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WHITE PAPER

European Union Medical Devices Regulation: Electronic Labeling

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Navigating your business wisely.
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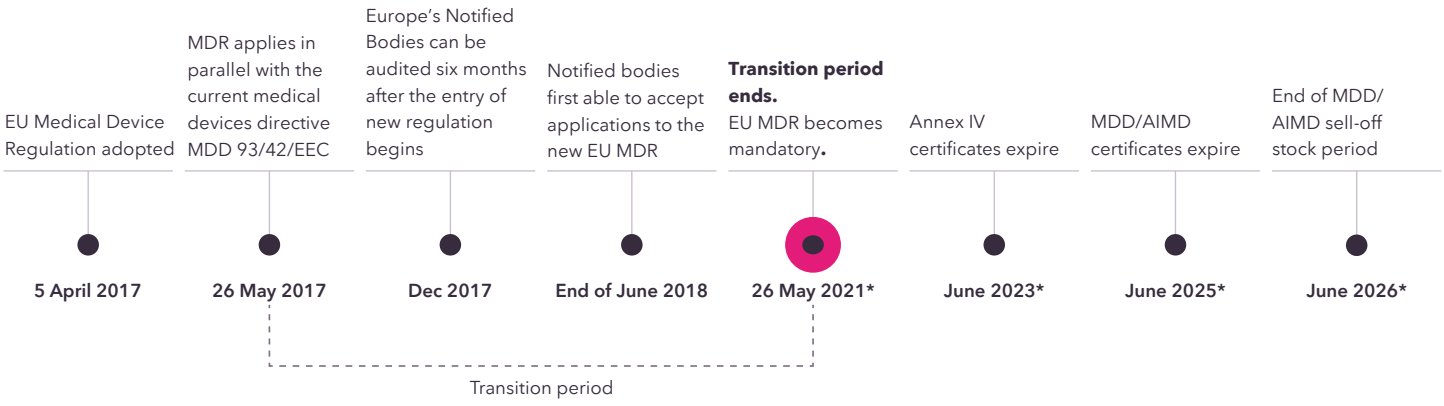
Introducing the European Union Medical Devices Regulation (EU MDR)

The May 2017 release of a new MDR in the Official Journal of the European Union marked the start of a three-year transitional period within the medical devices industry. Manufacturers, suppliers, notified bodies, and national competent authorities must comply with the new regulation which was to take effect in May 2020 but has been postponed one year due to the COVID-19 virus.

The changes made in the new MDR are significant and immense. Compared with its predecessor, the Medical Devices Directive (MDD), the new EU MDR is less focused on the pre-approval stage of medical device manufacturing and instead promotes a life cycle approach to medical device regulation. Part of this new approach includes a drastic reinterpretation of the role of the Instructions for Use (IFU) and the regulated method for which this information is passed along to end-users and patients.

When the MDD came into law in 1992, electronic labeling (e-labeling) did not. Manufacturers had to rely on printed materials as the means of communicating product, safety, and compliance information for many years. Replacing printed with digital media has proven advantageous for manufacturers for some time now. However, a clear set of requirements and regulations surrounding e-labeling was varied and conflicting among the notified bodies and member states under the MDD regulation. The EU MDR is novel as it mandates controlled regulations and provides manufacturers with a documented and clear path forward regarding e-labeling within the EU market.



* Date impacted by Covid-19

Timeline of Important EU MDR Dates and Milestones

Electronic Labeling Focus

The EU MDR emphasizes the safety, transparency, and traceability of devices throughout the supply chain, including any associated user labeling or IFU. Device manufacturers need to plan and prioritize how best to provide user labeling or electronic IFU (eIFU) to company websites, or provide an alternative if a website does not exist. This new requirement will place greater emphasis on e-labeling as the new discipline for providing labeling content.

Many device manufacturers are already posting their IFUs electronically, so e-IFU is not a new concept within the life sciences industry. Prior to the EU MDR, no published regulations existed that prevented a manufacturer from posting labeling content electronically. However, the new EU MDR states that all manufacturers who have a website must make the IFU available on that website.

The business appeal of e-labeling is substantial. Traditional printed literature and IFU production is resource intensive, both from manufacturing and environmental perspectives. The EU MDR requires IFUs to be printed in all 24 European languages, potentially doubling the current number of paper leaflet pages and causing difficulty in implementation. This could also mean that printed IFUs no longer fit in the box supplied with a device. An eIFU can reduce these associated cost and packaging concerns; however, manufacturers must consider the options for transitioning from printed to electronic IFU.

1. UDI

UDI has its own dedicated section within EU MDR: Article 27 of Regulation (EU) 2017/745 ('MDR').

2. More Serial and Lot Numbers

This change was part of UDI, however the EU MDR requires more products to be serialized than FDA UDI.

3. Highlight Authorized EU Representatives

Every manufacturer whose registered place of business is outside the EU is required to be licensed in the EU.

4. Warnings and Precautions

This change may have the biggest impact. MDR mandates that all warnings related to a device must be printed on labeling.

5. Blood and Tissue Derivatives

EU MDR provides regulation for Medtech innovations not previously covered by MDD; ie nanotechnology, the use of computer software, or medicines.

6. Label Spacing Differences

To address the new regulations and possible new labeling congestion, the recent final ruling by the FDA no longer requires English text alongside symbols for the purpose of freeing up space.

7. eIFUs

EU MDR introduces requirements for electronic IFUs and the 'absorption of substances' that dictate changes in labeling processes.

8. Medical Device Symbol

Under EU MDR, manufacturers of medical devices must now include a new field on their labels: a clear, symbolic indication that the product is a medical device.

Major Areas of Impact to IFUs per EU MDR

Exploring Options for eIFU

To meet electronic labeling requirements, there are different paths that can be considered depending on the manufacturer's approach (outlined below).

Post Current IFU to an Acceptable Website

The simplest and least expensive means of adhering to the EU MDR regulation is to post a PDF version of the current IFU to a website. Per the General Data Protection Regulation (GDPR) requirements, a PDF document is acceptable because it is "resistant to software or hardware intrusion." The website must provide version control to clearly distinguish between the current and previous versions of the eIFU. In addition to being the least expensive method of meeting the requirement, it also presents the lowest risk. However, it is important to note that this method does not provide any benefit other than compliance.

Separate Multi-language IFU into Individual, Single-language IFUs

Similar to the process mentioned above, this option uses PDF documents. However, the existing multi-language IFU is separated into individual, single-language IFUs before being posted to a website. Users are directed to an eIFU in their language of choice, instead of the multi-language version. From a labeling artwork perspective, separating the languages into unique files is already common practice, so would not add to an existing process. In a traditional print IFU scenario, the individual language files are combined into one multi-language print booklet. This entire step of combining the language files would be eliminated. Translation vendors typically charge extra for this type of multi-language formatting and without the need, the cost would be eliminated. This method provides cost savings and the added benefit as the first step toward e-labeling and on-demand printing.

Incorporate New Innovations and Formats

For some it may be advantageous to create a new labeling document, one that is more general in nature and covers a wide range of products. An example may be a document with a "user guide" feel, which relies more on images and graphics to convey product safety and instructions. eIFUs also lend themselves to greater creativity, paving the way for animation, video, and voice prompts for additional guidance. Hyperlinks to other published resources and real-time access to online specialist can also be included. While this solution is the most complex in terms of implementation and control, it may reduce the effort to manage the website by having fewer documents that require less updating.

Advantages of Using e-Labeling

Removing reliance on physical labels in product packaging saves cost, time, paper, and space, while eliminating the risk of IFUs becoming lost or separated from their associated devices. Electronic versions have the potential to be more accessible and durable as they are not subject to fading, contamination, or absent pages.

The use of e-labeling also makes it possible for the end-user or patient to access the current safety information: eIFU content can be updated immediately and frequently to reflect post-market surveillance, further enhancing device safety and improving patient outcomes.

In addition to compliance, e-labeling also presents an opportunity for manufacturers to streamline processes for managing, posting, and updating their labeling content more broadly. To maximize the associated benefits and take advantage of greater control and cost-efficiencies, medical device manufacturers will need to adopt a more coordinated approach to labeling management. This approach could be one that helps with the migration to e-labeling, while also alleviating the time and effort required to manage regional translations and market-specific variations of regulated content.

Options for Posting eIFUs

Once a manufacturer has made a decision on which eIFU format to pursue, a decision must be made as to where the eIFU will be posted. To comply with EU MDR requirements, manufacturers have 2 choices regarding where to post the information and make it accessible to others: use an existing website or third-party web hosting service.

Use of an Existing Website

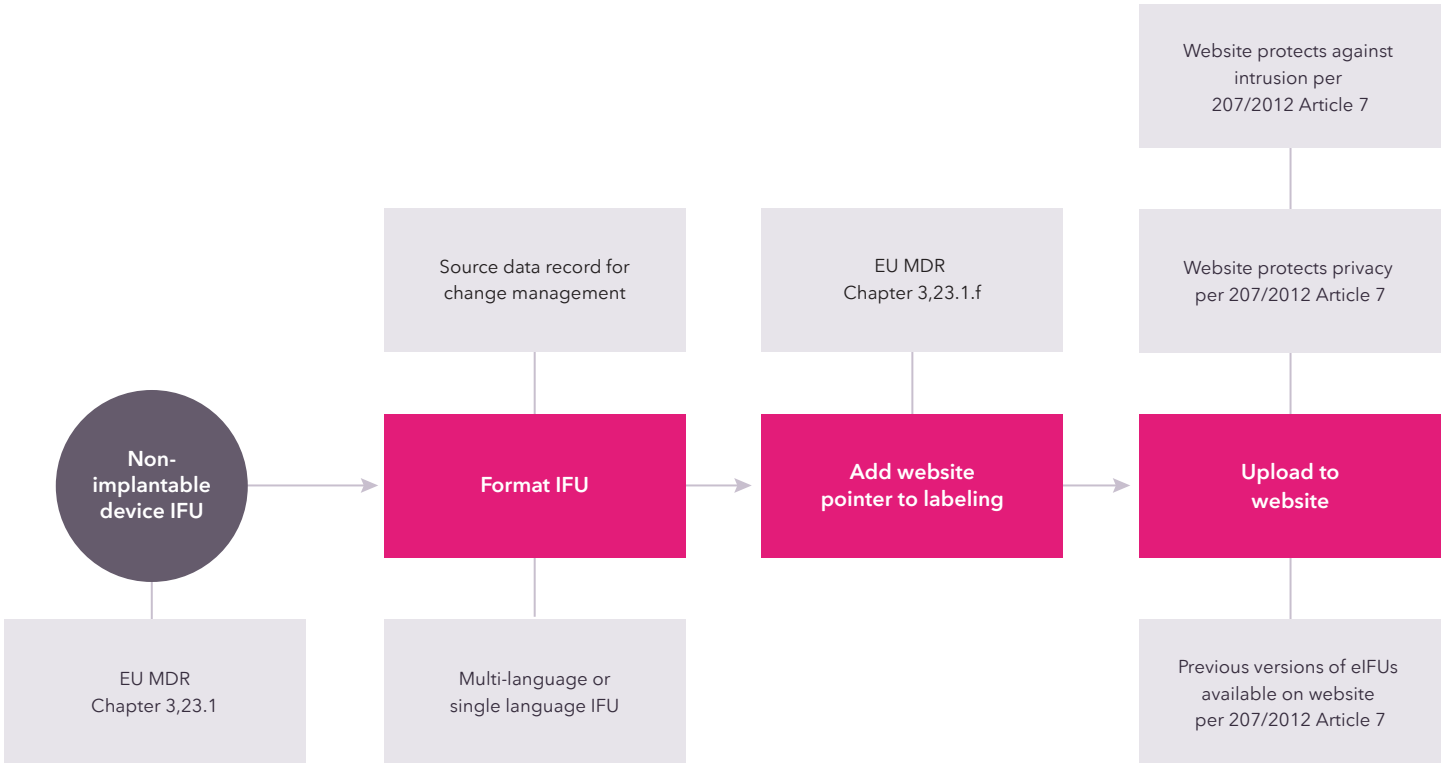
Since the regulation applies to manufacturers that already have a website, the simplest solution is to use a section of the existing website to host this information, most likely in PDF format. While this approach comes with the benefit of using a website infrastructure already available to the manufacturer, the company must be sure that the website complies with all requirements.

The EU MDR references EU regulation 207/2012 requires that the website chosen by the manufacturer must meet 3 requirements, including:

- Be protected against hardware and software intrusion
- Fulfill the requirements of Directive 95/46/EC (since replaced by GDPR)
- Make available all previous versions of the IFU issued in electronic form and their date of publication

Use a Contract Web Hosting Service

A third-party contract web hosting service can offer an appealing option for manufacturers unsure if their websites meet the necessary requirements, or for those who do not want to bear the monetary and time costs associated with bringing an existing website into compliance. These services are specifically built for e-labeling hosting and are validated to meet the EU MDR eIFU website requirements and all requirements for 207/2012.



Basic Paths to EU MDR Compliance for eIFUs | Non-Implantable Medical Devices

Conclusion

The new eIFU requirements in the EU MDR create unique challenges for the industry. Each manufacturer must develop, implement, and maintain a plan to make new information available online and to maintain the information once implemented. While the EU MDR requirements pose challenges for all manufacturers, they also create the possibility for increased access to information and increased safety for patients and healthcare providers. Compliance with the new EU MDR requirements also offer the possibility for future cost savings through the removal or reduction of paper IFUs.

In the end, creating an e-labeling campaign is not an easy endeavor. The obstacles associated with e-labeling usually revolve around underlying process problems. If hiccups in a company's operations are addressed before the launch of e-labeling materials, the transition will be smoother down the road.

PRA can help you navigate through the interpretation of the new regulation and mitigate any associated challenges. We can provide this through a full or partial assessment of current IFU content, processes and/or strategies, and by making industry-based recommendations for cost savings, process efficiencies, and implementation. PRA can make the process of working through these complex labeling changes simpler and more comprehensible.

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