Symbols Glossary

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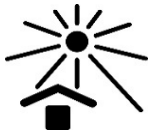
SYMBOL	SYMBOL TITLE	DESCRIPTION	STANDART TITLE
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/ EEC, 93/42/EEC and 98/79/EC.	EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2016). Ref no: 5.1.1
	Date of manufacture	Indicates the date when the medical device was manufactured.	EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2016). Ref no: 5.1.3
	Use-by date	Indicates the date after which the medical device is not to be used.	EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2016). Ref no: 5.1.4
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2016). Ref no: 5.1.5
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2016. Ref no: 5.1.6
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2016). Ref no: 5.2.3

	Do not resterilize	Indicates a medical device that is not to be resterilized.	EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2016). Ref no: 5.2.6
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2016). Ref no: 5.2.7
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2016). Ref no: 5.2.8
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2016). Ref no: 5.3.2
	Keep dry	Indicates a medical device that needs to be protected from moisture.	EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2016). Ref no: 5.3.4
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2016). Ref. no: 5.4.2
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2016). Ref. no: 5.4.3

	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.	EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2016). Ref. no: 5.4.4
	In vitro diagnostic medical device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.	EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (ISO 15223-1:2016). Ref. no: 5.5.1
	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.	EN ISO 15223-1 5.4.5 Reference Annex B for the general prohibition symbol and negation symbol
	Contains or presence of phthalates (DEHP)	Indicates the presence of Phtalates (DEHP)	EN 15986:2011 Clause 4.2
	CE Mark	Indicates manufacturer declaration that the product complies with applicable European regulations	765/2008/EC 768/2008/EC MDD 93/42/EEC Articles 4,11,12,17, Annex II) RED 2014/53/EU (Articles 19, 20, Annex II)
	CE Mark with Notified Body Reference	Indicates conformity of products where the notified body performed conformity assessment.	765/2008/EC 768/2008/EC MDD 93/42/EEC Articles 4,11,12,17, Annex II) RED 2014/53/EU (Articles 19, 20, Annex II).
	Prescription use	Caution: Federal law restricts this device to sale by or order of a physician	21 CFR 801.109

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