






































This is a general glossary to assist comprehension of symbols which may appear in the labeling for this product.

Symbol	Title of Symbol	Description of Symbol	Standard
Rx only	Prescription Device or Product	Federal law restricts this device to sale by or on the order of a licensed practitioner.	21 CFR 809.10 (a)(4)
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	ISO 15223-1:2016(E) Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 15223-1- 5.1.1
	Authorized Representative in the European Community	Indicates the Authorized representative in the European Community.	ISO 15223-1:2016(E) Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 15223-1-5.1.2
	Date of Manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1:2016(E) Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 15223-1-5.1.3
 YYYY-MM-DD or YYYY-MM* *ISO 8601	Use-by Date	Indicates the date after which the medical device is not to be used.	ISO 15223-1:2016(E) Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 15223-1-5.1.4
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2016(E) Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 15223-1-5.1.5
	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.	ISO 15223-1:2016(E) Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 15223-1-5.1.6
	Sterilized Using Ethylene Oxide	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1:2016(E) Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 15223-1-5.2.3
	Sterilized Using Irradiation	Indicates a medical device that has been sterilized using irradiation.	ISO 15223-1:2016(E) Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 15223-1-5.2.4
	Lower Limit of Temperature	Indicates the lower limit of temperature to which the medical device can be safely exposed.	ISO 15223-1:2016(E) Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 15223-1-5.3.5

Symbol	Title of Symbol	Description of Symbol	Standard
	Upper Limit of Temperature	Indicates the upper limit of temperature to which the medical device can be safely exposed.	ISO 15223-1:2016(E) Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 15223-1-5.3.6
	Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1:2016(E) Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 15223-1-5.3.7
	Biological Risks	Indicates that there are potential biological risks associated with the medical device.	ISO 15223-1:2016(E) Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 15223-1-5.4.1
	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.	ISO 15223-1:2016(E) Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 15223-1-5.4.2
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1:2016(E) Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 15223-1-5.4.3
	Caution, Consult Accompanying Documents	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 15223-1:2016(E) Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 15223-1- 5.4.4
	In vitro Diagnostic Medical Device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.	ISO 15223-1:2016(E) Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 15223-1-5.5.1
	Negative Control	Indicates a control material that is intended to verify the results in the expected negative range.	ISO 15223-1:2016(E) Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 15223-1-5.5.3
	Positive Control	Indicates a control material that is intended to verify the results in the expected positive range.	ISO 15223-1:2016(E) Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 15223-1-5.5.4
	Contains Sufficient for <n> Tests	Indicates the total number of IVD tests that can be performed with the IVD.	ISO 15223-1:2016(E) Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 15223-1-5.5.5
	Exclamation Mark	Indicates the possible presence of the following; irritant, dermal sensitizer, acute toxicity, narcotic effects, respiratory tract irritation.	OSHA's HCS, Appendix C to §1910.1200, Section C.4.1, C.4.2, C.4.3 (Classified in Accordance with Appendix A.1)

Symbol	Title of Symbol	Description of Symbol	Standard
	Skull and Crossbones	Indicates the presence of acute toxicity.	OSHA's HCS, Appendix C to §1910.1200, Sections C.4.1, C.4.2, C.4.3 (Classified in Accordance with Appendix A.1)
	Corrosion	Indicates the presence of corrosives.	United States Department of Labor Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard (HCS), Appendix C to §1910.1200, Section C.4.5 (Classified in Accordance with Appendix A.3)
	Health Hazard	Indicates the possible presence following health hazards; carcinogen, respiratory sensitizer, reproductive toxicity, target organ toxicity, mutagenicity, aspiration toxicity.	OSHA's HCS, Appendix C to §1910.1200, Section C.4.11 (Classified in Accordance with Appendix A.8)
	Flame	Indicates the possible presence of the following; flammables, self reactives, pyrophorics, self-heating, emits flammable gas, organic peroxides.	OSHA's HCS, Appendix C to §1910.1200, Section C.4.19 (Classified in Accordance with Appendix B.6)
	Flame Over Circle	Indicates the presence of oxidizers.	OSHA's HCS, Appendix C to §1910.1200, Section C.4.26 (Classified in Accordance with Appendix B.13)
	Dead Tree and Fish	Hazardous to the environment.	CLP Regulation (EC) 1272/2008
	General Warning Sign / "Attention"	To signify a general warning.	ISO 7010-W001
	Warning; Laser Beam	To warn of a laser beam.	ISO 7010-W004
	Warning; Biological Hazard	To warn of a biological hazard.	ISO 7010-W009
	Warning; High Voltage	To warn of electricity.	ISO 7010-W012
	Warning; Hot Surface	To warn of a hot surface.	ISO 7010-W017
	Warning; Crushing of Hands Pinch Point	To warn of a closing motion of mechanical parts of equipment.	ISO 7010-W024

Symbol	Title of Symbol	Description of Symbol	Standard
	European Conformity	Indicates the medical device conforms to European Medical Directive 93/42/EEC and meets applicable health, safety, and environmental requirements. If the mark is accompanied by a number, conformity is verified by the indicated notified body.	European Medical Directive 93/42/EEC, Article 17
	Canadian Standards Association	Indicates the medical device was tested and has met the certification requirements for component products.	Standards Council of Canada (SCC) and the U.S. Occupational Safety and Health Administration (OSHA)
	Electric Testing Laboratories	Indicates that the product has been tested by an accredited third party testing laboratory, and meets the applicable safety standards and minimal requirements for sale or distribution within North America.	ANSI/AAMI STD ES60601-1, IEC STDS 60601-2-18 and 60601-2-37. Certified to CSA STD C22.2 No. 60601-1
	Waste Electrical and Electronic Equipment	Goods are marked with this symbol to show that they were produced after 13th August 2005, and should be disposed of separately from normal household waste so that they can be recycled.	2002/96/EC
	Restriction of Hazardous Substances China RoHS	Indicates that the product has an environmentally friendly use period of 50 years.	Administrative Measure on the Control of Pollution Caused by Electronic Information Products

Hologic, Inc.
10210 Genetic Center Drive
San Diego, CA 92121 USA

Customer Support: +1 844 Hologic (+1 844 465 6442)
customersupport@hologic.com

Technical Support: +1 888 484 4747
molecularsupport@hologic.com

For more contact information visit www.hologic.com.

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