



# Mecomed Position Paper On Electronic Instruction For Use (E-IFU)

## Introduction

In a period characterized by rapid digital transformation and technological advancements, the adoption of Electronic Instructions for Use (e-IFU) stands out as a critical evolution in the medical device sector.

e-IFU represents a significant leap towards enhanced efficiency, sustainability, and improved user experience. This position paper explores the integration of e-IFU, addressing the regulatory challenges and potential benefits as the industry moves towards digital solutions.



## Executive Summary

This paper offers an overview of the Electronic Instructions for Use (e-IFU), highlighting the need for regulatory enhancement and industry collaboration. Representing the Medical Technology industry in the Middle East & Africa Region, Mecomed's position is that electronic Instructions for Use (e-IFU) should become the default form for professional-use medical devices across the Middle East Africa region, with paper copies available free of charge upon request. Mecomed also supports, in alignment with international best practices, a phased and risk-based approach to eventually in the future extending e-IFU access to lay users and IVDs, ensuring accessibility and safety."



Globally, e-IFU is embraced for their real-time updates, accessibility, and environmental benefits. Evidence from MedTech Europe supports a strong preference for e-IFU among healthcare professionals due to its ease of access and sustainability. This paper calls for collaborative efforts for higher adoption of e-IFU in the MEA Region and standardized implementation, ensuring security and accessibility to enhance healthcare delivery.

## Global Adoption and Advantages of e-IFU

Globally, there is a clear and growing acceptance of electronic Instructions for Use (e-IFU) by both regulatory authorities and the medical device industry. e-IFU has been authorized for professional use across numerous countries, including the European Union (EU)<sup>8</sup> Australia, the United States, Canada, Saudi Arabia, Bahrain, Turkey, the United Kingdom, Japan, Singapore, South Korea, India, Malaysia, Chinese Taipei, Thailand, Vietnam, New Zealand and Brazil. Furthermore, acceptance continues to expand with e-IFU for lay users now permitted in India, Thailand, Vietnam and South Korea.

This global acceptance highlights the crucial role e-IFU plays in ensuring that healthcare professionals, as well as lay users, where permitted, have instant access to the most up-to-date instructions. By delivering timely and accurate information e-IFU enhances safety and efficacy while also helping to reduce waste and environmental footprint.

Additionally, e-IFU facilitates a more straightforward process for all users to search through content and quickly find necessary information. The shift towards flexible formats in patient information materials aligns with global trends, emphasizing the relevance and timeliness of adopting e-IFU systems.



### References

Commission Implementing Regulation (EU) 2025/1234 of June 25, 2025, amending Regulation (EU) 2021/2226, entered into force on July 16, 2025. It extends eligibility to all medical devices intended for use by healthcare professionals.  
Implementing regulation - EU - 2025/1234 - EN - EUR-Lex

## e-IFU provides several benefits to healthcare professionals, patients, and caregivers, including

### Up-to-date information

Also, they have internet access based on its widespread use. e.g. E-IFU is accessible online, taking advantage of the internet's widespread availability.

### Increased utility

e-IFU are searchable, which reduces the time to find specific information for both professional and lay users.

### Durability

Unlike paper IFU, which can suffer from wear and tear, fading, or contamination, e-IFUs remain intact and legible. This durability ensures that instructions are always clear and accessible, thus enhancing long-term usability and safety.

### Supply chain efficiency

e-IFU can streamline the medical device supply chain by reducing the need for physical printing, storage, and manual distribution of paper IFU. This reduction not only lowers operational costs but also contributes to a more reliable and resilient supply chain.

### Increased availability

e-IFU can be accessed via multiple platforms whenever the users need them, which is especially important in a hospital environment where paper IFUs are likely to be disposed of. Also, they have internet access based on its widespread use. This accessibility ensures that critical information is always available at the point of care.

### Enhanced accessibility

e-IFU offer more language options, the possibility to zoom in text and pictures, or in some software, use of dictation. These features improve accessibility for users, including those with visual impairments or other disabilities.

### Support for innovation

e-IFU facilitate rapid adoption of new technologies, including quick updates for software modifications and the integration of artificial intelligence (AI) technologies. This capability allows manufacturers to keep pace with technological advancements, ensure compliance with evolving regulations, and provide users with the most effective and efficient device instructions.

### References

Notification No. 2024-18, March 27, 2024" include the full list of devices eligible for e-IFU. As per Article 2 (Designation Scope) Clause (1), devices listed in the Appendix, regardless of use environment, can provide IFUs on the manufacturer's website.

## Enhancing Sustainability and Efficiency with e-IFU

Electronic Instructions for Use (e-IFU) is environmentally sustainable, reducing product waste and the overall carbon footprint. By reducing paper usage, e-IFU supports environmental sustainability efforts by minimizing deforestation, reducing carbon emissions associated with printing and transportation, and decreasing landfill waste aligns with global initiatives to promote eco-friendly practices across industries..

To meet user's needs, manufacturers must provide paper IFU free of charge and within defined timelines upon request. This ensures continued access to essential information and supports the safe use of devices.

In addition, e-IFU simplify lifecycle management. For products already distributed or in storage, the use of e-IFU alleviates the burden of updating by eliminating the need for reprinting and manual replacement of paper leaflets. This capability not only reduces logistical challenges but also ensures that all products, regardless of their distribution status, have access to the latest information.



## Supporting Evidence from Industry's Surveys

The European MedTech Association conducted a survey for the purpose of scope expansion of e-IFU Regulation in the European Union. The survey demonstrated that key employees in the healthcare sector expressed a stronger preference for electronic format over paper formats.: Over 90% of respondents of the second MedTech Europe survey for hospital pharmacists, procurement and other admin staff indicated that they prefer e-IFU.

Detailed survey information is available over the below link:

E-IFU is easier to store and access.

E-IFU is easier to search and navigate.

E-IFU is easier to find the latest version.

E-IFU can be consulted anywhere.

E-IFU reduces waste.

The electronic instructions for use (e-IFU) regulation (EU Regulation 2021/2226) has been updated by EU Regulation 2025/1234, which expands the possibility of e-IFU to all professional use devices. The medical technology industry welcomed this initiative as it marks a crucial moment in the digitalization of healthcare information.

### References

COMMISSION IMPLEMENTING REGULATION (EU) 2021/2226 (Article 5 (3) includes the provision of the 7 days).  
<https://www.medtecheurope.org/wp-content/uploads/2022/11/medtech-europe-position-paper-on-eifu-extension-to-all-professional-use-mds.pdf>

## Collaborative Efforts and Regulatory Alignment

The Medtech industry is open to collaborating with healthcare professionals to address the e-IFU implementation in the healthcare setting. It is understood that there will be requirements that manufacturers must meet to be aligned with global standards for e-IFU such as:

- Conducting risk assessments
- Ensuring accurate labelling
- Offering support and training to help users effectively access and utilize e-IFU.
- Providing robust cybersecurity measures, as e-IFU should be available via secure platforms.
- Making paper IFU available upon request at no additional cost and without undue delay to ensure that users who prefer or require paper copies can access them easily.



Access options for both electronic and paper IFUs can include:

### Electronic Access

Users can obtain digital versions of IFU through direct links provided on mobile apps or official websites, facilitating immediate access.

### Paper Copies

Users can request printed IFU free of charge, which should be delivered without undue delay.

### Instructions for Access

Clear instructions on how to request and access both electronic and paper IFU are provided.

## Future Directions and Regulatory Considerations

It should be noted that, there is an ongoing discussion about expanding the scope of e-IFU implementation to include lay users, and a notable example of this is Australia's TGA, which has conducted a public consultation in 2024 to gather feedback on providing instructions for use in more flexible formats, including provision of e-IFU to lay user. The majority of the response to the consultation was in favor of expanding the availability of e-IFU. Additionally, in September 2025, MedTech Europe (MTE) published a position statements advocating for the broader acceptance of e-IFU for lay users, reinforcing its ongoing efforts to expand their adoption. .

### References

TGA consultation summary was published in August 2024.

<https://www.medtecheurope.org/news-and-events/news/electronic-instructions-for-use-eifu-for-certain-medical-devices-intended-for-lay-users>.

## Conclusion and Recommendation

The transition to e-IFU represents a significant step toward enhancing the efficiency, sustainability, and user-centricity of healthcare delivery. By adopting e-IFU, we can significantly reduce the environmental impact associated with paper use and streamline and simplify the distribution of up-to-date information.

By adopting e-IFU, we can significantly reduce the environmental impact associated with paper use as enabling e-IFU will keep deforestation at bay, preserve energy, and water, and overall lower the impact of the healthcare sector on the environment, while maintaining high standards of safety and efficacy of medical devices for the patient

We thank you for your consideration on this matter and look forward to working collaboratively on this topic, through feedback and discussions that will allow us to address different perspectives, and which we would be honored to see successful through the publication of a note or circular specific to the e-IFU and framing its application in the country.



## References

01

Australia Electronic Instructions for Use - e-IFU, For professional users of MDs (including IVDs) Guidance, V 1.0, Aug 2018 - Eligible devices are limited to those intended for use by professional users, and not for supply to the general public. Currently, Australia only allows e-IFU for professional use for certain device types. However, the public consultation that closed recently will likely expand the scope as highlighted in the following survey results for TGA consultation: Instructions For Use for Medical Devices - Therapeutic Goods Administration - Citizen Space (tga.gov.au)

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02

Brazil ANVISA Collegiate Board of Directors RDC 751/2022, Dated: Sep 15th, 2022 (previous provision on e-IFU: Normative Instruction - IN No. 4, Article 2; 15 June 2012 Article 54) - The exclusive availability of non-printed format instructions for the following products is prohibited: I - health use equipment that has an indication of: a) domestic use in general, including those for use in home care service ) Lay operation, regardless of the place of use; II - health materials used by lay public. RDC 751/2022, Art 50-54

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03

Bahrain Circular No. 2 (2021), Dated: 17 January 2021, Subject: Using "Electronic IFU" - To: all importers of medical devices and manufacturers, as per NHRA role in monitoring the import and marketing of medical devices in the Bahrain market and ensuring safety and public health protection. the authority would like to draw the attention of all importers of medical devices and manufacturers to the fact that in addition to the many benefits of using "Electronic IFU" including: • Easy access to the latest information related to the use of the medical device, • Searchable, which reduces search time for specific information, • It offers more language options and the ability to enlarge text and image. However, the use of this type of IFU is limited only to professional users who receive training on the use of e-IFU and it is not permissible to use it by lay people in order to ensure the safety use of the medical device

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04

Canada File No. 15-107097-797 26-Jun-2015 - For devices that are not sold to the general public, this information may be provided as downloadable from the internet and/or on electronic data storage devices, such as compact disc, digital video disc or universal serial bus (USB) flash drive. Paper copies should be made available to users upon request at no charge.  
Guidance Document: Guidance for the Labelling of Medical Devices, not including in vitro diagnostic devices - Appendices for the Labelling of Soft, Decorative, Contact Lenses and Menstrual Tampons - Canada.ca

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05

EU: COMMISSION IMPLEMENTING REGULATION (EU) 2025/1234 of 25 June 2025 amending Implementing Regulation (EU) 2021/2226 as regards the medical devices for which the instructions for use may be provided in electronic form - Manufacturers may provide instructions for use in electronic form instead of paper form where those instructions relate to devices referred to in Article 1(4) of Regulation (EU) 2017/745 intended for use by professional users.

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06

India Medical Device Rules (2017) - (Amendment) Rules, 2019. The amendment dated 15 January 2019, inserted the term "electronic instructions for use" (e-IFU) into the Medical Devices Rules, 2017., formally accepting e-IFU for medical devices and equipment. India Medical Device Rules (2017) - (Amendment) Rules, 2019. The amendment dated 15 January 2019, inserted the term "electronic instructions for use" (e-IFU) into the Medical Devices Rules, 2017., formally accepting e-IFU for medical devices and equipment.

07

Japan - The new Japanese regulation eliminates the ability to provide e-IFU in physical format for professional users. The new law requires all IFUs to be provided in electronic-only format, uploaded and maintained on a regulator-owned application, accessible by all customers. This does not apply to patient IFUs - PMD Act Article 68, Paragraph 2 Item1 states requirement about e-IFU to be published on PMDA website - PMD Act Article 68, Paragraph 2 Item 2 states requirement about items to be contained in e-IFU. Japan: Information regarding newly introduced electronic package inserts

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08

Malaysia MDA/GD/0026: REQUIREMENTS FOR LABELLING OF MEDICAL DEVICES - Dated: 21 November 2022 Stated that: Electronic IFU (e-IFU) is eligible for devices that are limited to those intended for use by professional users only. Paper-form IFU is required and additional electronic IFU is optional for home use devices. Malaysia MDA/GD/0026: REQUIREMENTS FOR LABELLING OF MEDICAL DEVICES - Dated: 21 November 2022 Stated that: Electronic IFU (e-IFU) is eligible for devices that are limited to those intended for use by professional users only. Paper-form IFU is required and additional electronic IFU is optional for home use devices.

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09

Saudi Arabia: e-IFU requirements for Medical device professional use are available in Annex 10 REQ1: REQ1En\_0.pdf (sfda.gov.sa)

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10

South Korea: According to Article 2 (Designation Scope) Clause (1) of MDSF Notification 2024-115, every medical devices that have been approved, certified, or notified under the subcategory name (item name) and listed in the Appendix included in the Appendix of Notice No. 2024-18, regardless of their use environment (e.g., medical institution or home use) are eligible for the provision of eIFU, specifically, IFU can be provided on the Manufacturer website.

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11

Singapore's labeling requirements guided by GN-23 (June 2018) 'Guidance on Labeling for Medical Devices'- This document notes that paper IFUs should be provided except where specified. Several additional requirements note that for e-Labeling: \*IFU may be provided in paper or non-paper format for professional-use devices, \*When provided in a form other than paper, the customer must have instructions on how to view and access the IFU, \*The internet address must be clearly printed on the physical label of the device, \*The electronic labeling must be identical to what would be provided in paper, and what is submitted. Singapore: GN-23: Guidance on Labelling for Medical Devices, rev 1.1, March 2020

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12

Thailand ASEAN Medical Device Directive (Article 10), Thailand Ministry of Public Health`s Notification 137, Section 260 D (original language): Rules, Procedures and Conditions for Labels and Package Inserts of Medical Devices, Clause 5.

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13

Vietnam, reference to Decree No. 98/2021/ND-CP Link in the original language : Nghị định số 98/2021/NĐ-CP của Chính phủ: Về quản lý trang thiết bị y tế  
Non-official English translation (by Vietnamese professional registration service)  
<https://dione.vn/blogs/medical-devices/decreed-no-98>

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APAC e-IFU position paper reference : APAC position paper (Towards MedTech Efficiency & Sustainability through e-Label & e-IFU- September 2024 )

