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Symbols to Be Used In Labelling Of Medical Devices

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Abstract

This document specifies different symbols used to express information supplied for a medical device. This document is applicable to symbols used in a broad spectrum of medical devices, that are available globally and to meet different regulatory requirements. These symbols can be used on the medical device itself, on its packaging, or in the accompanying information. The requirements of this document are not intended to apply to symbols specified in other standards.

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Introduction

Definition

A medical device can be any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material, or another similar or related article, intended by the manufacturer to be used, alone or in combination for the medical purpose [1].

The term Labelling includes all information provided with the device. This includes labels, symbols, warnings, instructions, or control labels applied to the device or incorporated into the design by color, printing, machining, or molding [2].

The symbol is a graphical representation appearing on the label and/or associated documentation of a medical device that communicates characteristic information without the need for the supplier or receiver of the information to have knowledge of the language of a particular nation or people [3].

ISO15223-1:2021 identifies requirements for symbols used in medical device labeling that convey information on the safe and effective use of medical devices. It also lists symbols that satisfy the requirements of this document.

ISO 15223-1:2021 is applicable to symbols used in a broad spectrum of medical devices, which are marketed globally and therefore need to meet different regulatory requirements.

These symbols may be used on the medical device itself, on its packaging, or in the associated documentation. The requirements of this document are not intended to apply to symbols specified in other standards [4].

The necessity of using symbols in labeling of Medical devices

1. The labeling of each uniquely labeled medical device can communicate the same information using stand-alone symbols or symbols with adjacent explanatory text.
2. Exporters probably use labels with stand-alone symbols because it is cheaper to a design labeling with a common set of stand-alone symbols versus creating a labelling with no symbols for each nation with different language.
3. The use of graphical symbols as an alternative to written text has many advantages for manufactures who have space limitations on their labels.
4. Graphical symbols are items that carry information essential for their safe and proper use.
5. Symbols used in medical device labeling convey information on the safe and effective use of medical devices [5].

Classification of Medical Devices

Medical devices are classified into classes based on the intended use and risk that a device enacts on the patient/ user [6, 7, 8, 9, and 10].

Medical device classification in different countries:

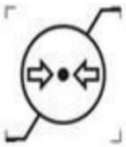
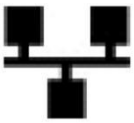
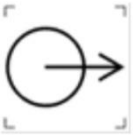
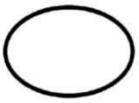
Countries	Medical Device Classification			
INDIA	Class-A	Class-B	Class-C	Class-D
USA	Class-I	Class-II	Class-III	-
EU	Class-I	Class-IIa, IIb	Class-III	-
CANADA	Class-I	Class-II	Class-III	Class-IV
AUSTRALIA	Class-I	Class-IIa, IIb	Class-III	-

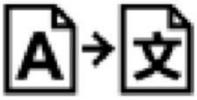
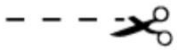
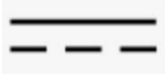
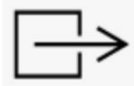
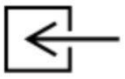
***Note:** In the classification of Medical devices, as the level of classes increases the level of risk increases**,** similarly decrease in the level of classes decreases the level of risk.

Different Symbols Used in Labelling of Medical Device

Different symbols used in the labeling of medical devices which are marketed globally are given below [3, 11, 12]

 Manufacturer	 Date of Manufacturer	 Use-by Date	 Medical Device	 Unique Device Identifier
 EC Rep	 Batch code	 Catalog#	 Serial#	 Non-sterile
 sterile	 Sterilized using Ethylene oxide	 Sterilized using irradiation	 Sterile Fluid Path-EO (ETO Ethylene- Oxide)	 Sterile Fluid Path- R (Irradiation)
 Fragile, handle with care	 Keep away from sunlight	 Keep dry	 Humidity limitation	 Do not use if package is damaged
 Lower limit of temperature	 Upper limit of temperature	 Temperature limit	 Consult instructions for use	 Consult instructions for use (Electronic Format)
 caution	 Contains or presence of natural rubber latex	 Product is not made with natural rubber latex	 Non-pyrogenic	 Drops per milliliter
 Liquid filter with port size	 One-way Valve	 Labeling	 CE Mark European Conformity	 CE Mark with Notified Body Reference # ###
 Alert	 Does not contain lead	 Does not contain DEHP	 Contains or presence of Phthalates bis(2-ethylhexyl phthalates (DEHP)	 Contains or presence of Phthalates bis(2-ethylhexyl phthalates (DEHP)

QTY Quantity	IPX1 Protected against dripping water	IPX2 Protected against vertically falling water drops	IPX3 Protected against spraying water	Class 1 Class 1 Mains Protection
 General Warning Sign	 Warning Electricity	 General Mandatory Action Sign	 Refer to instruction manual/ booklet	 Pb Lead Waste Disposal
 WEEE	 Dangerous Voltage	 To indicate correct upright position of the transport package	 Atmospheric pressure Limitation	 RF Transmitter
 Wired Ethernet Interface Port	 Alarm Volume Control	 Output Terminal	 Certification Mark	 Equipotential Terminal (Ground)
 Type CF Part	 Type BF Part	 Regulatory Compliance Mark	 FCC Compliance Mark	 Wireless Registration
 CSA Compliance	 Bell	 Bell Cancel	 Locking, general	 Country of Manufacture
 Single sterile barrier system	 Double sterile barrier system	 Single sterile barrier system with protective packaging inside	 Single sterile barrier system with protective packaging outside	 Importer
 Distributor	 Model number	 Sterilized using vaporized Hydrogen peroxide	 Health care center or doctor	 Date
 Patient number	 Patient name	 Patient identification	 Patient information website	 Single patient – multiple use

 Contains humanblood or plasma derivatives	 Contains a medicinal substance	 Contains biological material of animal origin	 Contains biological material of human origin	 Contains hazardous materials
 Contains Nano materials	 Translation	 Repackaging	 Do not re-use	 Do not re-sterilize
 Biological risk	 Contains sufficient for <n> test	 Magnetic Resonance (MR) safe	 MR Condition	 (MR) Unsafe
 Control	 Positive control	 Negative control	 Degree of protection	 Serial interface
 No pushing	 Highly flammable	 Defibrillation proof Type CF applied part	 Defibrillation proof Type BF applied part	 General symbol for recover/ recyclable
 Fluid path	 Non-pyrogenic fluid path	 Protective earth; protective ground	 Class II equipment	 Do not stack
 Unlocking	 For IVD performance evaluation only	 Cut	 Oil; Fluid	 Stacking limit by number
 Alternating current	 Direct current	 Output; exit	 Input; entrance	 Input/output

Conclusion

Therefore, the symbols used on the labeling of medical devices convey information about the safety and effective use of medical devices, which are marketed globally and therefore meet different regulatory requirements.

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