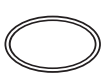
United States Title 21 of the Code of Federal Regulations (CFR) Part 801 - Labeling			
Symbol	Symbol Title	Explanatory Text	Standard Reference
Rx only	Prescription Use Only	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.	Section 801.109 (b) (1)
ISO-15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements			
Symbol	Symbol Title	Explanatory Text	Standard Reference
	Manufacturer	Indicates the medical device manufacturer.	5.1.1
EC REP	Authorized Representative in the European Community	Indicates the authorized representative in the European Community / European Union.	5.1.2
	Date of Manufacture	Indicates the date when the medical device was manufactured.	5.1.3
	Use-by date	Indicates the date after which the medical device is not be used.	5.1.4
LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5
REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	5.1.6
	Importer	Indicates the entity importing the medical device into the locale.	5.1.8
	Country of manufacture	To identify the country of manufacture of products.	5.1.11
STERILE	Sterile	Indicates a medical device that has been subjected to a sterilization process.	5.2.1
STERILE EO	Sterilized by ethylene oxide treatment	Indicates a medical device that has been sterilized using ethylene oxide.	5.2.3
STERILE R	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	5.2.4
	Do Not Re-sterilize	Indicates a medical device that is not to be re-sterilized.	5.2.6
	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.	5.2.7
	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.	5.2.8
	Single Sterile Barrier System	Indicates a Single Sterile Barrier System	5.2.11
	Double Sterile Barrier System	Indicates a Double Sterile Barrier System	5.2.12
	Single sterile barrier system with protective packaging inside	Indicates a single sterile barrier system with protective packaging inside.	5.2.13

Symbol	Symbol Title	Explanatory Text	Standard Reference
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.	5.3.1
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	5.3.2
	Keep Dry	Indicates a medical device needs to be protected from moisture.	5.3.4
	Upper limit of temperature	Indicates the upper limit of temperature to which the medical device can be safely exposed.	5.3.6
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	5.3.7
	Humidity Limitation	Indicates the range of humidity to which the medical device can be safely exposed.	5.3.8
	Atmospheric Pressure Limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	5.3.9
	Do not re-use	Indicates a medical device that is intended for one single use only.	5.4.2
	Consult instructions for use or consult electronic instructions for use.	Indicates the need for the user to consult the instructions for use.	5.4.3
	Caution	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.	5.4.4
	Contains latex or presence of natural rubber	Indicates the presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device.	5.4.5
	Not made with natural rubber latex	Indicates that neither the medical device nor the packaging of the medical device contains the presence of natural rubber latex.	5.4.5 and Annex B.2 and Guidance for Industry and US Food and Drug Administration Staff - Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex; Issued on December 2, 2014
	Single patient multiple use	Indicates a medical device that may be used multiple time (multiple procedures) on a single patient.	5.4.12
	Medical Device	Indicates the item is a Medical Device.	5.7.7
	Unique device identifier	Indicates a carrier that contains unique device identifier information.	5.7.10
ISO 7000 Graphical symbols for use on equipment - Registered symbols - Committee: ISO/TC 145/SC 3 ICS: 01.080.20			
Symbol	Symbol Title	Explanatory Text	Standard Reference
	This way up	To indicate correct upright position of the transport package.	0623

European Medical Device Directive 93/42/EEC / European Medical Device Regulation 2017/745			
Symbol	Symbol Title	Explanatory Text	Standard Reference
CE 0000	Article 17 / Article 20	CE Conformity Marking and Notified Body Number	Product conforms to the applicable requirements for a medical device as set forth in the regulation and assessed by the certifying notified body.
CE	Article 17 / Article 20	CE Conformity Marking	Product conforms to the applicable requirements for medical device as set forth in the regulation.
BS EN 15986:2011 – Medical devices – Symbol for use in the labelling of medical devices. Requirements for labelling of medical devices containing phthalates			
Symbol	Symbol Title	Explanatory Text	Standard Reference
	Does not contain DEHP	Indicates a medical device that does not contain the phthalate plasticizers DEHP.	Annex B
	Contains or presence of phthalate DEHP	Indicates presence of Bis (2-ethylexyl) phthalate (DEHP).	A.2
IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance			
Symbol	Symbol Title	Explanatory Text	Standard Reference
IP27	Degree of Ingress Protection Provided by Enclosure	Degree of protection against the penetration of solid foreign matter and liquids. Protected against solid objects greater than or equal to 12.5 mm diameter and protected against the effects of temporary immersion in water.	Table D.3, Symbol 2 IEC 60529
	Type BF applied part	To identify a type BF applied part complying with IEC 60601-1.	Table D.1, Symbol 20
Other Symbols			
Symbol	Symbol Title	Explanatory Text	Standard Reference
	Recyclable	Product packaging is recyclable.	N/A
	Do not flush	Likely to be used in a bathroom with significant potential to be flushed.	N/A
	Recycle: Electronic Equipment	Do not dispose of this product in unsorted municipal waste stream.	EN 50419
	MR Conditional	Item with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields, and the radiofrequency fields.	ASTM F2503 Table 2
GTIN	Global Trade Item Number	Indicates a number used to identify trade items at various packaging levels.	N/A
Therapeutic Goods Medical Device Regulation			
Symbol	Symbol Title	Explanatory Text	Standard Reference
Australian Sponsor	Australian Sponsor	Indicates the authorized sponsor in the Australian market.	N/A

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