Symbols Glossary

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Symbol	Symbol Title	Explanatory Text	Standard Title	Standard Reference
	Manufacturer	Indicates the medical device manufacturer.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.1.1 FDA Recognition # 5-117 ISO 7000 Reference #3082 FDA Recognition # 5-103
	EC Rep	Indicates the Authorized representative in the European Community.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.1.2 FDA Recognition # 5-117
	Date of Manufacturer	Indicates the date when the medical device was manufactured.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.1.3 FDA Recognition # 5-117 ISO 7000 Reference #2497 FDA Recognition # 5-103
	Use-by Date	Indicates the date after which the medical device is not to be used. Date format is YYYY-MM-XX	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General	ISO 15223-1 Reference #5.1.4 FDA Recognition # 5-117 ISO 7000 Reference #2607 FDA Recognition # 5-103
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.,	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.1.5 FDA Recognition # 5-117 ISO 7000 Reference #2492 FDA Recognition # 5-103
	Catalog #	Indicates the manufacturer's catalog # so that the medical device can be identified.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.1.6 FDA Recognition # 5-117 ISO 7000 Reference #2493 FDA Recognition # 5-103
	Serial #	Indicates the manufacturer's serial # so that a specific medical device can be identified.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.1.7 FDA Recognition # 5-117 ISO 7000 Reference #2498 FDA Recognition # 5-103
	Sterile	Indicates a medical device that has been subjected to a sterilization process.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.2.1 FDA Recognition # 5-117 ISO 7000 Reference #2499 FDA Recognition # 5-103
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.2.3 FDA Recognition # 5-117 ISO 7000 Reference #2501 FDA Recognition # 5-103
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.2.4 FDA Recognition # 5-117 ISO 7000 Reference #2502 FDA Recognition # 5-103
	Do not re-sterilize	Indicates a medical device that is not to be resterilized.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.1.6 FDA Recognition # 5-117 ISO 7000 Reference #2608 FDA Recognition # 5-103

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Symbol	Symbol Description	Explanatory Text	Standard Title	Standard Reference
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.2.7 FDA Recognition # 5-117 ISO 7000 Reference #2609 FDA Recognition # 5-103
	Do not use if package is damaged.	Indicates a medical device that should not be used if the package has been damaged or opened.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.2.8 FDA Recognition # 5-117 ISO 7000 Reference #2606 FDA Recognition # 5-103
	Sterile Fluid Path - EO (ETO Ethylene-Oxide)	Indicates the presence of a sterile fluid path within the medical device in cases when other part of the medical device, including the exterior,	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.2.9 FDA Recognition # 5-117
	Sterile Fluid Path - R (Irradition)	Indicates the presence of a sterile fluid path within the medical device in cases when other part of the medical device, including the exterior,	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.2.9 FDA Recognition # 5-117
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.3.1 FDA Recognition # 5-117 ISO 7000 Reference #0621 FDA Recognition # 5-103
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General	ISO 15223-1 Reference #5.3.2 FDA Recognition # 5-117 ISO 7000 Reference #0624 FDA Recognition # 5-103
	Keep dry	Indicates a medical device that needs to be protected from moisture.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.3.4 FDA Recognition # 5-117 ISO 7000 Reference #0626 FDA Recognition # 5-103
	Lower limit of temperature	Indicates the lower limit of temperature to which the medical device can be safely exposed. The temperature is indicated adjacent to the lower	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.3.5 FDA Recognition # 5-117 ISO 7000 Reference #0534 FDA Recognition # 5-103
	Upper limit of temperature	Indicates the upper limit of temperature to which the medical device can be safely exposed. The temperature is indicated adjacent to the	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.3.6 FDA Recognition # 5-117 ISO 7000 Reference #0533 FDA Recognition # 5-103
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.3.7 FDA Recognition # 5-117 ISO 7000 Reference #0632 FDA Recognition # 5-103
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General	ISO 15223-1 Reference #5.3.8 FDA Recognition # 5-117 ISO 7000 Reference #2620 FDA Recognition # 5-103
	Do not re-use	Indicates the temperature limits to which the medical device can be safely exposed.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.4.2 FDA Recognition # 5-117 ISO 7000 Reference #1051 FDA Recognition # 5-103

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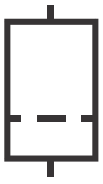
Symbol	Symbol Description	Explanatory Text	Standard Title	Standard Reference
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General	ISO 15223-1 Reference #5.4.3 FDA Recognition # 5-117 ISO 7000 Reference #1641 FDA Recognition # 5-103
	Consult instructions for use	Indicates that the manufacturer's instructions for use are available in an electronic format.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.4.3 Examples FDA Recognition # 5-117
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot,	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.4.4 FDA Recognition # 5-117 ISO 7000 Reference #0434A FDA Recognition # 5-103
	Contains or presence of natural rubber latex	Indicates the presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.4.5 FDA Recognition # 5-117 ISO 7000 Reference #2725 FDA Recognition # 5-103
	Product is not made with natural rubber latex	Indicates that natural rubber latex was not used in the manufacturing of the product, its container, or its packaging.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 5.4.5 Reference Annex B for the general prohibition symbol and negation symbol FDA Recognition #5-117
	Non-pyrogenic	Indicates a medical device that is non-pyrogenic	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.6.3 FDA Recognition #5-117 ISO 7000 Reference #2724 FDA Recognition # 5-103
	Drops per milliliter	Indicates the # of drops per milliliter. Note: symbols shown is 20 drops is an example only and will be replaced with appropriate drops per mL #.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.6.4 FDA Recognition #5-117 ISO 7000 Reference #2726 FDA Recognition # 5-103
	Liquid filter with port size	Indicates a device containing a liquid fluid filter on the medical device that contains a filter of a particular nominal pore size. Note: symbol shown is 15 um is an example only and will be	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.6.5 FDA Recognition #5-117 ISO 7000 Reference #2727 FDA Recognition # 5-103
	One-way Valve	Indicates a medical device with a valve that allows flow in only one direction.	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.6.6 FDA Recognition # 5-117 ISO 7000 Reference #2728 FDA Recognition # 5-103

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SYMBOL	SYMBOL DESCRIPTION	EXPLANATORY TEXT	STANDARD TITLE	STANDARD REFERENCE
℞ only	Labeling	The symbol for Prescription Device Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.	Guidance for Industry and FDA on Alternative to certain Prescription Device Labeling Requirements	NA
CE	CE Mark European Conformity Conformité Européene	Signifies European conformity (CE) mark Indicates manufacturer declaration that the product complies with applicable European regulations	Guide to the implementation of directives based on new approach and global approach	NA
CE XXXX CE XXXX	CE Mark with Notified Body Reference # ###	Signifies European conformity (CE) mark Indicates conformity of products where the notified body performed conformity assessment. Notified body reference # is displayed.	Guide to the implementation of directives based on new approach and global approach	NA
	Does not contain lead	Indicates that lead was not used in the manufacturing of the product.	NA	NA
	Quantity	Indicates the # of unit per package	NA	NA
	General Warning Sign	Signifies a general warning	Graphical symbols - Safety colours and safety signs - Registered safety signs	ISO 7010 Reference # W001 FDA Recognition # 5-116
	Warning Electricity	Warning Electrical Hazard	Graphical symbols - Safety colours and safety signs - Registered safety signs	ISO 7010 Reference # W012 FDA Recognition # 5-116
	General Mandatory Action Sign	Mandatory action	Graphical symbols - Safety colours and safety signs - Registered safety signs	ISO 7010 Reference # M001 FDA Recognition # 5-116

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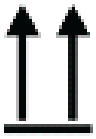
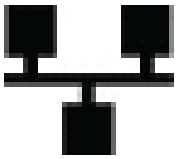
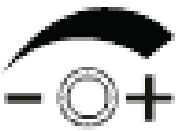
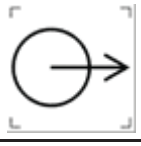
Symbol	Symbol Description	Explanatory Text	Standard Title	Standard Reference
	Refer to instruction manual/ booklet	Signifies that the instruction manual/booklet must be read	Graphical symbols - Safety colours and safety signs - Registered safety signs	ISO 7010 Reference #M002 FDA Recognition # 5-116
	Alert	Alert	Radio & Telecommunications Terminal Equipment Directive	R&TTE Directive 1999/5/EC
	WEEE	Signifies waste from electrical and electronic equipment	Waste Electrical and Electronic Equipment Directive	WEEE Directive 2002/96/EC
	Dangerous Voltage	Signifies dangerous voltage	Graphical Symbols for Use on Equipment	IEC 60417 Reference # 5036 FDA Recognition # 5-102
	To indicate correct upright position of the transport package	Signifies that this way should be placed up	Graphical symbols for use on equipment -- Registered symbols	ISO 7000 Reference # 0623 FDA Recognition # 5-103
	Atmospheric Pressure Limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference # 5.3.9 FDA Recognition # 5-117
	RF Transmitter	Indicates a radio frequency is transmitted	Graphical Symbols for Use on Equipment	IEC 60417 Reference # 5140 FDA Recognition # 5-102
	Wired Ethernet Interface Port	Indicates location of wired ethernet interface port	NA	NA
	Alarm Volume Control	Indicates control for alarm volume	NA	NA
	Output Terminal	Indicates the output terminal for the nurse call interface port	Graphical Symbols for Use on Equipment	IEC 60417 Reference # 5035 FDA Recognition # 5-102
	Certification Mark	C-tick certification mark	Australian Communications and Media Authority	Australian Communicationsand Media Authority

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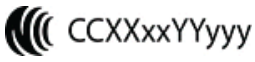
Symbol	Symbol Description	Explanatory Text	Standard Title	Standard Reference
	Lead Waste Disposal	Indicates separate waste collection for batteries containing lead	Directive 2006/66/EU on Batteries and Accumulators and Waste Batteries and Accumulators	Directive 2006/66/EU
	Equipotential Terminal (Ground)	Identifies terminals for equipotential (ground)	Graphical Symbols for Use on Equipment	IEC 60417 Reference # 5021 FDA Recognition # 5-102
IPX1	Protected against dripping water	Protected against vertically falling water drops	Degrees of protection provided by enclosures (IP Code)	IEC 60529
IPX2	Protected against vertically falling water drops	Protected against water drops up to 15 degree angle	Degrees of protection provided by enclosures (IP Code)	IEC 60529
IPX3	Protected against spraying water	Protected against spraying water up to a 60 degree angle	Degrees of protection provided by enclosures (IP Code)	IEC 60529
	Type CF Part	Indicates part complies with higher degree of protection against electric shock as defined by IEC 60601-1	Graphical Symbols for Use on Equipment	IEC 60417 Reference # 5335 FDA Recognition # 5-102
	Type BF Part		Graphical Symbols for Use on Equipment	IEC 60417 Reference # 5333 FDA Recognition # 5-102
	Regulatory Compliance Mark	Signifies compliance with Australian Communications and Media Authority (ACMA)	NA	Australian Communications and Media Authority (ACMA)
	FCC Compliance Mark	Complies with limits for Class B digital device established by FCC Rules, Part 15	NA	Title 47 United States Code of Federal Regulations Part 15.19
	Wireless Registration	Taiwan National Communications Commission (NCC) Wireless Registration # XXxxYYyyy	NA	National Communications Commission of Taiwan (NCC)
	CSA Compliance	The “C” and “US” indicators adjacent to the CSA Mark signify that the product has been evaluated to the applicable CSA and ANSI/UL	NA	CSA International

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Symbol	Symbol Description	Explanatory Text	Standard Title	Standard Reference
Class 1	Class 1 Mains Protection	Mains supply equipment using protective earth	NA	NA
	Bell	To identify switches which operate bells, e.g. alarms	Graphical symbols for use on equipment—Registered Symbols	ISO 7000 Reference No. 5013 FDA Recognition # 5-103
	Bell Cancel	To identify the control whereby a bell may be switched off or to indicate the operating status of the bell.	Graphical symbols for use on equipment—Registered Symbols	ISO 7000 Reference No. 5576 FDA Recognition # 5-103
	Locking, general	To identify on a control that a function is locked or to show the locked status.	Graphical symbols for use on equipment—Registered Symbols	ISO 7000 Reference No. 5569 FDA Recognition # 5-103
	Contains or presence of phthalates bis(2-ethylhexyl) phthalates (DEHP)	Contains or presence of phthalates bis(2-ethylhexyl) phthalates (DEHP)	Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates	BS EN 15986:2011 EN 15986:2011(E) Clause 4.2 Annex A
	Contains or presence of phthalates bis(2-ethylhexyl) phthalates (DEHP)	Contains or presence of phthalates bis(2-ethylhexyl) phthalates (DEHP)	Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates	BS EN 15986:2011 EN 15986:2011(E) Clause 4.2 Annex A
	Does not contain DEHP	Contains less then 0.1% Phthalates—DEHP	Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates	BS EN 15986:2011 EN 15986:2011(E) Annex B