# Digital label for Authorised Representative and Importer

# Position paper




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## Why support the adoption of digital labels for devices? [1] [2]

Mandatory requirements for additional product information[3] for medical devices (MDs) and *in vitro* diagnostic medical devices (IVDs) have exponentially increased recently - due not only to MD Regulation (MDR)[4] and IVD Regulation (IVDR)[5], but also due to the application of horizontal legislations to the medical technology sector.

Under the current legislative system in the EU, both **essential information** (information needed for a safe use of the device) as well as **additional** information must be included on the product's printed label as per MDR Annex I General Safety and Performance Requirements (GSPRs), 23.2, 23.3. and IVDR Annex I GSPR, 20.2. **MedTech Europe, AESGP, COCIR and Euromcontact** view this additional information as non-essential to the safe and effective use of the device, as it is unrelated to identification of the device, warnings and precautions, handling & use information (storage, sterility, etc.).

Therefore, we call on the European Commission to allow via the upcoming MDR/IVDR legislative revision, as a first step, that the importer information[6] and authorised representative information[7] may be provided via a digital label. We believe that eventually **all information which is not essential for the (safe) use of the device should be provided in digital format** – pending the outcomes of the dedicated Innovative Health Initiative (IHI) Call 10 Digital label project.[8]

Several information technologies and cloud-based solutions already exist today to support and provide digital label and electronic information within cross sectoral industries, such as electronic equipment, food, baby formula and supplement industries. Digital labelling solutions as an effective way of demonstrating compliance have already been adopted by 56% of the world's economy based on Digital Europe data from 2019.[9]

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[1] *A digital label is a form of e-labeling provided as an array of additional elements and topics supporting a MedTech product's identity and its safe and effective use, which is additional to the critical information on the printed label. Access to the digital label is achieved, for example within a printed machine-readable data carrier in the form of barcodes, 2D data matrix, QR codes, etc., which provides a scannable functional link to curated digital landing pages (websites) where the additional information for end users will be displayed.* Source https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/HORIZON-JU-IHI-2025-10-01-two-stage

[2] *Labeling serves to identify a device and its manufacturer and to communicate information on safety, use, and performance. In some jurisdictions, "**labeling**" is referred to as "information supplied by the manufacturer" and **may be physical or electronic (also known as e-labeling)**. Labeling includes the label, instructions for use, and information related to the identification, technical description, intended purpose, and proper use of the medical device and IVD medical device, as applicable.* Source: https://www.imdrf.org/sites/default/files/2024-04/IMDRF%20GRRP%20WG%20N52%20%28Edition%202%29.pdf

[3] such as compliance markings, device disposal instructions, local information or economic operators' details

[4] Medical device regulation EU 20127/745 (MDR)

[5] *In vitro* diagnostic medical device regulation EU 2017/746 (IVDR)

[6] As per MDR/IVDR Art. 13.3

[7] As per MDR GSPR 23.2 d) and IVDR 20.2 d)

[8] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/HORIZON-JU-IHI-2025-10-01-two-stage

[9] https://cdn.digitaleurope.org/uploads/2018/06/E-labelling_flyer2019_WEB-2.pdf

Use of digital label in the medical technologies sector is aligned with the European Commission's Green Deal[10], with the World Health Organisation (WHO)'s vision to accelerate digital health transformations as outlined in the Global Strategy on Digital Health 2020-2025[11] and would equally support innovation and competitiveness in the EU. Notably, digital label would solve the following problems:

- Overcrowded labels with small fonts that make key safety and use information hard to find. Moving additional details to digital form declutters the labels, hereby improving usability for users.
- Increased amount of packaging needed to accommodate all required information on physical label, which leads to increased waste and higher amounts of $CO_2$[12]. Digital label can help eliminate the need for additional packaging and hereby contributes further to achieving EU Green Deal goals.
- Other horizontal European Regulations that impact the medical technology sector already allow the use of a data carrier for product information, such as the Ecodesign for Sustainable Products Regulation EU 2024/1781 (e.g. Digital Product Passport), EU Battery Regulation 2023/1542, Packaging and Packaging Waste Regulation EU 2025/40[13]. Given that MDR/IVDR requires product information physically, this creates a discrepancy. Use of digital label will drive alignment between MDR/IVDR and EU horizontal regulations impacting the medical technology sector.

Regarding **importer and authorised representative (AR) information in particular**, the need to update the entire physical label and other pre-printed material when the manufacturer changes an importer or AR would be eliminated thanks to digital label, contributing to smoother and faster product availability as well as to the EU Green Deal goals. **In this paper, MedTech Europe, AESGP, COCIR and Euromcontact present reasons why a digital means of providing specifically the importer and AR information should be prioritised**.

## European authorised representative (AR)

The recently published amendment ISO 152231-1/2021: Amd 1:2025 adds a defined term for authorised representative and modifies the EC REP symbol to be non-country and region specific. It should be noted that this is an administrative change without added value for patients or the safety of devices. However, it represents a significant implementation burden for manufacturers and may trigger regulatory consequences in non-EU regions, where devices with the changing labels are registered.

In the current situation, where the publication of harmonised standards is impacted as a consequence of ongoing litigation before the European Court of Justice, and given the absence of a clear transition strategy for replacing the EC REP symbol with the EU REP symbol, it is essential that manufacturers have the flexibility to implement the symbol change when this can be aligned with other planned labelling changes. In order to minimise any impact of this administrative change (delay in product availability, raising cost, re-labelling

[10] https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal_en

[11] WHO (2021). Global strategy on digital health 2020 – 2025: iris.who.int/bitstream/handle/10665/344249/9789240020924-eng.pdf?sequence=1

[12] Which is in contradiction with requirements of EU Packaging and Packaging Waste Regulation EU 2025/40

[13] Packaging and Packaging Waste Regulation EU 2025/40 Preamble (70): *There should be no multiplication of labels on packaging. In order to avoid this, where other Union legal acts require information on the packaged product to be available digitally through a data carrier, the information required under this Regulation for the packaging and for the packaged product under the other Union legal act should be accessible via the same data carrier. That data carrier should comply with the requirements under this Regulation or other applicable Union law. In particular, where the packaged product is covered by Regulation (EU) 2024/1781 or other Union law requiring a digital product passport, that digital product passport should also be used for providing the relevant information under this Regulation (…)*

waste…), we call on the European Commission to allow the AR information to be provided through a digital label when using the new version of the aforementioned symbol. Such a change will not create any new risks as the symbol itself is unrelated to the essential device information; hence device use and safety will not be negatively impacted.

## Importer

Importer details as per MDR/IVDR Art. 13.3 must be provided on the device itself, its packaging or in a document accompanying the device. The guidance document MDCG 2021-27 states that importer details can be included in "accompanying documentation" as long as it reaches the end user. However, the nature of the accompanying information has been much debated in recent years. To ensure that importer details do reach the end user, allowing this information to be provided digitally is the most suitable option. It removes the possibility of misplacement or loss of physical accompanying documentation before the product reaches the end user.

Where the physical label is used for including importer details, if the manufacturer has to change importers, this means having to update and reprint the whole of the physical label merely to change the importer information. This process leads to unnecessary paper waste, additional CO2 release, impact on device availability in terms of delays and ultimately creates an increase in costs.

**MedTech Europe, AESGP, COCIR and Euromcontact, therefore, call on the European Commission to allow manufacturers to provide importer and authorised representative details via a digital label**. This approach would align with the recent expansion of electronic Instructions for Use (eIFU) [14] to all devices used by professionals, whereby manufacturers may already include importer details in the electronic IFU.

## Further considerations

As of 2026, the European Database on Medical Devices (EUDAMED) will provide both device information and economic operators' information. Hence, the device label (or accompanying documentation for importer) will no longer be the sole source of device information. Alternative ways to access importer and AR information exist via the manufacturer's website and (electronic) Instructions for Use. Manufacturers may also include information in the IFU on how to use the digital label to access the information that it holds.
Last but not least, the global impact of these specific labelling requirements for AR and importers cannot be underestimated – many jurisdictions are requesting specific local information, which further exacerbates the issue of overcrowded labels. Changes to importer or AR details on CE-marked devices also affect global registrations, creating administrative complexity and potential delays. Considering these implications, the EU has an opportunity to take a leading role[15] on the global stage towards the recognition and use of digital labels; by starting with importer and AR information as part of the upcoming MDR/IVDR revision.

[14] 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
[15] IHI Project 10 Digital Label: https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/HORIZON-JU-IHI-2025-10-01-two-stage

## Conclusion

Moving the AR and importer information to the digital label would help de-clutter the physical label, making it easier for users to find information which is essential for safe use of devices. Endorsing a digital label would ensure faster device access by eliminating multiple steps from manufacturers' processes and supply chains, hereby supporting simplification and encouraging competitiveness.

MedTech Europe, AESGP, COCIR and Euromcontact urge the European Commission to allow provision of AR and importer information via digital format **within the ongoing legislative revision of MDR/IVDR**. This would address multiple ends; simplification, reducing environmental impact and supporting competitiveness with faster device availability. We stand ready to further engage on this topic and support the European Commission's work.

Eventually, all information that is non-essential to the safe and effective use of the device should move onto a digital label. **This should be tackled as a next step pending the outcomes of the IHI Digital Label project[16] via future iterations of digital label through implementing acts and standardisation initiatives.**

[16] It should be noted that only the information considered non-essential is considered in scope of digital label. All essential product information for a safe use of the physical device should always stay physically on the device label. The IHI digital label project will work on a mapping between essential and non-essential information.

## 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.

**The Association of the European Self-Care Industry (AESGP)** is a non-profit organisation which represents the manufacturers of non-prescription medicines, food supplements and self-care medical devices* in Europe, an area also referred to as consumer healthcare products. https://aesgp.eu/
**Self-care medical devices are generally available without medical prescription and are self-administered*.

**COCIR** is the European Trade Association representing medical imaging, radiotherapy, health ICT and electromedical industries. Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. We provide a wide range of services on regulatory, technical, market intelligence, sustainability, standardisation, international and legal affairs. COCIR is also a founding member of DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association. https://www.cocir.org/

**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.

## For more information, please contact:

**MedTech Europe**
Jana Russo, Manager Medical Devices, j.russo@medtecheurope.org

**AESGP:**
Paul-Etienne Schaeffer, Life Sciences Regulatory Affairs Manager, p.schaeffer@aesgp.eu

**COCIR:**
Ajda Mihelčič, Director of Technical & Regulatory Affairs, mihelcic@cocir.org

**EuromContact**
Laure-Anne Copel, Secretary General, secretariat@euromcontact.eu