
























Symbol Glossary

SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD REFERENCE	STANDARD TITLE
	CE marking	(43) 'CE marking of conformity' or 'CE marking' means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing	EU 2017-745 EU 2017-746 Reference no. ANNEX V	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/ EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/ EEC and 93/42/EEC
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1: 2021 Reference no. 5.1.1. (ISO 7000-3082 2011-10-02)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.
	Date of manufacture	Indicates the date when the medical device was manufactured	ISO 15223-1: 2021 Reference no. 5.1.3. (ISO 7000-2497 2004-01-15)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.
	Authorized Representative in the European Community / European Union	Indicates the authorized representative in the European Community / European Union	ISO 15223-1: 2021 Reference no. 5.1.2	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.
	Product is not made with natural rubber latex	Indicates that natural rubber latex was not used in the manufacturing of the product, its container, or its packaging.	ISO 15223-1 5.4.5 Reference Annex B for the general prohibition symbol and negation symbol FDA Recognition #5-117	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation	ISO 15223-1: 2021 Reference no. 5.2.4. (ISO 7000-2502 2004-01-15)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.
	Do not re-use	Indicates a medical device that is intended for one single use only	ISO 15223-1: 2021 Reference no. 5.4.2. (ISO 7000- 1051 2004-01-15)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.







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	Do not resterilize	Indicates a medical device that is not to be resterilized.	ISO 15223-1: 2021 Reference no. 5.2.6. (ISO 7000- 2608 2004-01-15)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	ISO 15223-1: 2021 Reference no. 5.3.2. (ISO 7000-0624 2014-06-04)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.
	Keep dry Keep away from rain	Indicates a medical device that needs protection from moisture.	ISO 15223-1: 2021 Reference no. 5.3.4. (ISO 7000-0626 2014-06-04)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.
	Do not use if package is damaged and consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.	ISO 15223-1: 2021 Reference no. 5.2.8. (ISO 7000-2606 2004-01-15)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.
	Manufactured in the USA and/or applies to medical devices sold in the USA	Manufactured in the USA and/or applies to medical devices sold in the USA.	N/A	N/A
	Prescription Use Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.	N/A	N/A
	Catalogue number Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified	ISO 15223-1: 2021 Reference no. 5.1.6. (ISO 7000-2493 2004-01-15)	Medical devices — Symbols to be used with medical device labels, labeling, 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	ISO 15223-1: 2021 Reference no. 5.1.5. (ISO 7000-2492 2004-01-15)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.

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	Use-by date Use by date	Indicates the date after which the medical device is not to be used	ISO 15223-1: 2021 Reference no. 5.1.4. (ISO 7000-2607 2004-01-15)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.
	Quantity	Indicates the quantity	N/A	N/A
	Unique device identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1: 2021 Reference no. 5.7.10.	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.
	Importer	Indicates the entity importing the medical device into the locale	ISO 15223-1: 2021 Reference no. 5.1.8. (ISO 7000-3725 2019-11-01)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.
	Distributor	Indicates the entity distributing the medical device into the locale	ISO 15223-1: 2021 Reference no. 5.1.9. (ISO 7000-3724 2019-11-01)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.
	Single sterile barrier system	Indicates a single sterile barrier system	ISO 15223-1: 2021 Reference no. 5.2.11. (ISO 7000-3707 2019-10-18)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.
	Double sterile barrier system	Indicates two sterile barrier systems	ISO 15223-1: 2021 Reference no. 5.2.12. (ISO 7000-3704 2019-10-18)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.
	Single sterile barrier system with protective packaging inside	Indicates a single sterile barrier system with protective packaging inside	ISO 15223-1: 2021 Reference no. 5.2.13. (ISO 7000-3708 2019-10-18)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.

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	Single sterile barrier system with protective packaging outside	Indicates a single sterile barrier system with protective packaging outside	ISO 15223-1: 2021 Reference no. 5.2.14. (ISO 7000-3709 2019-10-18)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.
	Medical device	Indicates the item is a medical device	ISO 15223-1: 2021 Reference no. 5.7.7	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1: 2021 Reference no. 5.3.7. (ISO 7000-0632 2014-06-04)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.
	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	ISO 15223-1: 2021 Reference no. 5.4.4. (ISO 7000-0434A 2004-01-15)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1: 2021 Reference no. 5.4.3. (ISO 7000-1641 2004-01-15)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide	ISO 15223-1: 2021 Reference no. 5.2.4. (ISO 7000-2502 2004-01-15)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.