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REGULATORY REQUIREMENTS FOR EU MEDICAL DEVICE LABELING – NEW CHANGES

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ABSTRACT

Medical equipment labeling is any data related to equipment focused on the patient.It is planned to help guarantee that theequipment is utilized safely, effectively, and successfully. The primary purpose of supplying these labels is to assist the target peoples about the usage and applications without the intervention of healthcare professionals or physicians. To produce the quality standards in labeling as per European Union (EU) medical device regulations (MDR), the present article may help the manufacturers in their development. The article is drafted according to the EU MDR 2017/745.

INTRODUCTION

1.1European Union:

The European Union (EU) is a political and financial association of 27 parts found principally in Europe. Its individuals have a joined region of 4,233,255.3 km^2 (1,634,469.0 sq mi) and an expected all-out populace of around 447 million. The 27 section states of the EU includes Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland. The euro (€) is the authority cash of 19 out of 27 EU nations. These nations are aggregately known as the Eurozone. The banner utilized is the Flag of Europe, which comprises a circle of 12 brilliant stars on a blue foundation. Initially planned in 1955 for the Council of Europe, the banner was received by the European Communities, the archetypes of the current Union, in 1986. The Council of Europe gave the banner a representative portrayal in the accompanying terms, though the authority emblematic depiction embraced by the EU overlooks the reference toward the "Western world."**[1]**

1.2 Label and Labeling concepts:

As per Article 2 of EU MDR 2017/745**[2]**, 'Label' means the written, printed, or graphic information appearing either on the device itself or on the packaging of each unit, or on the packaging of multiple devices."Labeling" includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce**[3, 4]**.

As per article 7 of EU MDR 2017/745 - Claims

In the labelling, IFU, making accessible, placing into administration and publicizing of devices, it will be precluded to utilize text, names, brand names, pictures and metaphorical or different signs that may deceive the client or the patient as to the device'sintended purpose, safety and performance**[2]**.

1.3 Medical device:

As per Article 2**[2]**,'Medical device' means any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

1. diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
2. diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, — investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
3. Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood, and tissue donations.

1.4 Classification as per EU MDR:

Chapter V, Section 1, Article 51 of EU MDR 2017/745, has four main categories. Those are: Class I, Class IIa, Class IIb, and Class III. Class I are low-risk and Class III high-risk devices. Detailed rules on medical device classification were found in MDR 2017/745 Annex VIII **[2]**.

2. Guidelines of Medical devices in the European Union:

To ensure medical devices' quality and safety, the European Union (EU) has released a new Medical Device Regulation (MDR) in May 2017. Initially, there was a transition period of 3 years to implement the new EU MDR 2017/745. Accordingly, most of the articles of the regulation should be enforced

3. EU Labeling requirements for Medica device as per MDR: EU MDR 2017/745, Annex 1, chapter III, paragraph 23.2**[2]** 'Information on the label' outlines what must be included. Manufacturersshallensurethatthedeviceisaccompaniedbytheinformation/labels that must be available in an official Union language(s)determined by the Member State in which the device is made available to the user or patient. Chapter III highlights the requirements regarding the information supplied with the device.

3.1 General Requirements:

- Information supplied by the manufacturer must appear available on the manufacturer website
- Labels must be human and machine-readable and having barcodes / RFID (radio- frequency identification).
- Instructions for Use (IFU) with the device package
- eIFU
- Residual risks

3.2 Package labeling:

The label shall bear all of the following particulars:

- the name or trade name of the device;
- details of device identification and package contents;
- the name, registered trade name or registered trademark of the manufacturer and the address of its registered place of business;
- if the manufacturer has its registered place of business outside the Union, the name of the authorised representative and address of the registered place of business of the authorised representative;
- Indication regarding if the device contains any medicinal substance including human blood or plasma derivative, tissues, or cells of the animal or human origin
- Declaration of CMR and endocrine-disruptors if any
- Unique Device Identification (UDI) as per Article 27(4) and Part C of Annex VI

- Details of time limit for using or implanting the device safely expressed at least in terms of year and month;
- Date of manufacture
- An indication of any special storage and/or handling conditions;
- If it is a sterile device, information about the sterility and method of sterilization; Symbol for "Do not use if package opened or damaged";
- Warnings or precautions to the user of the device;
- If a device is single-use, reprocessed (An indication of that fact; the number of reprocessing cycles already performed; limitation)
- if the device is custom-made, the words 'custom-made device';
- If the device is intended for clinical investigation, the words 'exclusively for clinical investigation';
- If a device composed of any substance(s) or combination to be introduced into the human body via a body orifice or applied on the skin or local dispersion
- serial number (SN) for active implantable devices, and the serial number or the lot number for other implantable devices;
- Serial number of all active implantables

3.3 Instructions for Use:

- Indications, contraindications, patient target groups, and intended user
- Clinical benefits to be expected
- Web links to Summary and Safety of Clinical Performance (SSCP)
- Performance characteristics of the device
- Information to software and accessories verification
- details of any preparatory treatment or handling of the device before it is ready for use or during its use
- Residual risks, undesirable side effects
- Requirements for special facilities, or training, or particulars of qualifications of the device users
- Precautions related to materials having CMR(carcinogenic, mutagenic, or toxic to reproduction) substances, or endocrine-disrupting substances
- Information supplied regarding implantable devices as per article 18
- Methods of safe disposable of device
- Information regarding the absence of clinical benefits and risks
- Information, when the user should consult a health care professional
- A notice to the user and/or patient that if any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established
- An indicationthat a device can be reused only if it is reconditioned under the responsibility of the manufacturer to comply with the general safety and performance requirements;
- Information to the software of the device, including minimum requirements
- Information for devices intended for use together with other devices and/or general purpose equipment
- Indication of sterile condition
- Indication of non-sterile condition
- Indication of single-use, if it is
- Details and nature of the device emits radiation for medical purposes
- date of issue of the instructions for use or, if they have been revised

3.4 Sterile packaging

The following particulars shall appear on the sterile packaging:

- indication of sterile packaging
- declaration on "sterile condition"
- method of sterilization
- manufacturer details
- device description
- if the device is intended for clinical investigation, the words 'exclusively for clinical investigation';
- if the device is custom-made, the words 'custom-made device',

- month and year of manufacture
- time limits of usage or implantation of the device
- detailed instructions to the users on what to do if the sterile packaging is damaged or unintentionally opened before use.

3.5 Summary of Safety and Clinical Performance (SSCP)

- A Summary of Safety and Clinical Performance (SSCP) for implantable devices and class III devices
- The IFU must include a statement noting where healthcare professionals and patients can find the SSCP in Eudamed.

3.6 Patient implant card

Implant cards must be provided to the patient with a permanent implant that contains:

- Device name
- Serial number or lot or batch number
- Unique Device Identification (UDI) in a human and machine-readable format
- Name, address, and the website of the manufacturer
- Device type

Implant cards must also contain:

- Name of the patient or patient ID
- Name and address of the healthcare institution which performed the implantation
- Date of implantation
- Symbols may be used to illustrate these requirements
- Implantable systems provide challenges
- UDI

4. Use of Symbols In-Compliance with EU MDR

Symbols are efficient, cost-saving, and internationally understood concepts to convey the required information to a medical device's user. MedTech Europe is the European trade association for the medical technology industry, including diagnostics, medical devices, and digital health. MedTech Europe's December 2019 document (Version 2.0) "Use of Symbols to Indicate Compliance with the MDR" guides symbols that can be used until an international harmonized standard is available. Must align with MDR 2017/745/EU. Currently, these symbols are being considered in the revision of ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied **[6, 7]**. More detailed information on symbols to be used on labeling can be accessed at **[8, 9, 10]**.

5. Major changes in medical device labeling after EU MDR

EU MDR introduces additional information that needs to be included on labels and guiding organizations to design new label templates having extra space for data, not previously part of the labeling system.

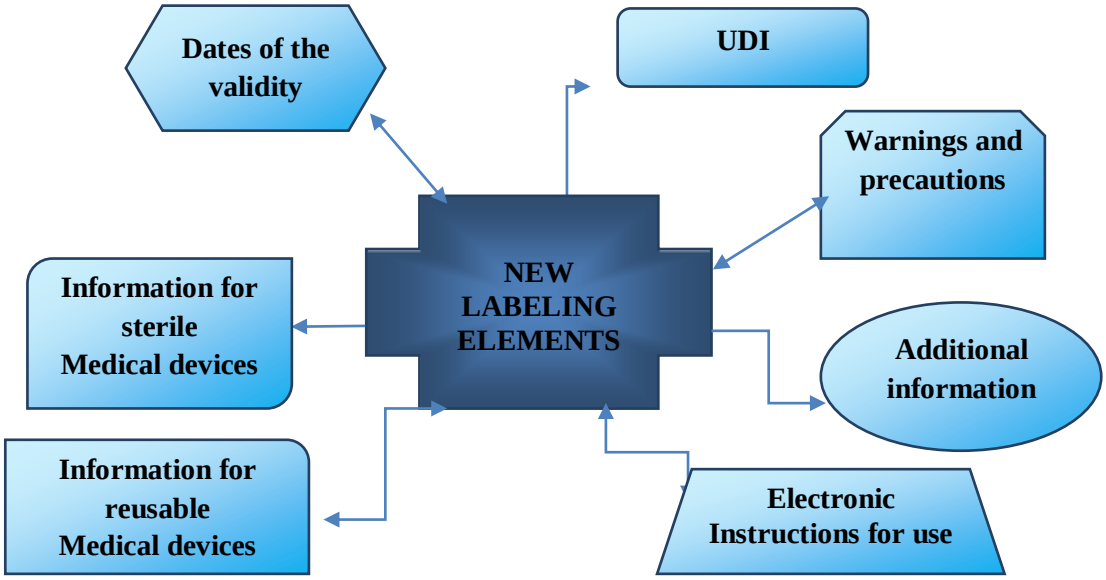
The following are ten significant changes:

1. UDI Content
2. Serial numbers and lot numbers
3. Highlight authorized EU representatives
4. Warnings and Precautions on the label
5. Label must declare the presence of any CMR or endocrine-disrupting substances
6. Labels must indicate blood and tissue derivatives
7. Details of reprocessing cycles for single-use devices
8. eIFU link
9. Label spacing differences
10. Medical device symbol

	Medical Device
	Contains human blood or plasma derivatives
	Contains a medicinal substance
	Contains hazardous substances
	Contains biological material of human origin
	Contains biological material of animal origin
	Sterilized using vaporized hydrogen peroxide

	Single Patient - multiple use
	Translation
	Repackaging
	Person identification
	Health care centre or doctor
	Date
	Patient information website

	ManufactureR
LOT SN	Batch code or Serial number
UDI	Unique Device Identifier



New Elements on the label of Medical device

6. EU MDR-Compliant Model label:

Device name
Company name
Device identification
CE Mark
Material
Ref. No.
Lot. No.
Expiry date
Warnings
Storage method
Manufacturer details
EC Representative
UDI-DI
Languages
Patient Information Website link
eIFU

CONCLUSION:

To achieve the high standards of quality and safety for medical devices produced, the device manufacturers must follow the new EU MDR 2017/745. The MDR has laid out the precise labeling requirements for medical devices. All the manufacturers must follow the labeling guidelines regarding general requirements, package labeling, instructions for use, sterile packaging, a summary of safety and clinical performance, and symbols in compliance with EU MDR.

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