TRIVIDIA HEALTH™

Symbols Glossary - Symbols Derived from Standards

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	ISO 15223-1 Reference no. 5.4.2	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
STERILIZE	ISO 15223-1 Reference no. 5.2.6	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.	Do not resterilize	Indicates a medical device that is not to be resterilized.
STERILE EO	ISO 15223-1 Reference no. 5.2.3	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
STERILE	ISO 15223-1 Reference no. 5.2.1	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.	Sterile	Indicates a medical device that has been subjected to a sterilization process.
STERILE R	ISO 15223-1 Reference no. 5.2.4	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.
LOT	ISO 15223-1 Reference no. 5.1.5	Medical devices — Symbols to be used with medical device labels, labeling 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.
REF	ISO 15223-1 Reference no. 5.1.6	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
SN	ISO 15223-1 Reference no. 5.1.7	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
CONTROL	ISO 15223-1 Reference no. 5.5.2	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.	Control	Indicates a control material that is intended to verify the performance characteristics of another medical device.
	ISO 15223-1 Reference no. 5.1.3	Medical devices — Symbols to be used with medical device labels, labeling 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. 5.1.1	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directive 90/385/EEC, 93/42/EEC and 98/79/EC.
	ISO 15223-1 Reference no. 5.1.4	Medical devices — Symbols to be used with medical device labels, labeling 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. 5.4.4	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.	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.
	ISO 15223-1 Reference no. 5.3.7	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
EC REP	ISO 15223-1 Reference no. 5.1.2	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.	Authorized representative in the European Community	Indicates the authorized representative in the European Community
	ISO 15223-1 Reference no. 5.3.4	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.	Keep dry	Indicates a medical device that needs to be protected from moisture
	ISO 15223-1 Reference no. 5.4.1	Medical devices - Symbols to be used with medical device labels, labeling 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. 5.4.3	Medical devices - Symbols to be used with medical device labels, labeling 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.
IVD	ISO 15223-1 Reference no. 5.5.1	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.	*In vitro* diagnostic medical device	Indicates a medical device that is intended to be used as an *in vitro* diagnostic medical device.
%	ISO 15223-1 Reference no. 5.3.8	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.

Symbols Glossary - Symbols Not Derived from Standards

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	N/A	N/A	For Single Patient Use Only	Custom symbol indicating device is for single patient use only.
Rx Only	21 CFR 801.109	Labeling-Medical devices; prominence of required label statements.	Prescription Only	Requires prescription in the United States.
FCC	Federal Communications Commission	Federal Communications Commission (FCC) Declaration of Conformity (DoC) Logo.	21 CFR Part 15	Meets FCC requirements per 21 CFR Part 15.
FCC ID:	47 CFR Part 15	Radio Frequency Devices (US).	Federal Communications Commission Number (FCC ID#)	Complies with United States Radio communication requirements.
CE	MDD 93/42/EEC (Annex XII) IVDD 98/79/EC (Annex X)	Medical Device Directive.	CE marking	Indicates that the product meets the provisions of the Directive that applies to it.
	N/A	N/A	Microliters/μL	Identifies the amount of sample, measured in microliters (μL), to use for each test strip.
	N/A	General symbol for recyclable.	Recycle	To indicate that the marked item or its material is part of a recovery or recycling process.
	N/A	Graphical symbols for use on equipment.	Peel here	Identifies the location to begin peeling off the plastic protector from the device before use.