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<br>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<br>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<br>ISO 15223-1-5.1.3 |
|  <br>YYYY-MM-DD<br>or YYYY-MM*<br>*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<br>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<br>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<br>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<br>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<br>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<br>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<br>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<br>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<br>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<br>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<br>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<br>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<br>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<br>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<br>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<br>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 |
|---|---|---|---|
| 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. | European Medical Directive 93/42/EEC, Article 17 |
| CSA® | **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) |
| ETL C US LISTED Intertek | **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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