engineering expertise and a strong scientific background. eurom is especially active in the fields of medical and laboratory technology, as well as photonics.

EuromContact is the European association representing manufacturers of contact lenses and lens care products. They address all major types of visual impairment, play a key role in myopia management, and offer irreplaceable solutions for specific eye conditions. By supporting eye health and enabling better vision, contact lenses improve the quality of life for millions of Europeans.

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