Symbols Glossary Definition

Symbols Derived from Standards

Symbol	Standard Reference	Standard Title	Symbol Title	Expanatory Text
	ISO 15223-1, Reference 5.1.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Manufacturer	Indicates the medical device manufacturer.
EC REP	ISO 15223-1, Reference 5.1.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Authorized representative in the European Community	Indicates the Authorized representative in the European Community.
	ISO 15223-1, Reference 5.1.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Date of manufacture	Indicates the date when the medical device was manufactured.
	ISO 15223-1, Reference 5.1.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Use-by date	Indicates the date after which the medical device is not to be used.
LOT	ISO 15223-1, Reference 5.1.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.

REF	ISO 15223-1, Reference 5.1.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
NON	ISO 15223-1, Reference 5.2.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	ISO 15223-1, Reference 5.2.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
**	ISO 15223-1, Reference 5.3.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	Keep away from sunlight	Indicates a medical device that needs protection from light sources.
2	ISO 15223-1, Reference 5.4.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

to be supplied — Part 1: General requirements



ISO 15223-1, Reference 5.4.3 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements. Consult instructions for use

Indicates the need for the user to consult the instructions for use.



ISO 15223-1, Reference 5.4.3 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements. Consult electronic instructions for use

Indicates the need for the user to consult the electronic instructions for use (eIFU) at the specified website location.



ISO 15223-1, Reference 5.4.4 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements Caution

Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.



ISO 15223-1, Reference 5.7.1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements. Patient number

Indicates a unique number associated with an individual patient.

Symbols Not Derived from Standards

Symbol	Standard Reference	Standard Title	Symbol Title	Expanatory Text
Rx Only	21 CFR 801.109	Labeling; Prescription devices	Prescription use only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
(E 0086	MDD 93/42/EEC Annex II; MDR 2017/745 Annex V	The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Directive and Medical Device Regulation.	European conformity	European conformity (CE) mark with Notified Body identification number for Class Im, Ir, Is, IIa, IIb, III medical devices Notified Body No. 0086: BSI, United Kingdom
C E 2797	MDD 93/42/EEC Annex II; MDR 2017/745 Annex V	The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Directive and Medical Device Regulation.	European conformity	European conformity (CE) mark with Notified Body identification number for Class Im, Ir, Is, IIa, IIb, III medical devices Notified Body No. 2797: BSI, Netherlands
MD	MDR 2017/745 Annex 1 23.2(q)	The requirements for indicating that a device is a medical device; Medical Device Regulation.	Medical device	Indicates that the device is a medical device.