














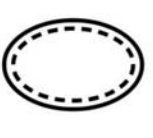







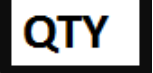
SYMBOLS GLOSSARY

| 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. 5.4.3 (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. |
|  | 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. |
|  | ISO 15223-1, Reference no. 5.3.1. (ISO 7000-0621) | Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements. | Fragile, handle with care | Indicates a medical device that can be broken or damaged if not handled correctly. |
|  | ISO 15223-1, Reference no. 5.3.4. (ISO 7000-0626) | 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. 5.3.7. (ISO 7000-0632) | 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. |
|  | IEC 60417-5032 | Graphical Symbols for Use on Equipment. | Alternating Current | To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals. |
|  | IEC 60417- 5031 | Graphical Symbols for Use on Equipment. | Direct Current | To indicate on the rating plate that the equipment is suitable |



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| | | | | for direct current only; to identify relevant terminals. |
| | IEC 60417-5172 | Graphical Symbols for Use on Equipment. | Class II equipment | To identify equipment meeting the safety requirements specified for Class II equipment according to IEC 61140. |
| | IEC 60417-5957 | Graphical Symbols for Use on Equipment. | For indoor use only | To identify electrical equipment designed primarily for indoor use. |
| | DIRECTIVE 2012/19/ EU | Graphical Symbols for Use on Equipment. | Collect Separately | Separate collection for waste of electrical and electronic equipment. Do not dispose of battery in municipal waste. The symbol indicates separate collection for battery is required. |
| | | | ETL Listed Mark | The ETL Mark is proof of product compliance to North American safety standards. |
| | ISO 7000 | Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements. | Distributor | To indicate the entity distributing the medical device into the locale. |
| | Internal Symbol | | Li-Ion Battery | To indicate that a Lithium battery must be recycled. |
| | 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. |



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|  | 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) 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/DIS 15223-1:2020(E) 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) 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. |
|  eIFU indicator | 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). |
| | 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. |