

SYMBOLS GLOSSARY

SYMBOL USED IN THE LABELING FOR THE DEVICE	DESIGNATION NUMBER AND TITLE OF THE STANDARD	TITLE OF THE SYMBOL	REFERENCE NUMBER OF THE SYMBOL	MEANING OF THE SYMBOL
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	Manufacturer	5.1.1	Indicates the medical device manufacturer.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	Country and date of manufacture (DE=Germany)	5.1.3 5.1.11	Indicates the country and date when the medical device was manufactured.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	Use-by date	5.1.4	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, labelling and information to be supplied – Part 1: General requirements	Batch code	5.1.5	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, labelling and information to be supplied – Part 1: General requirements	Catalogue number	5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	Sterilized using aseptic processing techniques	5.2.2	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, labelling and information to be supplied – Part 1: General requirements	Sterilized using ethylene oxide	5.2.3	Indicates a medical device that has been 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	Sterilized using irradiation	5.2.4	Indicates a medical device that has been 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	Do not resterilize	5.2.6	Indicates a medical device that is not to be resterilized.
	ISO 15223-1 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 and consult instructions for use	5.2.8	Indicates that 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 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	Single sterile barrier system	5.2.11	Indicates a single sterile barrier system
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	Single sterile barrier system with protective packaging inside	5.2.13	Indicates a single sterile barrier system with protective packaging inside

SYMBOLS GLOSSARY

SYMBOL USED IN THE LABELING FOR THE DEVICE	DESIGNATION NUMBER AND TITLE OF THE STANDARD	TITLE OF THE SYMBOL	REFERENCE NUMBER OF THE SYMBOL	MEANING OF THE SYMBOL
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	Single sterile barrier system with protective packaging outside	5.2.14	Indicates a single sterile barrier system with protective packaging outside
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	Fragile, handle with care	5.3.1	Indicates a medical device that can be broken or damaged if not handled carefully.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	Keep away from sunlight	5.3.2	Indicates a medical device that needs protection from light sources.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	Keep dry	5.3.4	Indicates a medical device that needs to be protected from moisture.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	Upper limit of temperature 25 °C (77 °F)	5.3.6	Indicates the upper 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, labelling and information to be supplied – Part 1: General requirements	Storage between 4 °C (39 °F) and 25 °C (77 °F).	5.3.7	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, labelling and information to be supplied – Part 1: General requirements	Do not re-use	5.4.2	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, labelling and information to be supplied – Part 1: General requirements	Consult instructions for use	5.4.3	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, labelling and information to be supplied – Part 1: General requirements	Caution	5.4.4	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, labelling and information to be supplied – Part 1: General requirements	Contains a medicinal substance	5.4.7	Indicates a medical device that contains or incorporates a medicinal substance.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	Medical Device	5.7.7	Indicates the item is a medical device.
	ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	Unique device identifier	5.7.10	Indicates a carrier that contains unique device identifier information

SYMBOLS GLOSSARY

SYMBOL USED IN THE LABELING FOR THE DEVICE	DESIGNATION NUMBER AND TITLE OF THE STANDARD	TITLE OF THE SYMBOL	REFERENCE NUMBER OF THE SYMBOL	MEANING OF THE SYMBOL
	ASTM F 2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	MR safe	3.1.13	An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic.
	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006	Causes skin irritation	H315	Skin Irritation means the production of reversible damage to the skin following the application of a test substance for up to 4 hours.
	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006	Flammable liquid	H226	Flammable liquid means a liquid having a flash point of not more than 60°C.
	21 CFR 801.109 Prescription devices	Federal law restricts this device to sale, distribution, and use by or on the order of a physician	N/A	The device is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.