Glossary of standard symbols

Symbol	Standard	Ref #	Title	Description
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC, 98/79/EC, and EU Regulation 2017/745.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.2	Authorized Representative in the European Community/ European Union	Indicates the Authorized Representative in the European Community/ European Union.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.3	Date of manufacture	Indicates the date when the medical device was manufactured.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.4	Use-by date	Indicates the date after which the medical device is not to be used.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.5	Batch code/ Lot number	Indicates the manufacturer's batch code so that the batch or lot can be identified.

Symbol	Standard	Ref #	Title	Description
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.1.7	Serial number	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	5.1.8*	Importer	Indicates the entity importing the medical device into the locale.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.2.1	Sterile	Indicates a medical device that has been subjected to a sterilization process.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.2.2	Sterilized using aseptic processing techniques	Indicates a medical device that has been manufactured using accepted aseptic techniques.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.2.3	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.

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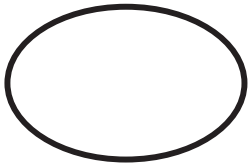
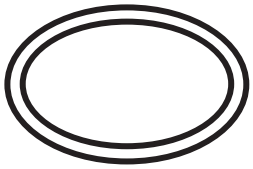
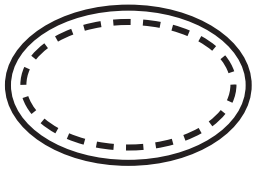
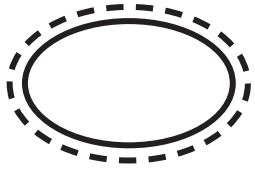
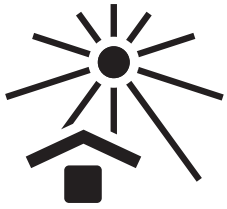
Symbol	Standard	Ref #	Title	Description
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.2.4	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.2.6	Do not resterilize	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	5.2.7	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.2.8	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.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.2.9	Sterile fluid path	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.

Symbol	Standard	Ref #	Title	Description
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.2.11*	Single sterile barrier system	Indicates a single sterile barrier system.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.2.12*	Double sterile barrier system	Indicates two sterile barrier systems.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.2.13*	Single sterile barrier system with protective packaging inside	Indicates a single sterile barrier system with protective packaging inside.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.2.14*	Single sterile barrier system with protective packaging outside	Indicates a single sterile barrier system with protective packaging outside.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.3.2	Keep away from sunlight	Indicates a medical device that needs protection from light sources.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.3.4	Keep dry	Indicates a medical device that needs to be protected from moisture.

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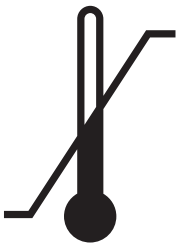
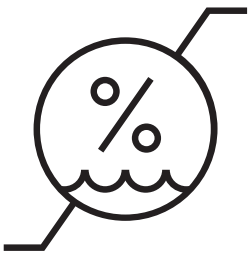
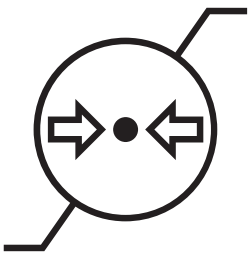
Symbol	Standard	Ref #	Title	Description
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.3.5	Lower limit of temperature	Indicates the lower limit of temperature to which the medical device can be safely exposed.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.3.6	Upper limit of temperature	Indicates the upper limit of temperature to which the medical device can be safely exposed.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.3.8	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.3.9	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.4.2	Do not re-use/ Single use only	Indicates a medical device that is intended for one single use only.

Symbol	Standard	Ref #	Title	Description
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.4.3	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** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.4.4	Caution NOTE: The definition for this symbol has changed in 2020 and is being removed from Cook labels. When this symbol is found **on a Cook label**, the (previous) definition to the right is correct.	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** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.4.4*	Caution NOTE: When this symbol is marked **directly on the medical device,** the definition to the right is correct.	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** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.4.5	Contains or presence of natural rubber latex	Indicates the presence of dry natural rubber or natural rubber latex as a material of construction within the medical device or the packaging of a medical device.

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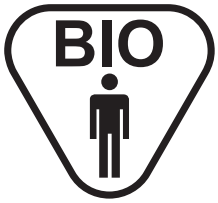
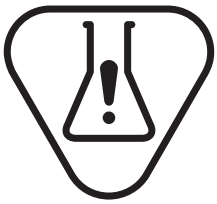
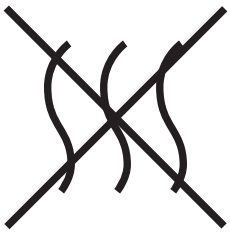
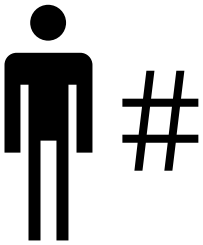
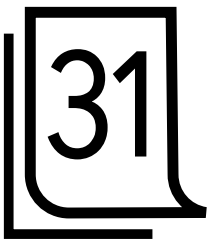
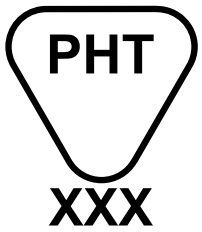
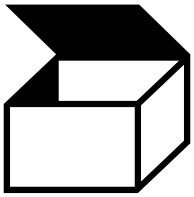
Symbol	Standard	Ref #	Title	Description
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.4.6*	Contains human blood or plasma derivatives	Indicates a medical device that contains or incorporates human blood or plasma derivatives.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.4.7*	Contains a medicinal substance	Indicates a medical device that contains or incorporates a medicinal substance.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.4.8*	Contains biological material of animal origin	Indicates a medical device that contains biological tissue, cells, or their derivatives, of animal origin.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.4.9*	Contains biological material of human origin	Indicates a medical device that contains biological tissue, cells, or their derivatives, of human origin.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.4.10*	Contains hazardous substances	Indicates a medical device that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties.

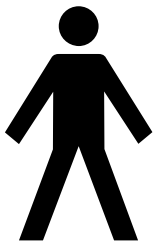
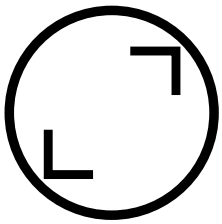
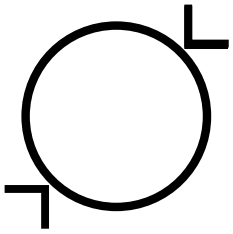
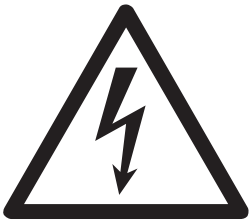
*Approved symbols currently awaiting ISO harmonization are denoted with an asterisk in the Ref # column.

Symbol	Standard	Ref #	Title	Description
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.6.3	Non-pyrogenic	Indicates a medical device that is non-pyrogenic.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.7.1*	Patient Number	Indicates a unique number associated with an individual patient.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.7.3*	Patient Identification	Indicates the identification data of the patient.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.7.4*	Patient information website	Indicates a website where a patient can obtain additional information on the medical product.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.7.5*	Health care centre or doctor	To indicate the address of the health care centre or doctor where medical information about the patient may be found.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.7.6*	Date	To identify the date that information was entered or a medical procedure took place.

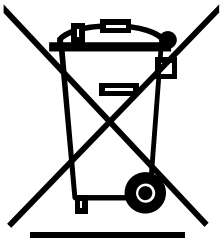
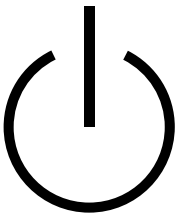
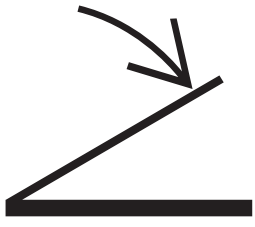
*Approved symbols currently awaiting ISO harmonization are denoted with an asterisk in the Ref # column.

Symbol	Standard	Ref #	Title	Description
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.7.7*	Medical Device	Indicates the item is a medical device.
	**ISO 15223-1** Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied	5.7.10*	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information.
	**ISO 7000/IEC 60417** Graphical symbols for use on equipment **BS EN 15986** Symbol for use in the labelling of medical devices – Requirements for labelling of medical devices containing phthalates	2725	Contains or presence of one or more phthalates, Phthalate chemical abbreviation(s) xxxx	Indicates the medical device contains one or more phthalates.
	**ISO 7000/IEC 60417** Graphical symbols for use on equipment	2794	Packaging unit	To indicate the number of pieces in the package.
	**ISO 7000/IEC 60417** Graphical symbols for use on equipment	5333	Type BF applied part	To identify a type BF applied part complying with IEC 60601-1.

*Approved symbols currently awaiting ISO harmonization are denoted with an asterisk in the Ref # column.

Symbol	Standard	Ref #	Title	Description
	**ISO 7000/IEC 60417** Graphical symbols for use on equipment	5840	Type B applied part	To identify a type B applied part complying with IEC 60601-1.
	**ISO 7000/IEC 60417** Graphical symbols for use on equipment	5845	Inner diameter	To indicate a reference to the inner diameter.
	**ISO 7000/IEC 60417** Graphical symbols for use on equipment	5846	Outer diameter	To indicate a reference to the outer diameter.
	**ISO 7010** Graphical symbols – Safety colours and safety signs – Registered safety signs	M002	Refer to instruction manual/ booklet	To signify that the instruction manual/ booklet must be read.
	**ISO 7010** Graphical symbols – Safety colours and safety signs – Registered safety signs	W001	General warning sign	To signify a general warning.
	**ISO 7010** Graphical symbols – Safety colours and safety signs – Registered safety signs	W012	Warning: Electricity	To warn of electricity.

Symbol	Standard	Ref #	Title	Description
	**ASTM F2503-20** Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Fig. 2	MR Safe	An item which poses no known health hazards resulting from exposure to any MR environment.
	**ASTM F2503-20** Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Fig. 4	MR Safe	An item which poses no known health hazards resulting from exposure to any MR environment.
	**ASTM F2503-20** Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Fig. 5	MR Conditional	An item with demonstrated safety in the MR environment within defined conditions.
	**ASTM F2503-20** Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Fig. 6	MR Conditional	An item with demonstrated safety in the MR environment within defined conditions.
	**ASTM F2503-20** Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Fig. 8	MR Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.
	**ASTM F2503-20** Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Fig. 9	MR Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.

Symbol	Standard	Ref #	Title	Description
	**BS EN 50419** Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE) **WEEE Directive 2012/19/EU**	Fig. 1	Recycle: Electronic Equipment	Separate collection for electrical and electronic equipment.
	**IEC 60417** Graphical symbols for use on equipment	5009	Stand-by	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.
	**IEC 60417** Graphical symbols for use on equipment	5031	Direct current	To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.
	**IEC 60417** Graphical symbols for use on equipment	5032	Alternating current	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	5114	Foot switch	To identify a foot switch or the connection for a foot switch.

Symbol	Standard	Ref #	Title	Description
IPN_1N_2	**IEC 60529** Degrees of protection provided by enclosures (IP Code)	N/A	Ingress protection rating NOTE: The higher the number, the greater the protection. When a number is not required to be specified, it is replaced by the letter X.	The first digit indicates the level of protection that the enclosure provides against the ingress of solid foreign objects. The second digit indicates the level of protection of the equipment inside the enclosure against the ingress of liquids.
Rx only	**21 CFR 801.15** **21 CFR 801.109**	(c) (1) (i) (F) (b) (1)	Prescription only	Caution: Federal (US) law restricts this device to sale by or on the order of a physician.
CE	**MDD 93/42/EEC** **MDR 2017/745** **Regulation (EC) 765/2008**	Annex XII Article 20 Annex II	CE marking, May include Notified Body Reference no. xxxx	Signifies European technical conformity.
Australian Sponsor	**Regulation 10.2** Therapeutic Goods (Medical Devices) Regulations 2002	Essential Principle 13.2 & 13.3	Australian sponsor	Identifies the Australian sponsor.

Symbol	Standard	Ref #	Title	Description
	Medicines and Medical Devices Act 2021	Part 4, Chapter 1, Section 16 (1) (f)	UKCA marking	Signifies Great Britain technical conformity.

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