MedTech Europe
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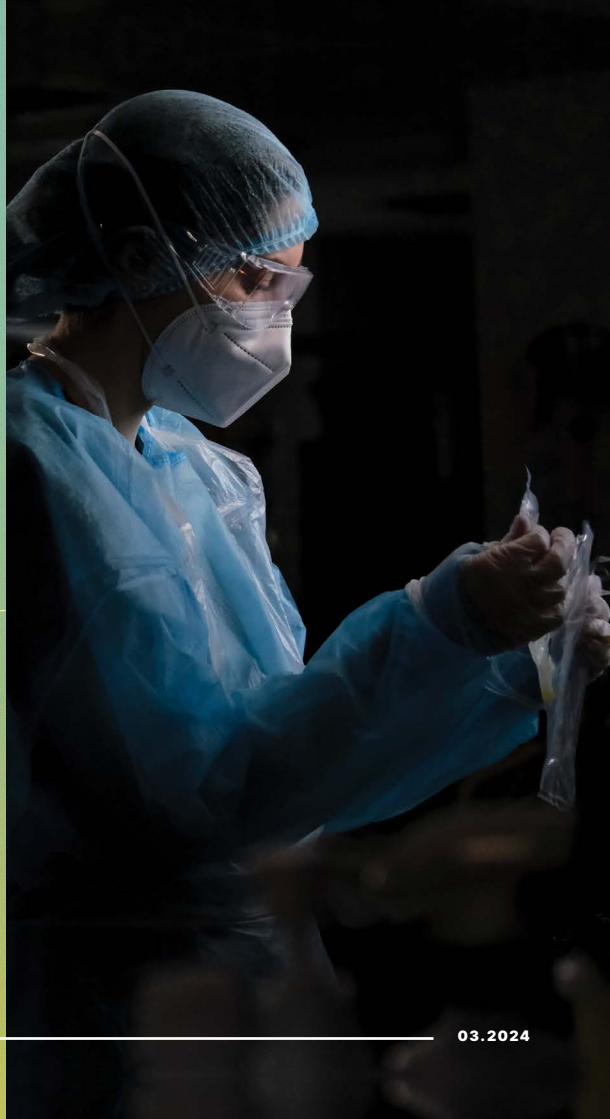
Medical Devices Regulation (MDR): New symbols for medical devices

Factsheet for healthcare professionals



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PURPOSE

The aim of this factsheet is to assist healthcare professionals (HCPs) – users of medical devices – in getting familiar with new symbols created in relation to the Medical Devices Regulation (EU) 2017/745 ('MDR').

BACKGROUND

The MDR has new requirements that ask for various kinds of information to be indicated on the label of the medical device.

There are 24 official languages in the EU, which creates a necessity to translate the information on labels, instructions for use, manuals, leaflets etc. depending on where the device is sold. Inclusion of internationally recognised and harmonised symbols instead of text is an efficient and valid way of providing the user with the information which is required by the MDR[1].

Symbols are a **tool** for conveying the required information and their use is encouraged by the MDR[2]. It is the **information itself** which is required to be on the device and symbols are one way of conveying that information.

1) MDR Annex 1, chapter III, 23.1. h

2) MDR Annex 1, chapter III, 23.1. h

Note: in addition to new symbols on labels and accompanying documentation, you may also notice changes to intended purpose and other indications to align with new definitions and requirements of the MDR.

Please note that if the symbol is part of a harmonised standard, it does **not** have to be accompanied by a description – as is the case for the symbols below. These symbols are part of the harmonised standard: EN 15223-1: 2021.

AS A USER OF MEDICAL DEVICES, YOU ARE LIKELY TO NOTICE THESE NEW SYMBOLS[3] ON LABELS AND OTHER ACCOMPANYING INFORMATION SUCH AS INSTRUCTIONS FOR USE, LEAFLETS, MANUALS ETC.

Medical Device

The MDR requires on the label an indication that the device is a medical device. This symbol (or an indication that the device is a medical device) must appear on all medical devices following the MDR. Some manufacturers may have included this symbol voluntarily in the past – i.e. before MDR application.

3) MDR Annex 1, chapter III, paragraph 23.2 'Information on the label'

The following symbols apply to specific circumstances when a medical device contains certain substance(s) or material:

Note: these symbols will be used only if applicable

Contains human blood or plasma derivatives

Contains a medicinal substance

Contains hazardous substances

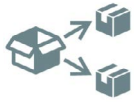
Contains biological material of human origin

Contains biological material of animal origin

When the medical device package went through a translation or repackaging by an importer or distributor, in certain cases this will be indicated on the label via these symbols:

Note: these symbols will be used only if applicable

Translation



Repackaging

One of the following symbols will be used **when the medical device is in a sterile barrier configuration**. The symbol used will depend on the specific situation.

Note: these symbols will be used only if applicable

Single sterile barrier system

Double sterile barrier system

Single sterile barrier system with protective packaging inside

Single sterile barrier system with protective packaging outside

Economic operators such as importer and distributor **may be** indicated via the following symbols:

Importer

Distributor

Other new symbols that you **may** see on label and other material:

Sterilized using vaporized hydrogen peroxide

Single Patient - multiple use

Contains nano materials

Unique Device Identification

This is an important symbol as UDI for class III implantable devices needs to be tracked by the HCP. Please see more information on this in MedTech Europe factsheet: MedTech Europe information leaflet on UDI and implant card availability - MedTech Europe

Note that additional national requirements for tracking UDI by HCPs may apply.

IMPLANT CARD

In addition, per MDR[4] if you are working with implantable devices you will have to give the patient an implant card (there are certain exceptions)[5] containing information about the device they have been implanted with. The implant card will be supplied to you by the manufacturer of the implant and it **may** contain the following new symbols. These symbols are contained in EN 15223-1: 2021.

The descriptions in the below table are based on the MDCG guidance 2019-8 v2, where they are used to indicate what needs to be filled in/what information is indicated. The original sources of the symbols remain the ISO and CEN standards.

Medtech Europe has already published a factsheet with information regarding implant card and UDI for healthcare[7] professionals, where you can find more information: mte-information-leaflet-for-hospitals.pdf (medtecheurope.org)

Patient name or patient ID

Here the symbol is used to indicate a **"device name[6]"**

Name and Address of the implanting healthcare institution/provider

Information website for patients

Date of implantation

4) MDR Art.18
5) MDR Art.18.3.
6) As per MDCG 2019-8 v2
7) MedTech Europe information leaflet on UDI and implant card availability - MedTech Europe

All symbols mentioned in the present factsheet are internationally recognised and they can be found on the ISO Online Browsing Platform (https://www.iso.org/obp) or in ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements. They are also part of the harmonised version of that standard EN 15223-1: 2021.

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