SYMBOLS GLOSSARY

Explanatory text of symbols used on product labeling and packaging

ISO 15223-1 Medical devices – symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements

Symbols Derived from Standards			
Symbol	Title	Description	Ref No.
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC. This symbol is accompanied by the name and address of the manufacturer.	5.1.1
EC REP	Authorized representative in the European Community	Indicates the authorized representative in the European Community This symbol is accompanied by the name and address of the authorized representative in the European Community.	5.1.2
	Date of manufacture	Indicates the date when the medical device was manufactured. Date format: YYYY-MM-DD	5.1.3
Exp.	Use-by date	Indicates the date after which the medical device is not to be used. Date format: YYYY-MM-DD	5.1.4
LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5
REF	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.	5.1.6
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.	5.3.1
Avoid sunlight	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	5.3.2
	Keep dry	Indicates a medical device that needs to be protected from moisture.	5.3.4

	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	5.3.7
	Consult instructions for use	Indicates the need for the user to consult the instructions for use. Consult "instruction for use for" an electronic instruction for use (e-IFU). Note: The e-IFU indicator can be a manufacture's website URL.	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.	5.4.4
	This way up	To indicate correct upright position of the transport package	ISO 7000 Reference no. 0623
Symbols not derived from Standards			
	Conformité Européenne or European Conformity	European conformity (CE) mark with Notified Body identification number for Class IIa, IIb, III medical devices. Notified Body No. 0123: TÜV SÜD Product Service GmbH, Germany	European Medical Device Directive 93/42/EEC (as amended by Directive 2007/47/EC) and Regulation (EU) 2017/745
	Prescription only	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed dentist or physician.	Indicates that the product is a medical device as defined in 21 CFR 801.15 (c)(1)(i) (F) and Federal Law (USA) restricts this device to sale by or on the order of a licensed physician (21 CFR 801.109)
	Medical Device	An indication that the device is a medical device.	At present no internationally standardized medical device symbol. ISO 15223-2 is under revision and will probably contain the symbols required by MDR. The MedTech Europe Association therefore published a (non-binding) guidance on the use of symbols in May 2019. It is recommended to use the following symbol and it is expected that exactly this symbol will be defined in the updated ISO 15223-2.

GHS labeling			
	Corrosion	Corrosive to metals, category 1 Skin corrosion, categories 1A, 1B, 1C Serious eye damage, category 1	GHS05 Danger or Warning
	Environment	Acute hazards to the aquatic environment, category 1 Chronic hazards to the aquatic environment, categories 1, 2	GHS09 Warning (for cat. 1) (for cat. 2 no signal word)
	Health hazard	Respiratory sensitization, category 1 Germ cell mutagenicity, categories 1A, 1B, 2 Carcinogenicity, categories 1A, 1B, 2 Reproductive toxicity, categories 1A, 1B, 2 Specific target organ toxicity following single exposure, categories 1, 2 Specific target organ toxicity following repeated exposure, categories 1, 2 Aspiration hazard, categories 1, 2	GHS08 Danger or Warning