Digitization for Medical Device

Digitization transformation Enhancing the Regulatory Affairs Compliance, data Accessibility, and environmental Sustainability

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Date: November 4th, 2025

AFRiSUMMIT

Agenda

- What is an e-labelling, e-signature and digital product certs?
- Benefits of Digitizing
- Regulatory Landscape
- Implementation Strategy
- Case Studies/Examples
- Conclusion and Next Steps

What is an e-IFU, e-labelling, e-signature and digital certification ?

An electronic Instruction for Use (eIFU) provides medical device instructions in a digital format instead of traditional paper.

E-signature: is a digital form of a signature used to authenticate the identity of the signer and to indicate their approval to a document. It is a legally recognized method of signing electronically and can be validated online in most of the cases.

While an electronic signature allows an individual to **approve a document**, an electronic seal is used to **guarantee the origin and integrity of a document issued by an organization**.

digital seal certs/Soft copy product certs: A digital seal is a piece of electronic data which, when applied to a document, verifies the document's data origin and integrity in accordance with the EU regulation eIDAS (electronic Identification, Authentication, and Trust Services). It also carries a digital fingerprint which can be used to verify the authenticity of the document to which it is applied.

E-label: a digital or electronic representation of a product label, packaging label, or identification tag. It contains important information about the product, such as branding, ingredients, instructions, or regulatory details, but is stored and displayed electronically rather than on physical paper or material.

Benefits of Digitization

1. Simplifies and accelerates access to information

2. Sustainability: Reduces paper usage, contributing to environmental goals.

3. Cost Efficiency: Reduces printing and distribution costs.

4. Real-Time Updates: Easy to update instructions, labels, certificates with the latest information.

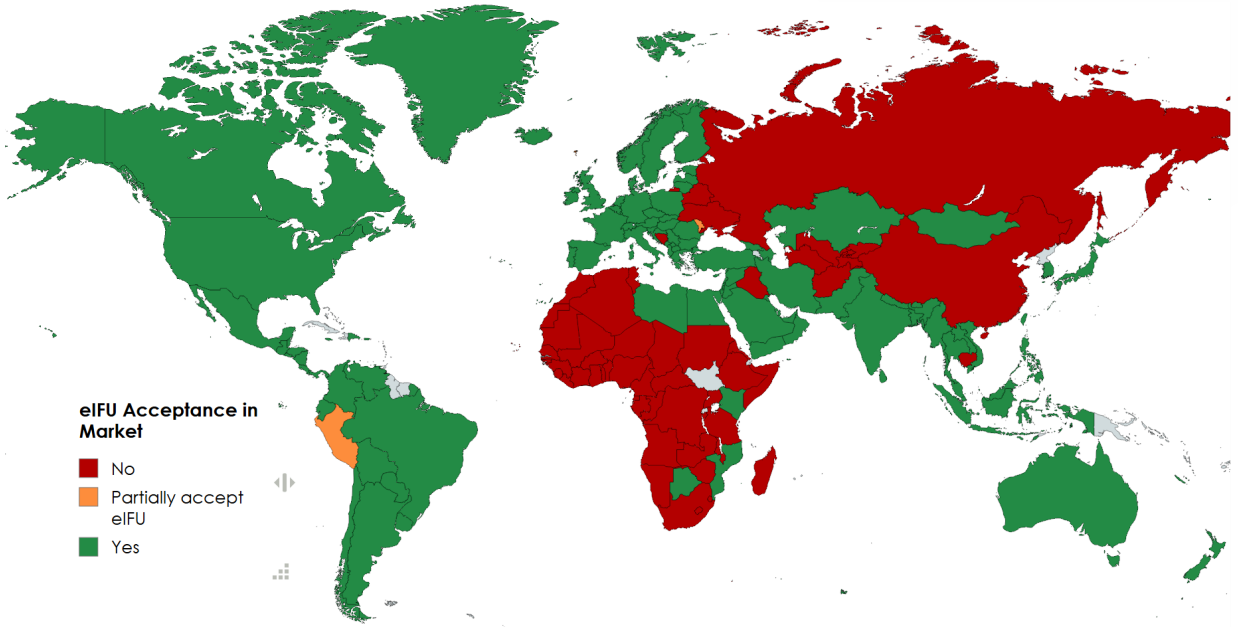
5. Improved User Experience and accessibility : Searchable content and interactive features.

Regulatory Landscape for e-IFUs

Major jurisdictions worldwide allow e-IFU for medical devices for professional use

The United States, for instance, has allowed the use of electronic IFU for 20 years for all prescription devices.

Other countries include Australia, Canada, Saudi Arabia, Bahrain, Egypt, Turkey, the United Kingdom, Japan, Singapore, South Korea, India, Malaysia, Chinese Taipei, Thailand, Vietnam, New Zealand and Brazil



Implementing regulation - EU - 2025/1234 - EN - EUR-Lex

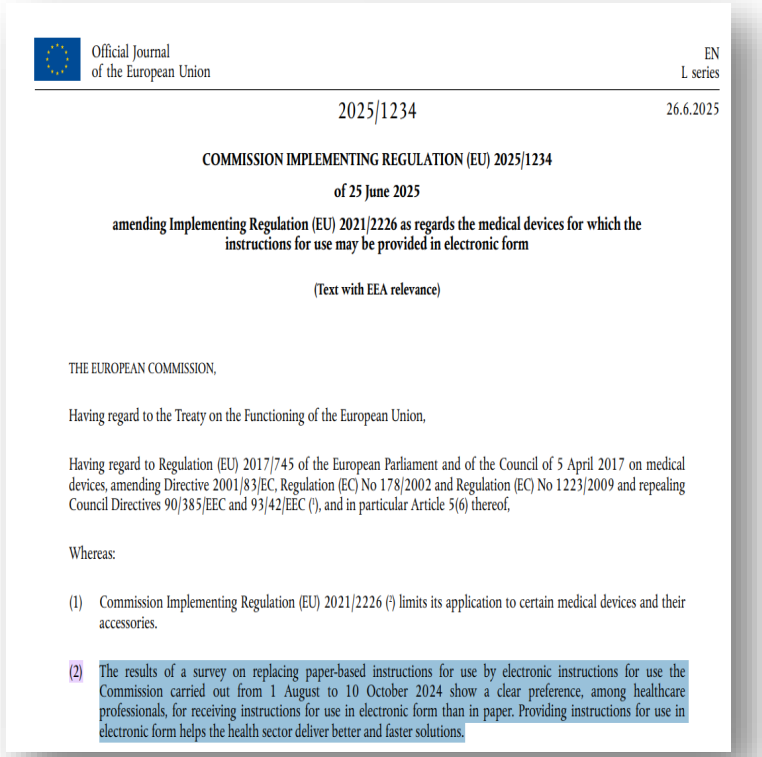
Implementation Strategy

- The results of a survey on replacing paper-based instructions for use by electronic instructions for use the Commission carried out from 1 August to 10 October 2024 show a clear preference, among healthcare professionals, for receiving instructions for use in electronic form than in paper. Providing instructions for use in electronic form helps the health sector deliver better and faster solutions.

On 25 June 2025, the European Commission published **Implementing Regulation (EU) 2025/1234**, which amends Implementing Regulation (EU) 2021/2226, clarifying when instructions for use (IFUs) for medical devices may be provided in electronic form (eIFUs) across the EU. The regulation **has gone into effect on *16 July 2025*.**

The amendment seeks to enhance accessibility, minimize dependence on paper, and simplify processes for manufacturers and users, while supporting the EU's digital transformation objectives in medical technologies.

Mecomed MEA industry group - position paper under review to reflect latest e-IFU status.



Official Journal of the European Union — EN, L series

2025/1234 — 26.6.2025

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (1), and in particular Article 5(6) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) 2021/2226 (2) limits its application to certain medical devices and their accessories.

(2) The results of a survey on replacing paper-based instructions for use by electronic instructions for use the Commission carried out from 1 August to 10 October 2024 show a clear preference, among healthcare professionals, for receiving instructions for use in electronic form than in paper. Providing instructions for use in electronic form helps the health sector deliver better and faster solutions.

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32025R1234#:~:text=(2)%20The%20results%20of%20a,deliver%20better%20and%20faster%20solutions.

Regulatory Landscape for e-signature & digital product certs. (e-notarization/e-legalization)

- FDA e-CFG
- Notified bodies CE certificates/digital seal certs
- ISO 13485: quality management certs
- e-CFS (EU authorities' free sale certificates).

Focus on Digital seal product certification !

What is a digital seal?

A digital seal is a piece of electronic data which, when applied to a document, verifies the document's data origin and integrity in accordance with the EU regulation eIDAS (electronic Identification, Authentication, and Trust Services). It also carries a digital fingerprint which can be used to verify the authenticity of the document to which it is applied. The application of a digital seal enhances the security of a document by making it tamper resistant. A certificate issued with a digital seal may replace the need for the certificate to be notarised in some jurisdictions.

What is "eIDAS"?

eIDAS (**e**lectronic **ID**entification, **A**uthentication and trust **S**ervices) is an EU regulation on electronic identification and trust services for electronic transactions in the European Single Market. It was established in EU Regulation (EU) 910/2014 of 23 July 2014 (**europa.eu**). It refers to a range of services that include verifying the identity of individuals and businesses online and verifying the authenticity of electronic documents. Although it is an EU based legislation, digital seals based on eIDAS are accepted in many other jurisdictions worldwide.

https://www.bsigroup.com/siteassets/pdf/en/insights-and-media/insights/brochures/bsi-md-digital-seal-brochure-en-gb.pdf

Implementation Strategy

How do I confirm the validity and/or authenticity of a digital seal?

To confirm the validity and/or authenticity of a digital seal:

1. Save the digitally sealed BSI certificate locally.
2. Visit the European Commission hosted **website**.
3. Click on "Validate a signature" from the sidebar menu.
4. Under "Signed file", click on "Choose File."
5. Select the saved file (i.e. the digitally sealed BSI certificate to be validated).
6. Click on Submit.

A validation report will be returned detailing the validation results. A valid digital seal will return **"Signatures status: 1 valid signature, out of 1"**

Why are the dates shown on the digital seal different to the dates shown on my BSI certificate?

BSI, in partnership with their Qualified Trust Service Provider (QTSP), possesses a renewable 5-year certificate (a licence) for digital seal application. Within the information panel of the digital seal is additional date information relating to this licence. Please note that these "**validity start**" and "**validity end**" dates are related to the digital seal itself. They are not related to and do not affect the certificate validity dates specified on the actual certificate.

What happens to MDR/IVDR/UKCA certificates already issued without the digital seal applied prior to November 2024?

Those certificates will continue to remain valid. Digital seals will be applied to those certificates when they are next re-issued or renewed (whichever comes first).

Are digital seals being applied to other certificate types such as ISO 13485 or MDSAP?

No. At this stage, digital seals are only being applied to MDR/IVDR and UKCA certificates. Other certificate types may be considered in the future for the application of digital seals.

Electronic product label process would support country specific requirements implementation.

E-labelling technique for medical device products

- video link

https://www.youtube.com/watch?reload=9&v=Qgh84-smkV8

Simplifies and accelerates dissemination of and access to information

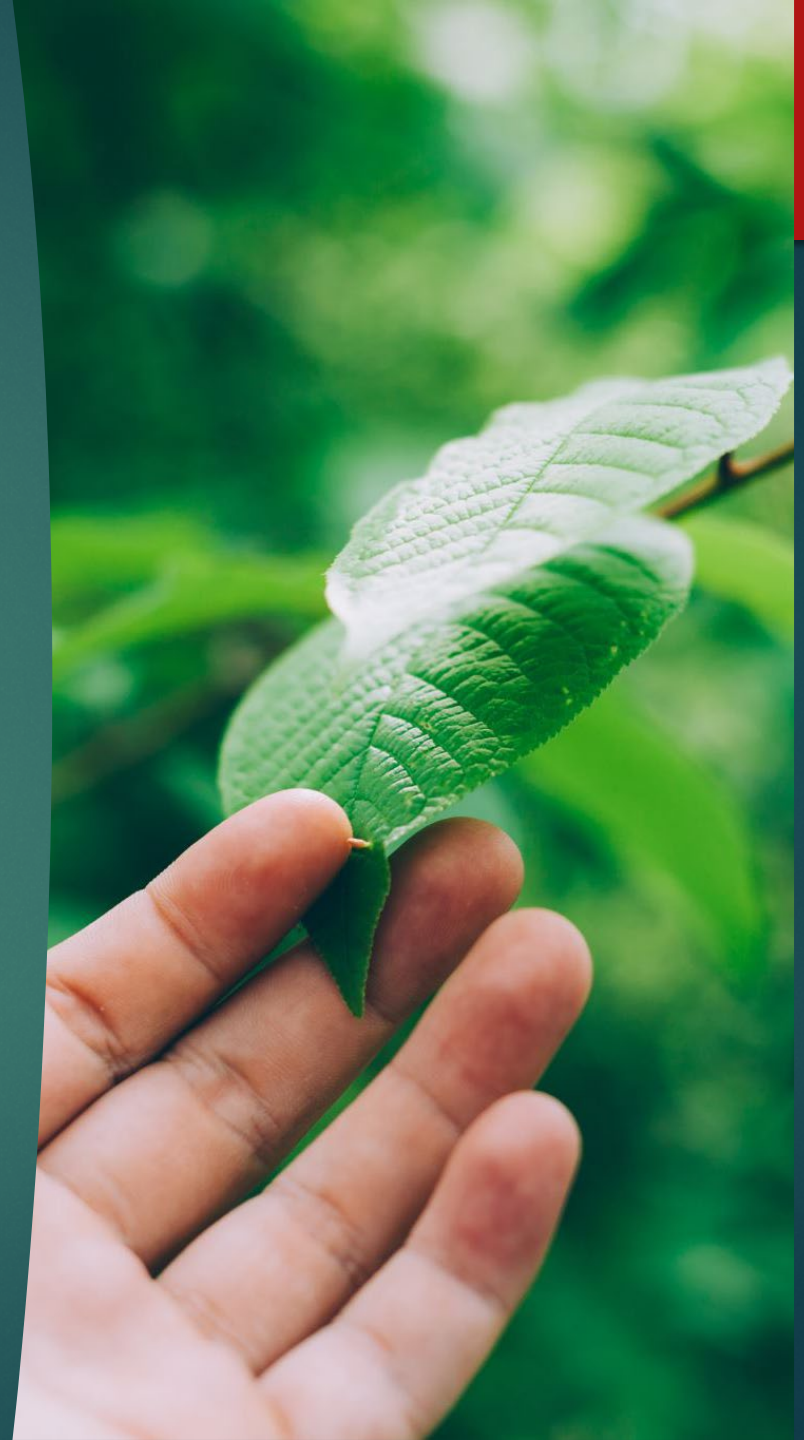
Enhances customer experience

Improves operational efficiency, strengthening the resilience of healthcare systems

Reduces environmental waste and carbon footprint

Conclusion

- eIFUs , e-signature, & digital product certs offer significant benefits in terms of accessibility, compliance, and cost efficiency.
- The regulatory landscape supports digitization when implemented responsibly.
- Call to Action: Embrace digitization as a step toward innovation and sustainability.



- THANK YOU

Questions?