







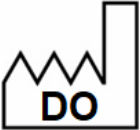




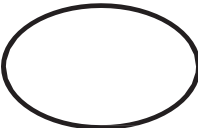

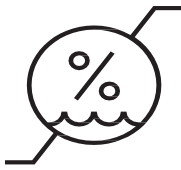
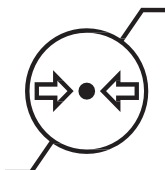











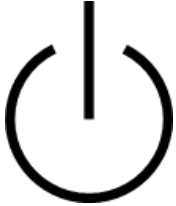


Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	ISO 15223-1, Reference 5.1.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1 General requirements.	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1, Reference 5.1.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1 General requirements.	Authorized representative in the European Community	Indicates the Authorized representative in the European Community.
	ISO 15223-1, Reference 5.1.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1 General requirements.	Authorized representative in the United Kingdom	Indicates the Authorized representative in the United Kingdom
	ISO 15223-1, Reference 5.1.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1 General requirements.	Authorized representative in Switzerland	Indicates the Authorized representative in Switzerland.
	ISO 15223-1, Reference 5.1.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1 General requirements.	Date of Manufacturer	Indicates the date when the medical device was manufactured.


Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	ISO 15223-1, Reference 5.1.4	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 5.1.5	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 5.1.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1 General requirements.	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1, Reference 5.1.11	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1 General requirements.	Country of manufacture	Indicates the country of manufacture of the medical device. DO is the Dominican Republic
	ISO 15223-1, Reference 5.2.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1 General requirements.	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.



Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	ISO 15223-1, Reference 5.2.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1 General requirements.	Do not resterilize	Indicates a medical device that is not to be resterilized.
	ISO 15223-1, Reference 5.2.7	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 sterilization process.
	ISO 15223-1, Reference 5.2.8	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 15223-1, Reference 5.2.11	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1 General requirements.	Single sterile barrier system	Indicates a single sterile barrier system
	ISO 15223-1, Reference 5.3.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1 General requirements.	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	ISO 15223-1, Reference 5.3.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1 General requirements.	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.
	ISO 15223-1, Reference 5.3.9	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1 General requirements.	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	ISO 15223-1, Reference 5.4.2	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 15223-1, Reference 5.4.3	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 5.4.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1 General requirements.	General warning sign	Indicates a general warning

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	ISO 15223-1, Reference 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 15223-1, Reference 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.
	ISO 7010 Reference M002	Graphical symbols – Safety colours and safety signs – Registered safety signs	Refer to instructions manual / booklet	Indicates that the instruction manual / booklet must be read.
	ASTM F2503-20 Reference Fig. 9	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	MR Unsafe	Indicates an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.
	BS EN 50419 Reference Fig. 1	Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE) WEEE Directive 2012/19/EU	Recycle: Electronic Equipment	Indicates the separate collection for electrical and electronic equipment.

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	Directive 2011/65/EU	Restriction of the use of certain hazardous substances in electrical and electronic equipment	Restrictions of Hazardous Substances	Indicates the medical device is lead-free
	IEC 60417 Reference 5009	Graphical symbols for use on equipment	Stand-by	Indicates 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 Reference 5031	Graphical symbols for use on equipment	Direct current	Indicates the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.
	IEC 6047 Reference 5172	Graphic symbols for use on electronic equipment	Class II equipment	Indicates the equipment meeting the safety requirements specified for Class II equipment according to IEC 61140

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	IEC 60601-1 Reference Table D.1, Symbol 21 (IEC 60417-5336)	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Defibrillation-proof Type CF applied part	Indicates a defibrillation-proof Type CF applied part complying with IEC 60601-1
IPX1	IEC 60601-1 (IEC 60529) Reference no. 6.3, Table D.3, Code 2	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Degree of protection	Indicates protection against vertically falling water drops.
R_xonly	21 CFR 801.109	Labeling; Prescription devices	Prescription use only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
CE 2797	MDD 93/42/EEC Annex II; MDR 2017/745 Annex V	The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Directive and Medical Device Regulation.	European conformity	European conformity (CE) mark with Notified Body identification number for Class Is, IIa, III medical devices Notified Body No. 2797: BSI, Netherlands

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	Reference Part 4, Chapter 1, Section 16 (1)(f)	Medicines and Medical Devices Act 2021	UKCA marking	Great Britain (UK) conformity mark with Notified Body identification number for Class Is, IIa, III medical devices Notified Body No. 0086: BSI, Great Britain
			Bluetooth® logo	Indicates wireless technology that allows the exchange of data between different devices.

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