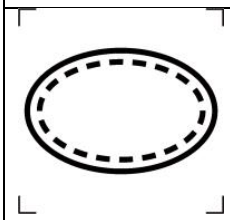
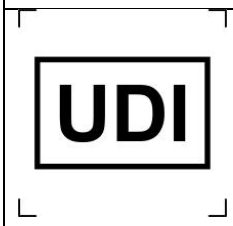
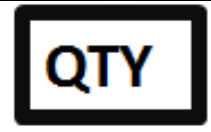
SYMBOLS GLOSSARY

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	ISO 15223-1, Reference no. 5.1.1 (ISO 7000-3082)	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1, Reference no. 5.1.2	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Authorised representative in the European Community	Indicates the authorised representative in the European Community / European Union
	ISO 15223-1, Reference no. 5.1.3 (ISO 7000-2497)	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Date of manufacture	Indicates the date when the medical device was manufactured.
	ISO 15223-1, Reference no. 5.1.4 (ISO 7000-2607)	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Use by date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1, Reference no. 5.1.5 (ISO 7000-2492)	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1, Reference no. 5.1.6 (ISO 7000- 2493)	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Catalogue number Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified ISO 15223 Catalogue number ISO 7000 Catalogue number

	ISO 15223-1, Reference no. 5.2.1 (ISO 7000-2499)	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Product subjected to a sterilisation process	Indicates a medical device that has been subjected to a sterilisation process.
	ISO 15223-1, Reference no. 5.2.4 (ISO 7000-2502)	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Sterilised using irradiation	Indicates a medical device that has been sterilised using irradiation.
	ISO 15223-1, Reference no. 5.2.6 (ISO 7000-2608)	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Do not resterilise	Indicates a medical device that is not to be resterilised.
	ISO 15223-1, Reference no. 5.2.7 (ISO 7000-2609)	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Non sterile	Indicates a medical device that has not been subjected to a sterilisation process.
	ISO 15223-1, Reference no. 5.2.8 (ISO 7000-2606)	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	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO/DIS 15223-1:2020(E) DRAFT Reference no. 5.2.13 (ISO 7000-3708)	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	Indicates a single sterile barrier system with protective packaging inside
	ISO 15223-1, Reference no. 5.4.1 (ISO 7000-0659)	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Biological risks	Indicates that there are potential biological risks associated with the medical device.

	ISO 15223-1, Reference no. 5.4.2 (ISO 7000-1051)	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 15223-1, Reference no. 5.4.3 (ISO 7000-1641)	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1, Reference no. 5.4.4 (ISO 7000-0434A)	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	ISO/DIS 15223-1:2020(E) DRAFT Reference no. 5.7.7	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Medical device	Indicates the item is a medical device.
	ISO/DIS 15223-1:2020(E) DRAFT Reference no. 5.7.10	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information.
	ISO 15223-1, Reference no. A.15	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Consult instructions for use or consult electronic instructions for use	Indicates consult instructions for use for an electronic instruction for use (eIFU)

SYMBOLS NOT FROM STANDARDS

SYMBOL	REFERENCE	TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	21 CFR 801.15(c)(1)(i)F	Labelling-Medical devices; prominence of required label statements.	Prescription only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
	21 CFR 801.109	Labelling-Prescription devices.		
	EU 2017-745 EU 2017-746 Reference no. ANNEX V	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/ EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/ EEC and 93/42/EEC	CE marking	(43) 'CE marking of conformity' or 'CE marking' means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing
	N/A	N/A	Global Trade Item Number	Custom symbol denoting global trade item number.
	N/A	N/A	Quantity	Custom symbol denoting number of medical devices units within a package