WHITE PAPER

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EU MDR – Medical Device Labeling Changes & Challenges

Global rollout of EU MDR and other UDI-type of regulations are driving all medical device companies to revisit their labeling processes to ensure they are all compliant across the extended supply chain. The European Medical Device Regulations (MDR) 2017/745 and In Vitro Diagnostic Regulations (IVD) 2017/746 were published on May 5, 2017 in the Official Journal of the European Union (OJEU).

The introduction of the new European Medical Device Regulation (EUMDR 2017/745) gives great importance to the end user to assist with the safe and proper use of a medical device(s). These days device labeling has become a critical business process for manufacturing companies, since the manufacturer/marketing authorizing holder need to continuously monitor product safety from PMS and update the label information as applicable. However, new European Medical Devices Regulation (MDR) brings added complexity and is pushing companies to review their labeling structure and design as they battle for organizational readiness. EU MDR, which began a 5-year pre-implementation period in May 2017, will be fully adopted in 2022. Information provided on a device label is a significant portion of this requirement and should be thoroughly developed and compiled by following the harmonized standards and expert guidance.

New Labeling Requirements

EU MDR regulations (Article 23.1, Chapter III of Annexure I) describe that each device must be accompanied by the information that identifies the device, its manufacturer, relevant safety and performance information. These aspects may appear on the device, packaging and in the IFU. In addition, if the manufacturer has a website the information must also be available there with current information. These basic requirements, which will be rigorously enforced from May 2020, mean that, more than ever before, companies must be in control of the data they are using for their products.

EU MDR introduces additional information that needs to be included on labels, causing organizations to design new label templates that make room for data not previously part of the labeling system. This poses the design and data challenge, and this must quickly be addressed to avoid a sticky situation as every manufacturer that ships products to Europe will have to change their labels.

What does it mean for the sticky label itself

EU MDR introduces new rules (EUMDR 2017/745) around these crucial materials. The regulation requires that all labels must include a standardized symbol(s) to indicate a package contains a medical device. Individual requirements are outlined in section 23.2 (Annex III) of the regulation. Though not all of them affect every manufacturer, a number of them have significant implications. Certainly, every change that requires new information to be added to the label will have operational repercussions.

Here are some major changes in the device label structure:

- Serial & Lot number
- Indication & Usage
- Warnings & Precautions
- UDI applied in Europe
- Include reprocessing cycles
- Harmonized symbols
- Information to blood and tissue derivatives
- Authorized Representative information (EU)
- CE Marking

Serial & Lot Number

The serial and lot number information falls under the UDI requirement for the EU economic area. However, MDR requires more products to be serialized than FDA UDI. Making the shift from batch labeling to a world where individual products need to be collaborating with the right label at the right time is a crucial challenge. It requires a continuous data-led labeling platform. Every active implantable device must have its own unique serial number. Other implantable devices will require a serial or lot number.

Warnings & Precautions

MDR regulations made mandate that all warnings relating to a device must be printed on the label. This information is crucial and shows greater impact during the product recalls or regulatory notifications due to safety assessment of the end-user. Previously, these were all included only in the IFU. Although the regulation says information can be kept to a minimum length with more detail in the IFU, newer compliance will require companies to add written text into labels as well. This change will probably have the biggest impact. The choice of inclusion of the number of warnings is the manufacturer's choice.

Harmonized symbols

One way to reduce the amount of space needed on the labels is to use symbols (EN ISO 15223). The usage of symbols helps to the manufacturer and also avoids having to provide the information in multiple languages. The MDR regulations allow that the information supplied by the manufacturer can be provided as internationally recognized symbols or in case of a suitable symbol is not included in EN ISO 15223-1; the symbol used needs to be described in the IFU.

UDI

The Unique Device Identification (UDI) is a system used to mark and identify medical devices within the healthcare supply chain.UDI has its own dedicated section within MDR. The EU guidelines are in line with the Global UDI initiative, and so the FDA UDI rules; MDR requires that a UDI label be directly attached to a medical device or to its packaging and include two identifiers: A UDI-DI (device identifier– linked to a manufacturer and device) A UDI-PI (production identifier– identifies unit of device production). So according to MDR regulations, all labels must include PI (GTIN) and DI components as textual and barcoded content.

Include reprocessing cycles

This is another data challenge for labeling platform. Under EU MDR, labels for single-use devices that can be reprocessed must be detailed with the number of reprocessing cycles as well as the number of times the device has been reprocessed to date. Manufacturers will need to integrate batch information from the ERP systems and identify data changes to each product. This requires capturing the information that is not included in the current labeling. Some manufacturers are considering stopping reprocessing single-use devices to avoid the ambiguity in the process.

Authorized EU Representatives

If the manufacturer has its registered place of business outside the Union, the name of the authorized representative and address of the registered place of business of the authorized representative must be provided on the label. Previously these details were included in the IFU. As per the new regulations and requirement, companies need to print this information on their commercial labels.

MDR also introduces requirements around electronic IFUs and the absorption of substances that dictate changes in labeling processes.

Labeling design & Strategy

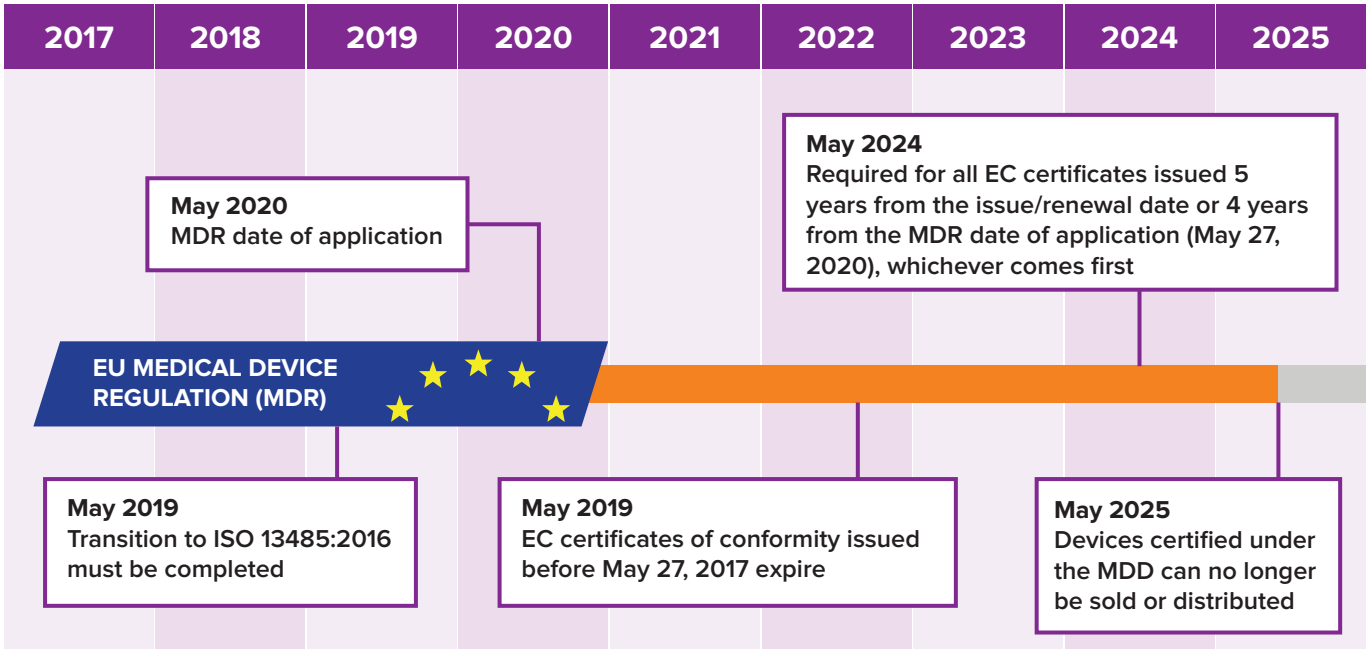
It is important to recognize that the implementation of approved labeling is a complex, expensive, time-consuming and labor-intensive process for the device manufacturer and its vendors. It is a challenging task to implement product labeling changes made under MDR regulations, especially with respect to getting the newly labeled product onto the field within a reasonably short period of time.

Managing the transition from the MDD to MDR requires good planning and implementation. Gap analysis is the key step to determine the current requirements with the evolving change of regulations. Gap analysis gives clear results about labeling gaps in which the data to be updated as per the current regulatory requirements.

MDR timeliness

The new EU MDR began a 3-year transition period in May 2017. Here are some deadlines you should commit to memory.

- **Mar 2019** – Transition to ISO 13485:2016 must be completed.
- **May 2020** – MDR date of application.
- **May 2022** – EC certificates of conformity issued before May 27, 2017 expire.
- **May 2024** – Required for all EC certificates issued 5 years from the issue/renewal date or 4 years from the MDR date of application (May 27, 2020), whichever comes first.
- **May 2025** – Devices certified under the MDD can no 0079b7be sold or distributed.



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