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

Symbol	Title of Symbol	Description of Symbol	Standard
Rx only	Prescription Device or Product	Federal law restricts this device to sale by or the order of a licensed practitioner.	21 CFR 809.10 (a)(4)
	Manufacturer	Indicates the medical device manufacturer.	ISO 15223-1:2021(E) Chapter 5.1.1 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 7000-3082 EU Directives 90/385/EEC, 93/42/EEC, 98/79/EC, 2017/745 and 2017/746.
EC REP	Authorized representative in the European Community/European Union	Indicates the authorized representative in the European Community/European Union.	ISO 15223-1:2021(E) Chapter 5.1.2 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied
	Date of Manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1:2021(E) Chapter 5.1.3 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 7000-2497
	Use-by Date	Indicates the date after which the medical device is not to be used.	ISO 15223-1:2021(E) Chapter 5.1.4 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 7000-2607 (YYYY-MM-DD) ISO-8601 (YYYY-MM)
LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2021(E) Chapter 5.1.5 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 7000-2492
REF	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.	ISO 15223-1:2021(E) Chapter 5.1.6 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 7000-2493

Symbol	Title of Symbol	Description of Symbol	Standard
STERILE EO	Sterilized Using Ethylene Oxide	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1:2021(E) Chapter-5.2.3 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 7000-2501
STERILE R	Sterilized Using Irradiation	Indicates a medical device that has been sterilized using irradiation.	ISO 15223-1:2021(E) Chapter 5.2.4 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 7000-2502
(thermometer symbol)	Lower Limit of Temperature	Indicates the lower limit of temperature to which the medical device can be safely exposed.	ISO 15223-1:2021(E) Chapter 5.3.5 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 7000-0534
(thermometer symbol)	Upper Limit of Temperature	Indicates the upper limit of temperature to which the medical device can be safely exposed.	ISO 15223-1:2021(E) Chapter 5.3.6 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 7000-0533
(thermometer symbol)	Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1:2021(E) Chapter 5.3.7 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 7000-0632
(biohazard symbol)	Biological Risks	Indicates that there are potential biological risks associated with the medical device.	ISO 15223-1:2021(E) Chapter 5.4.1 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 7000-0659
(do not reuse symbol)	Do not re-use	Indicates a medical device that is intended for one single use only.	ISO 15223-1:2021(E) Chapter 5.4.2 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 7000-1051

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Symbol	Title of Symbol	Description of Symbol	Standard
	Consult Instructions for Use or consult electronic Instructions for Use	Indicates the need for the user to consult the Instructions for Use.	ISO 15223-1:2021(E) Chapter 5.4.3 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 7000-1641
	Caution	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 15223-1:2021(E) Chapter 5.4.4 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO-7000-0434A
IVD	*In vitro* Diagnostic Medical Device	Indicates a medical device that is intended to be used as an *in vitro* diagnostic medical device.	ISO 15223-1:2021(E) Chapter 5.5.1 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied
CONTROL –	Negative Control	Indicates a control material that is intended to verify the results in the expected negative range.	ISO 15223-1:2021(E) Chapter 5.5.3 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 7000-2495
CONTROL +	Positive Control	Indicates a control material that is intended to verify the results in the expected positive range.	ISO 15223-1:2021(E) Chapter 5.5.4 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO 7000-2496
Σ	Contains Sufficient for <*n*> Tests	Indicates the total number of tests that can be performed with the medical device.	ISO 15223-1:2021(E) Chapter 5.5.5 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied ISO7000-0518
	Open Here	Identifies the location where the package can be opened and to indicate the method of opening it.	ISO 7000-3079 Graphical symbols for use on equipment.
	Do Not Use if Package is Damaged and consult Instructions for Use	Indicates 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. Note:*This symbol may also mean "Do not use if the product sterile barrier system or its packaging is compromised".*	ISO 15223-1:2021(E) Chapter 5.2.8 Medical Devices — Symbols to be used with medical device labels, labelling and information to be supplied ISO 7000-2606

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Symbol	Title of Symbol	Description of Symbol	Standard
	Exclamation Mark/ Health hazard/Hazardous to the ozone layer	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, Sections C.4.1, C.4.2, C.4.3 (Classified in Accordance with Appendix A.1) GHS07 CLP Regulation(EC) 1272/2008 Annex V
	Skull and Crossbones/ Acute Toxicity	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) GHS06 CLP Regulation (EC) 1272/2008
	Corrosion/Corrosive	Indicates the presence of corrosives.	OSHA's HCS, Appendix C to §1910.1200, Section C.4.5 (Classified in Accordance with Appendix A.3) GHS05 CLP Regulation (EC) 1272/2008
	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) GHS08 CLP Regulation (EC) 1272/2008
	Flame/Flammable	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) GHS02 CLP Regulation (EC) 1272/2008
	Flame Over Circle/ Oxidizing	Indicates the presence of oxidizers.	OSHA's HCS, Appendix C to §1910.1200, Section C.4.26 (Classified in Accordance with Appendix B.13-B.14) GHS03 CLP Regulation (EC) 1272/2008
	Environment	Indicates aquatic toxicity.	CLP Regulation (EC) 1272/2008 Chapter 3.1. GHS09
	General Warning Sign / "Attention"	To signify a general warning.	ISO 7010-W001
	Warning; Laser Beam	To warn of a laser beam.	ISO 7010-W004

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Symbol	Title of Symbol	Description of Symbol	Standard
	Warning; Biological Hazard	To warn of a biological hazard.	ISO 7010-W009
	Warning; Electricity	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
CE	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.	ISO 15223-1_2021(E) Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied EU Directives 90/385/EEC, 93/42/EEC Article 17 and Annex XII, 98/79/EC, 2017/745 and 2017/746
	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 the 13th of August 2005, and should be disposed of separately from normal household waste so that they can be recycled.	2012/19/EU, Article 12 and Annex IX

Symbol	Title of Symbol	Description of Symbol	Standard
	Restriction of Hazard-ous Substances China RoHS Chasing arrow	The product contains at least one hazard-ous substance but is safe to use during the Environmental Protection Use Peri-od (EPUP). This period is indicated by the number of years shown on the logo. When the period expires, the product should be property dsiposed of or recy-cled.	Standard SJ/T11364-2014 (China RoHS) Administrative Measure on the Control of Pollution Caused by Electronic Information Products.
	Fragile; handle with care	Indicates a medical device that can be broken or damaged if not handled care-fully.	EN ISO 15223-1:2021(E) Chapter 5.3.1 ISO 7000-0621
	This way up	To indicate correct upright position of the transport package.	ISO 7000-0623
	Mass; weight	To indicate mass. To identify a function related to mass.	ISO 7000-1321B
	Do not roll	To indicate that the transport package shall not be rolled or turned over but shall remain in the upright position.	ISO 7000-2405
	Stacking limit by number	To indicate that the items shall not be vertically stacked beyond the specified number, either because of the nature of the transport packaging or because of the nature of the items themselves.	ISO 7000-2403
SN	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO 15223-1:2021(E) Chapter 5.1.7 ISO 7000-2498
#	Patient number	Indicates a unique number associated with an individual patient.	ISO 15223-1:2021 Chapter 5.7.1 ISO 7000-2610
MD	Medical device	Indicates the item is *a* medical device.	ISO 15223-1:2021 Chapter 5.7.7

Symbol	Title of Symbol	Description of Symbol	Standard
⬭	Single sterile barrier system	Indicates a single sterile barrier system.	ISO 15223-1:2021 Chapter 5.2.11 ISO 7000-3707
UDI	Unique device identifier	Indicates a carrier that contains unique device identifier information.	ISO 15223-1:2021 Chapter 5.7.10
🧪?	For IVD performance evaluation only	Indicates an IVD medical device that is intended to be used only for evaluating its performance characteristics before it is placed on the market for medical diagnostic use.	ISO 15223-1:2021 Chapter 5.5.6 ISO 7000-3083

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

Customer Support: +1800 442 9892
                                  customersupport@hologic.com
Technical Support: +1 888 484 4747
                                  molecularsupport@hologic.com
For more contact information visit www.hologic.com.

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