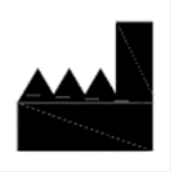






















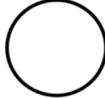











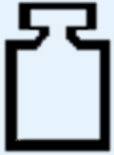


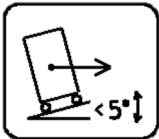


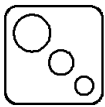

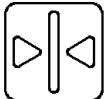
| Symbol | Description of symbol | Title and the designation number of standard | Reference number and Title of symbol |
|---|--|---|--|
|  | Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC. | ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | 5.1.1 Manufacturer |
|  | Indicates the authorized representative in the European Community. | ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | 5.1.2 Authorized representative in the European Community |
|  | Indicates the date when the medical device was manufactured. | ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | 5.1.3 Date of Manufacture |
|  | 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, labelling and information to be supplied — Part 1: General requirements | 5.1.4 Use-by date |
|  | 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, labelling and information to be supplied — Part 1: General requirements | 5.1.5 Batch code |
|  | Indicates the manufacturer's catalogue number so that the medical device can be identified. | ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | 5.1.6 Catalogue number |
|  | 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, labelling and information to be supplied — Part 1: General requirements | 5.2.3 Sterilized using ethylene oxide |
|  | 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, labelling and information to be | 5.2.4 Sterilized using irradiation |

| Symbol | Description of symbol | Title and the designation number of standard | Reference number and Title of symbol |
|---|--|---|---|
| | | supplied — Part 1: General requirements | |
|  | Indicates a medical device that should not be used if the package has been damaged or opened. | ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | 5.2.8 Do not use if package is damaged |
|  | Indicates the presence of a sterile fluid path within the medical device in cases when other parts of the medical device, including the exterior, might not be supplied sterile. | ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | 5.2.9 Sterile fluid path |
|  | Indicates a medical device that can be broken or damaged if not handled carefully. | ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | 5.3.1 Fragile, handle with care |
| | To indicate that the contents of the transport package are fragile and the package shall be handled with care. | ISO 7000 Graphical symbols for use on equipment - Registered symbols | Reference No. 0621 Fragile- handle with care |
|  | Indicates a medical device that needs protection from light sources. | ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | 5.3.2 Keep away from sunlight |
|  | 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, labelling and information to be supplied — Part 1: General requirements | 5.3.7 Temperature limit |
| | To indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used. | ISO 7000 Graphical symbols for use on equipment - Registered symbols | Reference No. 0632 Temperature limit |

| Symbol | Description of symbol | Title and the designation number of standard | Reference number and Title of symbol |
|---|---|---|--|
|  | Indicates the range of humidity to which the medical device can be safely exposed. | ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | 5.3.8 Humidity limitation |
|  | 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, labelling and information to be supplied — Part 1: General requirements | 5.4.2 Do not re-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, labelling and information to be supplied — Part 1: General requirements | 5.4.3 Consult instructions for use |
|  | 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, labelling and information to be supplied — Part 1: General requirements | 5.4.4 Caution |
|  | Indicates a medical device that is non-pyrogenic. | ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | 5.6.3 Non-pyrogenic |
|  | Indicates the number of drops per millilitre. | ISO 15223-1:2016(E): Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | 5.6.4 Drops per millilitre |
|  | To signify that the instruction manual / booklet must be read. | ISO 7010 Graphical Symbols – Safety colours and safety signs – Registered safety signs | Reference No. M002 Refer to instruction manual/booklet |

| Symbol | Description of symbol | Title and the designation number of standard | Reference number and Title of symbol |
|---|--|---|--|
|  | To identify a type B applied part complying with IEC 60601-1. | IEC 60417 Graphical Symbols for Use on Equipment | Reference No. 5840 Type B applied part |
|  | To identify a type BF applied part complying with IEC 60601-1. | IEC 60417 Graphical Symbols for Use on Equipment | Reference No. 5333 Type BF applied part |
|  | To indicate connection to the mains, at least for mains switches or their positions, and all those cases where safety is involved. | IEC 60417 Graphical Symbols for Use on Equipment | Reference No. 5007 "ON" (power) |
|  | To indicate disconnection from the mains, at least for mains switches or their positions, and all those cases where safety is involved. | IEC 60417 Graphical Symbols for Use on Equipment | Reference No. 5008 "OFF" (power) |
|  | To identify the switch or switch position by means of which part of the equipment is switched on in order to bring it into the stand-by condition, and to identify the control to shift to or to indicate the state of low power consumption. Each of different states of power consumption may be indicated using a corresponding colour. | IEC 60417 Graphical Symbols for Use on Equipment | Reference No. 5009 Stand-by |
|  | To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals. | IEC 60417 Graphical Symbols for Use on Equipment | Reference No. 5032 Alternating current |
|  | To identify any terminal which is intended for connection to an external conductor for protection against electric shock in case of | IEC 60417 Graphical Symbols for Use on Equipment | Reference No. 5019 Protective earth; protective ground |

| Symbol | Description of symbol | Title and the designation number of standard | Reference number and Title of symbol |
|---|---|--|--|
| | a fault, or the terminal of a protective earth (ground) electrode. | | |
|  | To identify the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential, not necessarily being the earth (ground) potential, e.g. for local bonding. | IEC 60417 Graphical Symbols for Use on Equipment | Reference No. 5021 Equipotentiality |
|  | To indicate correct upright position of the transport package | ISO 7000 Graphical symbols for use on equipment - Registered symbols | Reference No. 0623 This way up |
|  | To indicate that hooks shall not be used for handling the transport package. | ISO 7000 Graphical symbols for use on equipment - Registered symbols | Reference No. 0622 Use no hooks |
|  | To indicate that the transport package shall be kept away from rain and in dry conditions. | ISO 7000 Graphical symbols for use on equipment - Registered symbols | Reference No. 0626 Keep away from rain |
| IPX1 | To identify category AP equipment complying with IEC 60601-1 which also specifies the way in which this symbol has to be used. | IEC 60601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety IP degrees in accordance with IEC 60529 / EN 60529 | Ingress Protection Against Dripping Water (vertically falling drops) |
|  | To indicate that the transport package shall not be rolled or turned over but shall remain in the upright position. | ISO 7000 Graphical symbols for use on equipment - Registered symbols | Reference No. 2405 Do not roll |
|  | To indicate that the items shall not be vertically stacked, either because of the nature of the transport packaging or because of the nature of the items themselves. | ISO 7000 Graphical symbols for use on equipment - Registered symbols | Reference No. 2402 Do not stack |

| Symbol | Description of symbol | Title and the designation number of standard | Reference number and Title of symbol |
|---|--|--|---------------------------------------|
|  | To indicate mass. To identify a function related to mass. | ISO 7000 Graphical symbols for use on equipment - Registered symbols | Reference No. 1321A Mass; weight |
|  | Indicates the manufacturer's serial number so that a specific medical device can be identified. | ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | Reference 5.1.7 Serial number |
|  | Indicates a medical device that is not to be resterilized. | ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements | Reference 5.2.6 Do not resterilize |
| Symbols <u>not</u> from Standards | | | |
| Rx Only or ONLY | Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner. | FDA Quality System Regulation – Labeling requirements | 21 CFR Part 801.109 |
|  | Keep transport position when moving the device on more than a 5-degree slope. | NA | NA |
|  | Alarm sounds mute switch | NA | NA |
|  | Blood pump switch Green – ON Red – OFF | NA | NA |
|  | Bubble detector | NA | NA |
|  | Blood sensor | NA | NA |
|  | Clamp | NA | NA |