














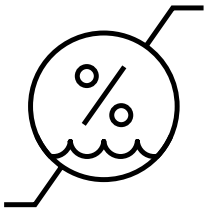
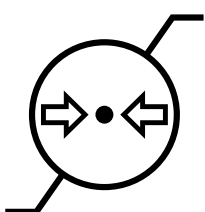

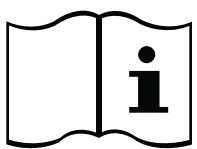




Glossary of Standard Symbols




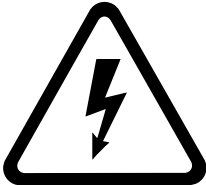


Symbol	Standard	Ref #	Title	Description
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC, 98/79/EC, and EU Regulation 2017/745.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.1.2	Authorized Representative in the European Community/ European Union	Indicates the Authorized Representative in the European Community/European Union.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.1.3	Date of manufacture	Indicates the date when the medical device was manufactured.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.1.4	Use-by date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.1.5	Batch code/Lot number	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.1.6	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.1.7	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.

Symbol	Standard	Ref #	Title	Description
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.1.8*	Importer	Indicates the entity importing the medical device into the locale.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.2.1	Sterile	Indicates a medical device that has been subjected to a sterilization process.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.2.2	Sterilized using aseptic processing techniques	Indicates a medical device that has been manufactured using accepted aseptic techniques.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.2.3	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.2.4	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.3.5	Lower limit of temperature	Indicates the lower limit of temperature to which the medical device can be safely exposed.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.3.6	Upper limit of temperature	Indicates the upper limit of temperature to which the medical device can be safely exposed.

*Approved symbols currently awaiting ISO harmonization are denoted with an asterisk in the Ref # column.

Symbol	Standard	Ref #	Title	Description
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.3.8	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.3.9	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.4.2	Do not re-use/Single use only	Indicates a medical device that is intended for one single use only.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.4.3	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 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.4.4*	Caution NOTE: When this symbol is marked directly on the medical device, the definition to the right is correct.	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.7.6*	Date	To identify the date that information was entered or a medical procedure took place.

*Approved symbols currently awaiting ISO harmonization are denoted with an asterisk in the Ref # column.

Symbol	Standard	Ref #	Title	Description
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.7.7*	Medical Device	Indicates the item is a medical device.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied	5.7.10*	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information.
	ISO 7010 Graphical symbols – Safety colors and safety signs – Registered safety signs	W001	General warning sign	To signify a general warning.
	ISO 7010 Graphical symbols – Safety colors and safety signs – Registered safety signs	W012	Warning: Electricity	To warn of electricity.
	IEC 60417 Graphical symbols for use on equipment	5032	Alternating current	To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.
	MDD 93/42/EEC MDR 2017/745 Regulation (EC) 765/2008	Annex XII Article 20 Annex II	CE marking, May include Notified Body Reference no. xxxx	Signifies European technical conformity.

*Approved symbols currently awaiting ISO harmonization are denoted with an asterisk in the Ref # column.

CSSS.0052.260128