

# SYMBOL GLOSSARY

## An explanation of symbols used in packaging

Symbol	Title	Standard	Reference No.	Description
<b>5.1 Manufacture</b>				
	Manufacturer	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.1.1	Indicates the medical device manufacturer.
	Authorized representative in the European Community	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.1.2	This symbol shall be accompanied by the name and address of the authorized representative in the European Community, adjacent to the symbol.
	Date of manufacture	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.1.3	Indicates the date when the medical device was manufactured.
	Use-by date	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.1.4	Indicates the date after which the medical device is not to be used.
	Batch code	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue number	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Serial number	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.1.7	Indicates the manufacturer's serial number so that a specific medical device can be identified.
<b>5.2 Sterility</b>				
	Sterile	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.2.1	Indicates a medical device that has been subjected to a sterilization process.
	Sterilized using aseptic processing techniques	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.2.2	Indicates a medical device that has been subjected to a sterilization process.
	Sterilized using Ethylene Oxide	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.2.3	Indicates a medical device that has been sterilized using ethylene oxide.
	Sterilized using irradiation	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.2.4	Indicates a medical device that has been sterilized using irradiation.
	Sterilized using steam or dry heat	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.2.5	Indicates a medical device that has been sterilized using steam or dry heat.
	Do not re-sterilize	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.2.6	Indicates a medical device that is not to be re-sterilized.
	Non-sterile	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.2.7	Indicates a medical device that has not been subjected to a sterilization process.
	Do not use if package is damaged	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.2.8	Indicates a medical device that should not be used if the package has been damaged or opened. This symbol may also mean "Do not use if the product sterile barrier system or its packaging is compromised".
	Sterile fluid path	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.2.9	Indicates the presence of a sterile fluid path within the medical device in cases when other parts of the medical device, including the exterior, might not be supplied sterile. The method of sterilization shall be indicated in the empty box, as appropriate.
<b>5.3 Storage</b>				
	Fragile, handle with care	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.3.1	Indicates a medical device that can be broken or damaged if not handled carefully.
	Keep away from sunlight Note: This symbol can also mean "Keep away from heat," as referenced in ISO 7000:1989.	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.3.2	Indicates a medical device that needs protection from light sources.
	Protect from heat and radioactive sources	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.3.3	Indicates a medical device that needs protection from heat and radioactive sources.
	Keep dry	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.3.4	Indicates a medical device that needs to be protected from moisture.
	Lower limit of temperature	ISO 15223 ISO 7000:2014 Reference no. 0534	5.3.5	Indicates the lower limit of temperature to which the medical device can be safely exposed
	Upper limit of temperature	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.3.6	Indicates the upper limit of temperature to which the medical device can be safely exposed.
	Temperature limit	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.3.7	Indicates the temperature limits to which the medical device can be safely exposed.
	Humidity limitation	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.3.8	Indicates the range of humidity to which the medical device can be safely exposed.
	Atmospheric pressure limitation	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.3.9	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
<b>5.4 Safe Use</b>				
	Biological risks	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.4.1	Indicates that there are potential biological risks associated with the medical device. Note: This symbol is not to be confused with the "Biohazard" sign intended to be used in the workplace.
	Do not re-use	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.4.2	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.
	Consult instructions for use	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.4.3	Indicates the need for the user to consult the instructions for use.
	Caution	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.4.4	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.
	Contains or presence of natural rubber latex	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.4.5	Indicates the presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device.
	Not made with natural rubber latex	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.	5.4.5 with Annex B.2 negation symbol	Indicates a medical device and the packaging of the medical device was not made with natural rubber latex.
	Medical device	ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	5.7.7	Indicates the item is a medical device.
	MR Unsafe	ASTM F2503-23 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Fig. 10	An item which poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.
<b>Others</b>				
	Exclamation mark	29 CFR 1900.1200	Section C.2.3.2	Irritant, dermal sensitizer, acute toxicity (harmful), narcotic effects, and/or respiratory tract irritation hazard.
	Flame over circle	29 CFR 1900.1200	Section C.2.3.2	Oxidizers hazard.
	Health hazard	29 CFR 1900.1200	Section C.2.3.2	Carcinogen, respiratory sensitizer, reproductive toxicity (harmful), target organ toxicity, mutagenicity and/or aspiration hazard.
	Top	ISO 7000 Graphical symbols for use on equipment.	0623	The package must always be transported, handled and stored in such a way that the arrows always point upwards.
	Recycling code	Public domain symbol	#21 PAP	Recycling symbol for mixed paper magazines, mail
	Prescription use only	N/A	N/A	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician, dentist, or licensed practitioner.
	European Conformity	EU Regulation 2017/745 Annex v	N/A	Certification mark that indicates conformity with applicable health, safety, and environmental protection standards for products sold within the European Economic Area (EEA)
	Warning!	ISO 7010 W001 Graphical symbols -- Safety colors and safety signs -- Part 2: Design principles for product safety labels	N/A	Indicates a potential injury to the user of the medical device
	Limited Quantity	49 CFR	172.315	Indicates hazardous materials that can be shipped in limited quantities.