TATA ELXSI

Impact of EU MDR on Medical Device Labeling

Table of Contents

Abstract

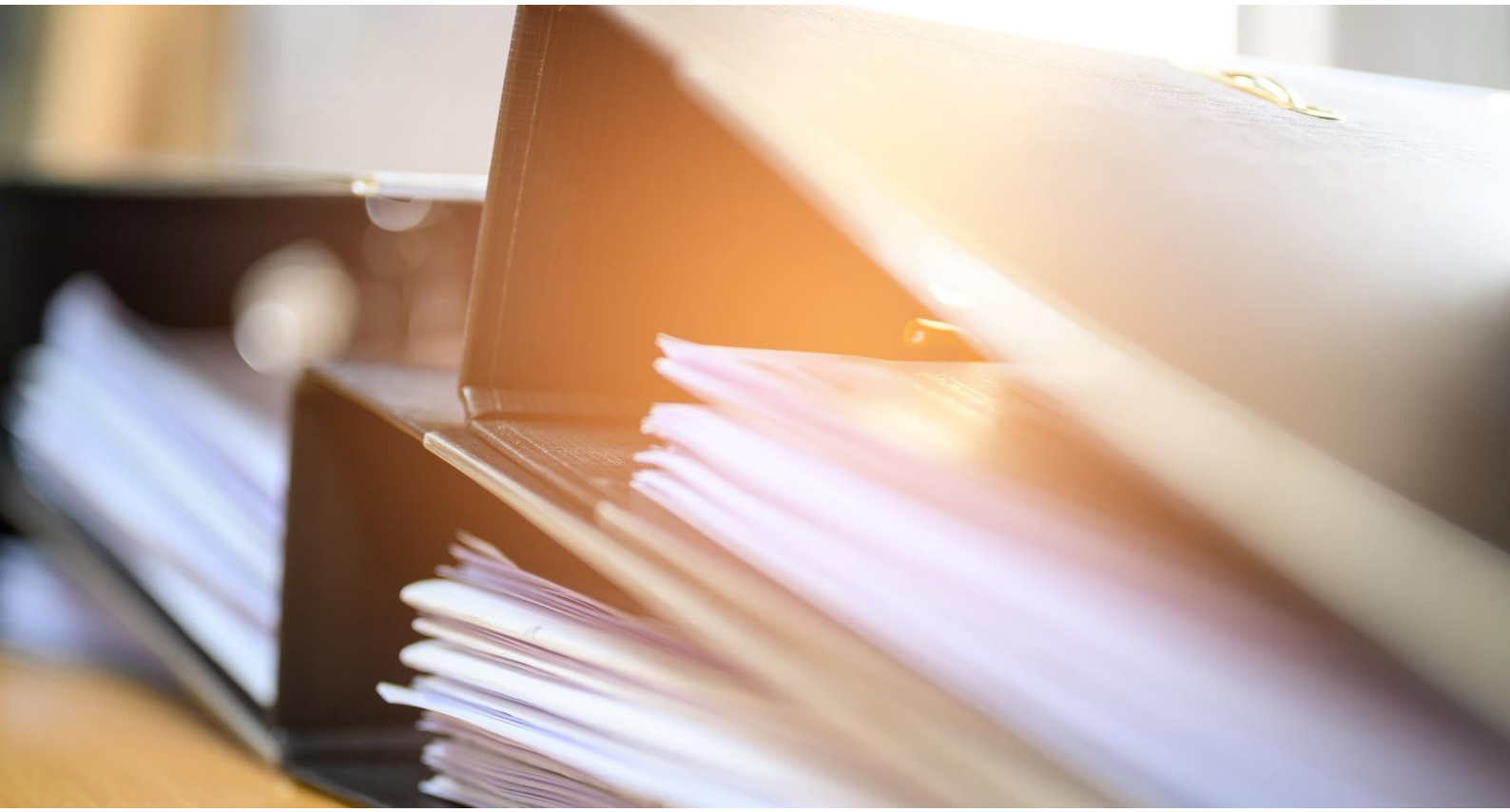
Medical device manufacturers see labeling as an essential element for maintaining compliance, conveying high safety and character standards, enhancing operational efficiency, and ensuring brand consistency. However, amendments in the regulatory requirements in major geographies have led to changes in compliance requirements for labeling for medical devices across the globe. One such crucial change in the European region is the introduction of the new EU Medical Device Regulation (MDR) 2017/745. The new regulations call for increased cross-functional collaborations to ensure an effective change process. These new regulations will have significant implications on the labeling operations of every MedTech manufacturer that operates in the region.

One of the essential components of the development process is the accurate labeling of a medical device. The different labels on the device must properly communicate the device's safety, usage, performance, and manufacturing-specific information. Medical device labels cover a variety of details, including Instructions for Use (IFU), storage and maintenance, installation requirements, etc. As per the EU MDR, all medical devices must have a Unique Device Identification (UDI) that identifies the general type of the device. This ensures device traceability and facilitates seamless post-market surveillance activities. In addition, common symbols are utilized for communicating traits that exist across multiple devices. While the US, the EU, and Canada standards vary slightly, the basic principle remains the same. Finally, medical device manufacturers must include specific product guidelines, handling procedures, and other vital product safety information on the labels.

Introduction

Medical device labeling is an integral part of the device itself as it provides critical risk/benefit information and clear instructions for safe use. It is one of the most heavily scrutinized parts of the product authorization process (e.g., the CE marking process in Europe or the 510K process in the USA). The cost of failing to label a medical device correctly or including all the appropriate information can be significant for manufacturers. Incorrect or insufficient labeling can lead to export bans, financial penalties, and potential reputational damage, while the omission of crucial information can cause costly delays to market entry. Further, improper labeling of a medical device can result in counterfeit devices, and the associated device recalls may prove to be a costly affair for the manufacturer, importers, and distributors.

Therefore, manufacturers are exploring measures to cope with the stringent and constantly evolving regulatory requirements for the labeling of medical devices. Additionally, they are also investing in rebranding, centralizing the labeling process, and implementing the corporate standards across the organization.



EU MDR and Medical Device Labeling Overview

By now, everyone in the MedTech industry is familiar with the new European Union Medical Device Regulations (EU MDR) 2017/745. EU MDR compliance was released in 2017 by the European Parliament and the Council of the European Union. The new regulations intend to ensure a high standard of safety and quality for medical devices manufactured in or are being supplied and marketed in the member countries of the European Union.

EU MDR replaces the previous European Union Medical Device Directives (EU MDD) and Active Implantable Medical Device Directives (AIMDD).

The EU MDR is significantly more comprehensive and detailed and has ***123 articles and 17 annexes.*** Below is the timeline to implement the new regulations:

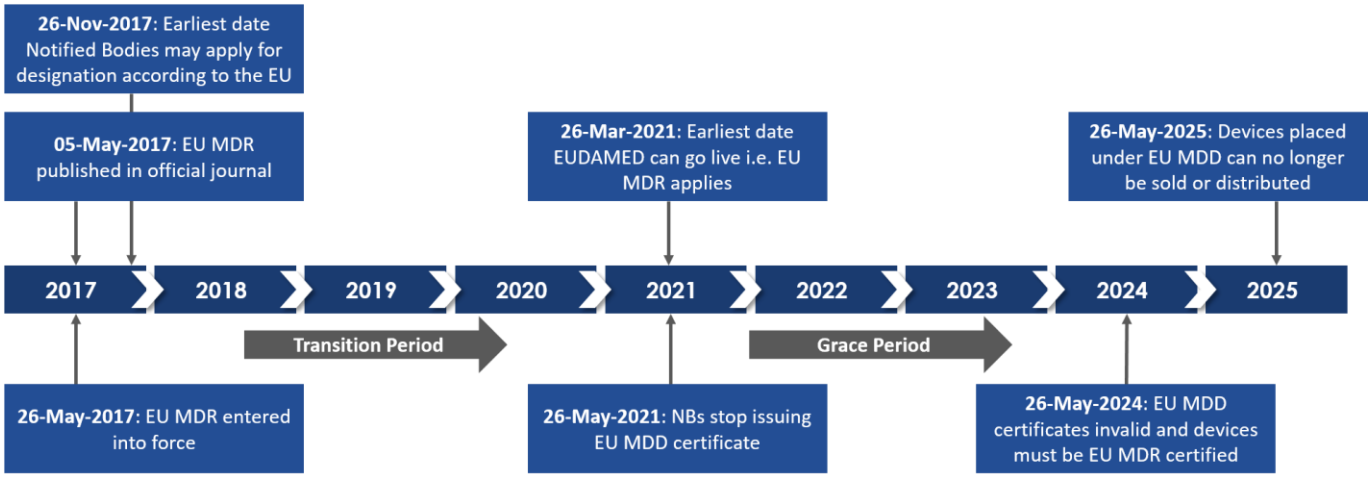


Figure 1 – EU MDR Implementation Timeline

LABELING

Labeling is a broad term that encompasses any written, printed, or graphic matter on, or included with, the device or the packaging. As per ISO 13485 section 3.8, medical device labeling symbols, warnings, the information presented on a User Interface (UI), and documentation are all considered as medical device labeling.

LABELING VS. LABEL

Labeling	Any information conveyed by the manufacturer that is provided for, associated with, or affixed to, a medical device or any of its containers or wrappers.
Label	Any written, printed, or graphic information that is provided upon the medical device.

ELEMENTS OF MEDICAL DEVICE LABELING

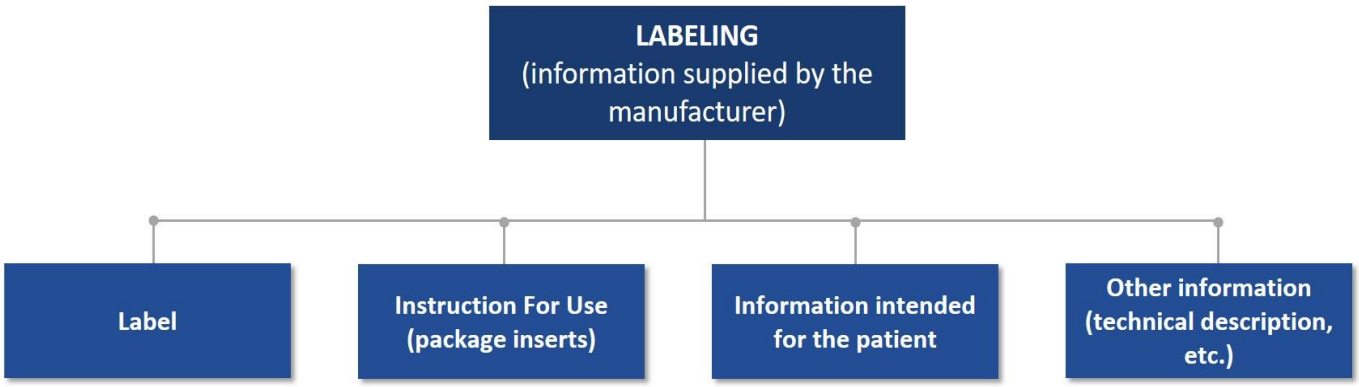


Figure 2 – Elements of Medical Device Labeling

The image below is an example of a medical device label:

Figure 3 – Medical Device (Sample Label)

WHY IS LABELING IMPORTANT

A picture is said to be worth a thousand words. However, in the case of the medical devices industry, an image can ensure significant cost savings for the manufacturer. For devices being sold globally, manufacturers may incur considerable expenses in language translations. Additionally, text-based information takes up valuable real estate off of the labels. On the other hand, Universally recognized 'Symbols' can be used on labels and packaging material for multiple geographies globally.

Figure 4

Medical device labeling is a critical aspect of the manufacturing process. Labeling must be accurate to ensure market access and the safe and proper use of medical devices by hospitals, caregivers, and patients. Therefore, labeling is one of the most heavily scrutinized parts of the product authorization process (e.g., the CE marking process in Europe or the 510K process in the USA). Failing to label a medical device correctly or to include all the appropriate information in a label can have severe repercussions for the manufacturers. Furthermore, incorrect or insufficient labeling can lead to product recalls or export bans, resulting in monetary penalties and possible reputation damage. The omission of key information can also cause costly delays to market entry.

Impact of EU MDR on Labeling

REQUIREMENT FOR MEDICAL DEVICE LABELING: EU MDD VS. EU MDR

EU MDD	EU MDR
--	EU MDR is more comprehensive and detailed compared to EU MDD. EU MDR is the combination of EU MDD and EU AIMDD.
EU MDD comprises 23 articles and 12 annexes.	EU MDR consists of 123 articles and 17 annexes.
Annex 1 essential requirements, section 13.3 information on label consists of 14 explicit requirements.	• EU MDR Annex 1 General Safety Performance Requirement, Chapter 3, section 23.2 information on label consists of 19 requirements. • There is an additional section 23.3 specifically for sterile packaging labels.
Name or Trade Name	
--	Annex I, section 23.2The label shall bear all of the following particulars: (a) the name or trade name of the device.
Device description/ contents/ intended purpose	
Annex 1, 13.4 If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use. Annex 1, 13.3 (b) the details strictly necessary to identify the device and the contents of the packaging, especially for the users.	Annex I, section 23.2 (b) the details strictly necessary for a user to identify the device, the contents of the packaging, and, where it is not obvious for the user, the intended purpose of the device. Annex I, section 23.3 The following particulars shall appear on the sterile packaging: (e) a description of the device.

EU MDD	EU MDR
Manufacturer's address	
Annex1, 13.3 (a) the name or trade name and address of the manufacturer.	Annex I, section 23.2 (c) the name registered trade name or registered trademark of the manufacturer and the address of its registered place of business. Annex I, section 23.3 (d) the name and address of the manufacturer.
Authorized representative	
Annex 1, 13.3 (a) For devices imported into the community, given their distribution in the community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorized representative where the manufacturer does not have a registered place of business in the area.	Annex I, section 23.2The label shall bear all of the following particulars: (d) 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.
Blood products / medicinal substances	
Annex 1, 13.3 (n) in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.	Annex I, section 23.2 (e) where applicable, an indication that the device contains or incorporates: — a medicinal substance, including human blood or plasma derivatives.
Items of animal origin	
--	Annex I, section 23.2 (e) where applicable, an indication that the device contains or incorporates:— tissues or cells of animal origin, or their derivatives, as referred to in Regulation (EU) No 722/2012.

EU MDD	EU MDR
Toxic substances/ Phthalates	
Annex 1, 7.5 If parts of a device (or a device itself) intended to administer and/or remove medicines, body-liquids, or other substances to or from the body, or devices intended for transport and storage of such body fluids or substances, contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, of category 1 or 2, per Annex I to Directive 67/548/EEC, these devices must be labeled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as a device containing phthalates.	Annex I, section 23.2 (f) where applicable, information labeled per Section 10.4.5.: Where devices, parts thereof, or materials are used therein as referred to in Section 10.4.1. contain substances referred to in points (a) or (b) of Section 10.4.1. in a concentration above 0.1 % weight by weight (w/w), the presence of those substances shall be labeled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances. Sales package label, if above 0.1%, w/ CAS#; info in IFU.
LOT/ Serial Number	
Annex1, 13.3 (d) where appropriate, the batch code, preceded by the word 'LOT', or the serial number.	Annex I, section 23.2 (g) the lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate. (s) for active implantable devices, the serial number, and other implantable devices, the serial number or the lot number.
Catalogue Number	
--	Annex I, section 23.1 Each device shall be accompanied by the information needed to identify the device and its manufacturer.

EU MDD	EU MDR
UDI barcode/ Human readable	
--	Annex I, section 23.2 (h) the UDI carrier referred to in Article 27(4) and Part C of Annex VI.
Use-by date	
Annex 1, 13.3 (e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month.	Annex I, section 23.2 (i) an unambiguous indication of the time limit for using or implanting the device safely, expressed at least in terms of year and month, where this is relevant. Annex I, section 23.3 (i) an unambiguous indication of the time limit for using or implanting the device safely expressed at least in terms of year and month.
Date of manufacture	
Annex 1, 13.3 (l) year of manufacture for active devices other than those covered by (e). This indication may be included in the batch or serial number.	Annex I, section 23.2 (j) where there is no indication of the date until when it may be used safely, the date of manufacture. This date of manufacture may be included as part of the lot number or serial number, provided the date is clearly identifiable. Annex I, section 23.3 (h) the month and year of manufacture.
Special storage/ Handling conditions	
Annex 1, 13.3 (i) any special storage and/or handling conditions (j) any special operating instructions	Annex I, section 23.2 (k) an indication of any special storage and/or handling condition that applies.

EU MDD	EU MDR
Annex 1, 5 The devices must be designed, manufactured, and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	
Sterilization	
Annex 1, 13.3(c) where appropriate, the word 'STERILE'(m) where applicable, method of sterilization	Annex I, section 23.2 (l) if the device is supplied sterile, an indication of its sterile state and the sterilization method. Annex I, section 23.3 (b) a declaration that the device is in a sterile condition (c) the method of sterilization
Warnings/ Precautions (General warnings/ IFU)	
Annex 1, 13.3 (k) any warnings and/or precautions to take	Annex I, section 23.2 (m) warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device, and any other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, considering the intended users.
Single-use restricted	
Annex 1, 13.3 (f) where appropriate, an indication that the device is for single use. A manufacturer's indication of single-use must be consistent across the community.	Annex I, section 23.2 (n) if the device is intended for single-use, an indication of that fact. A manufacturer's indication of single-use shall be consistent across the Union.

EU MDD	EU MDR
Medical device identification	
Annex 1, 13.3 (h) If the device is intended for clinical investigations, the words 'exclusively for clinical investigations'.	Annex I, section 23.2 (q) an indication that the device is a medical device. If the device is intended for clinical investigation only, the words 'exclusively for clinical investigation'. Annex I, section 23.3 (f) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations'.
Indication of sterile packaging	
--	Annex I, section 23.3 (a) an indication permitting the sterile packaging to be recognized as such.
Sterile packaging damage	
--	Annex I, section 23.3 (j) an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.
Labeling non-sterile Product	
Annex 1, 8.6 The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.	Annex I, section 11 (8) The labeling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition in addition to the symbol used to indicate that devices are sterile.
Items of human origin	
--	Annex I, section 23.2 (e) where applicable, an indication that the device contains or incorporates: — tissues or cells, or their derivatives, of human origin.

EU MDD	EU MDR
Devices composed of substances introduced via body orifice or skin	
--	Annex I, section 23.2 (r) in the case of devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body, the overall qualitative composition of the device and quantitative information on the main constituent or constituents responsible for achieving the principal intended action.
Single-use reprocessed	
--	Annex I, section 23.2 (o) if the device is a single-use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles.
Custom made devices	
Annex 1, 13.3 (g) if the device is custom-made, the words 'custom-made device'.	Annex I, section 23.2 (p) if the device is custom-made, the words 'custom-made device'. Annex I, section 23.3 (g) if the device is custom-made, the words 'custom-made device'.
Devices used in combination with other devices or equipment	
Annex 1, 9.1 If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices.	Annex I, section 14.1 If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system, shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use.

EU MDD	EU MDR
Any restrictions on use must be indicated on the label or in the instructions for use.	
Devices that emit radiation	
Annex 1, 11.4.1The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user, and ways of avoiding misuse and eliminating the risks inherent in installation.	Annex I, Section 16.1 (b) The operating instructions for devices emitting hazardous or potentially hazardous radiation shall contain detailed information as to the nature of the emitted radiation, the means of protecting the patient and the user, and ways of avoiding misuse and reducing the risks inherent to installation as far as possible and appropriate. Information regarding the acceptance and performance testing, the acceptance criteria, and the maintenance procedure shall also be specified.

Table 1 – EU MDD vs. EU MDR Labeling Requirements

CHANGES IN LABEL CONTENT

- Name or trade name of the device
- Manufacture date (or expiration date)
- An indication that the equipment/product is a medical device
- Any warnings or precautions that should be immediately communicated to the user
- eIFU – Add the web address

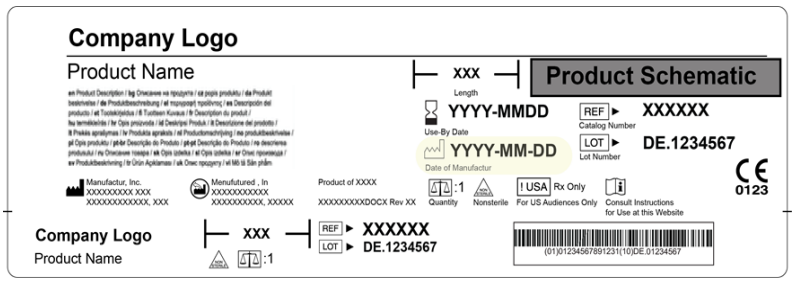


Figure 5: Sample Label

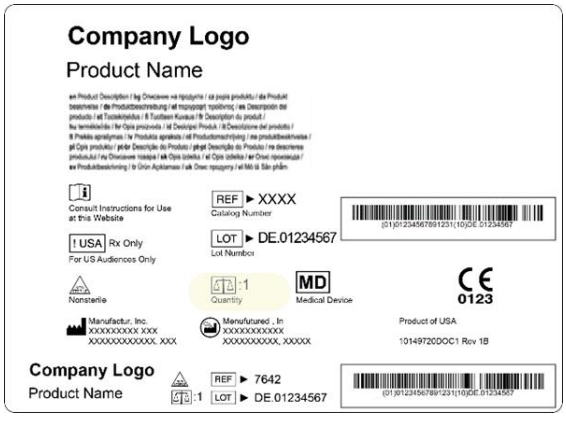


Figure 6: Sample Label

- Explicit requirements for sterile barrier labeling
  - Identification of the sterile barrier
  - Declaration of the sterile condition (e.g. sterile, non-sterile)
  - Sterilization method
  - Manufacture date (month & year)
  - Expiration date (month & year)
  - Directive to check IFU if the package appears damaged

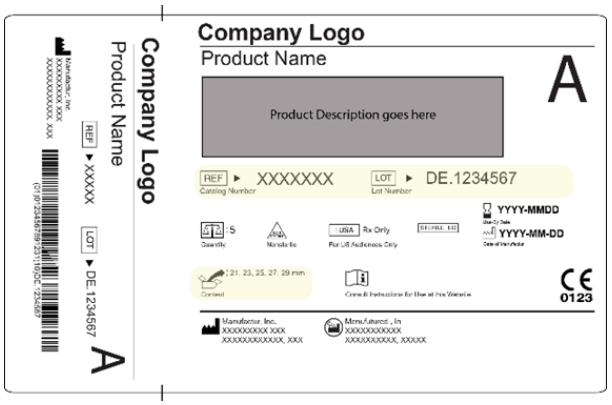


Figure 7: Sample Label

- Number of times a single-use device has been reprocessed
- The serial number is required for all active implantable
- Specific warning for medical devices including substances that are:
  - Carcinogenic
  - Mutagenic
  - Toxic to reproduction
  - Endocrine-disrupting properties
- An indication that the device contains tissue or cells of an animal or human origin

Figure 8: Label comparison: Before and after the implementation of EU MDR

MEDICAL DEVICE LABELING STANDARD: ISO 15223-1

ISO 15223-1 identifies requirements for symbols used in medical device labeling that convey information on the safe and effective use of medical devices.

In the current market, most medical device manufacturers are refereeing to ISO 15223-1: 2016. However, a '15223-1: 2021' version is also available with additional symbols that comply with the EU MDR 2017/745 requirements.

According to ISO 15223-1 standard, medical device labeling symbols are divided into 7 categories that are:

- Manufacturing
- Storage
- Safe use
- Sterility
- IVD specific
- Transfusion/ Infusion
- Others

Figure 9: Medical device labeling symbols

Best Practices: DOs & DON'Ts

Given the complex and lengthy nature of the updated labeling requirements, it can be challenging for medical device and pharmaceutical companies to comply with the new regulations. Discussed below are some best practices for successful transition programs. However, each jurisdiction (country, region, etc.) may have its own set of requirements that need to be implemented accordingly.

To efficiently implement the new labelling requirements, the manufacturers should:

- Include labeling design early on in your planning process.
- Identify the medical device by its make, model number, manufacturing date, and batch number or serial number.
- Include the manufacturer's and/or local representative's or distributor's contact information.
- List out the contents of the box, i.e. the items that are supplied with the device.
- Indicate warnings or cautions, if any, resulting from the risk management process.
- If applicable, use appropriate symbols on the device labels.
- Choose label materials that will stay readable for the life of the device and that are compatible with the cleaning and sterilizing methods outlined in the IFU.
- Get the labels reviewed by the regulatory subject matter experts labels before submitting the device for clearance.

Furthermore, the manufacturers should avoid:

- Including any content that contradicts the intended usage or describes or refers to an off-label use.
- Including any marketing claims that aren't backed up by data.
- Using the certifying body (e.g., CSA, ETL, UL) artwork on the product label without authorized consent.
- Making any changes to the device's labelling after it has received regulatory approval.

Conclusion

Implementing the new EU MDR can be complex and challenging for the manufacturers. This unprecedented change in the medical device regulations has compelled the global MedTech organizations to deliver safe, secure, and traceable medical devices in the European market and execute the new format of labeling information with utmost priority and caution. Failing to comply with the EU MDR labeling requirements may result in product discontinuation in the European region and even product recalls in many other regions. However, manufacturers can use this opportunity to streamline the entire labeling process by implementing the corporate standards across the organization and harmonizing the labels to reduce turnaround time and increase output efficiency. Therefore, the organizations must take small steps with the phased approach supported by the right technology/tool and start employing established and proven processes to ensure timely compliance.

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TATA ELXSI

ABOUT THE AUTHORS

AJAY ZINAGE

Senior Regulatory Compliance Consultant & Strategist

Ajay is a medical device professional with over 14 years of experience in medical devices product lifecycle. Ajay has worked with global medical device manufacturers and successfully led the commercialization of medium to high-risk devices. He has in-depth expertise in project management, design control, manufacturing operations, labeling & packaging, and securing regulatory compliance for developed and emerging markets. At Tata Elxsi, he leads a team of regulatory professionals responsible for submissions in more than 60 countries.

APURVA WANKHEDE

Engineer & SME – Medical Device Labeling

Apurva is a part of the labeling team for the healthcare & life sciences practice at Tata Elxsi. He has over 5 years of experience in the medical devices industry and worked on various regulatory compliance projects such as test method validation, DHF remediation, and labeling (Brexit, EU MDR, rebranding). He has also been certified with a Six Sigma green belt for reducing overall efforts in labeling associated projects. He takes a special interest in cross-functional collaboration and aspires to lead labeling remediation and similar regulatory compliance programs in the future.

ABOUT TATA ELXSI

Tata Elxsi, a part of Tata Group, is among the world's leading providers of design, engineering, and regulatory compliance services. With 15+ years of experience in catering to medical device and healthcare companies, Tata Elxsi has built a comprehensive services and solutions portfolio that adds value at every stage of the customer's product development lifecycle. Tata Elxsi is an established name in technology consulting, new product design, development, verification and validation, and regulatory compliance services.

Tata Elxsi also helps manufacturers standardize and automate labeling workflow across multiple manufacturing sites, thus saving significant costs associated with the product launch, sustenance, rebranding, and recalls due to mislabeling. Tata Elxsi's proprietary solutions, in addition to lower infrastructure and maintenance costs, ensure the critical regulatory compliance for their products thus allowing manufacturers to focus on other important aspects such as accessing new markets, expanding product lines and improving customer experience and satisfaction.

For more information,
please visit www.tataelxsi.com click here

ITPB Road Whitefield Bangalore 560048 India | Tel +91 80 2297 9123 | Fax +91 80 2841 1474

info@tataelxsi.com | www.tataelxsi.com

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