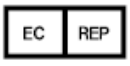
Symbol Glossary -English

Symbol	Definition	Reference
	Consult instructions for use	EN 980, Clause 5.18 ISO 7000-1641 ISO 15223-1, Clause 5.4.3 IEC 60601-1. Table D.1
	Catalog number	EN 980, Clause 5.10 ISO 7000-2493 ISO 15223-1 Clause 5.1.6
	Do not reuse; intended for use on one patient during a single procedure;	EN 980, Clause 5.2 ISO 7000-1051 ISO 15223-1, Clause 5.4.2
	Lower temperature limitation	EN 980 35.17.1 ISO 7000-0534 ISO 15223-1, Clause 5.3.5
	Upper temperature limitation	EN 980 5.17.2 ISO 7000-0533 ISO 15223-1, Clause 5.3.6
	Upper and lower temperature limitation	EN 980 Clause 5.17.3 ISO 7000-0632 ISO 15223-1, Clause 5.3.7
	Relative humidity range	ISO 7000-2620 ISO 15223-1, Clause 5.3.8
	Atmospheric temperature limitation	ISO 7000-2621 ISO 15223-1, Clause 5.3.9
	Statement of prescription*	21 CFR 801 801.15(c)(1)(i)F 21 CFR 801.109
	Battery operated	EC 60417-5002
	Lithium-ion battery	DOT-15004
	Flammable material	DOT-15004
	Contains or presence of phthalates, such as DEHP	EN 15986: Clause 4.2 ISO 7000-2725

Symbol	Definition	Reference
	Caution	EN 980, Clause 5.11 ISO 7000-0434A ISO 15223-1, Clause 5.4.4 IEC 60601-1.Table D.1
	Serial number	EN 980, Clause 5.5 ISO 7000-2498 ISO 15223-1, Clause 5.1.7
	Batch code	EN 980 Clause 5.3 ISO 7000-2492 ISO 15223-1, Clause 5.1.5
	Date of manufacture	EN 980, Clause 5.6 ISO 7000-2497 ISO 15223-1 Clause 5.1.3
	Manufacturer	EN 980, Clause 5.12 ISO 7000-3082 ISO 15223-1 Clause 5.1.1
	Use by date YYYY-MM-DD	EN 980, Clause 5.3 ISO 7000-2507 ISO 15223-1, Clause 5.1.4
	Product conformance with the applicable European Union Directives	765/2008/EC 768/2008/EC MDD 93/42/EEC Articles 4,11,12,17. Annex II
	Authorized Representative in the European Community	EN 980 Clause 5.13 ISO 15223-1: Clause 5.1.2
	Do not re-sterilize	EN 980, Clause 5.22 ISO 7000-2608 ISO 15223-1, Clause 5.2.6
	Quantity per box	EN980. Clause 5.7 ISO 7000-2499 ISO 15223-1, Clause 5.2.1
	Sterilized using ethylene oxide	EN 980, Clause 5.8.2 ISO 7000-2501 ISO 15223-1, Clause 5.2.3
	Sterilized through irradiation	EN 980, Clause 5.8.3 ISO 7000-2502 ISO 15223-1, Clause 5.2.4
	Non sterile	EN 980, Clause 5.23 ISO 7000-2609 ISO 15223-1, Clause 5.2.7

Symbol Glossary -English

Symbol	Definition	Reference
	Does not contain phthalates	BS EN 15986:2011
	Power on	EC 60417-5009
	Caution, this product contains natural rubber latex.	EN 980, Clause 6.2 ISO 15223-1, Clause 5.4.5
	Product not made with natural rubber latex.	NA
	Do not use if package is damaged	ISO 7000-2506 ISO 15223-1, Clause 5.2.8
	Caution- risk of electric shock	ISO 3864
	Keep away from sunlight	EN 980, Clause 5.20 ISO 7000-0624 ISO15223-1 Clause 5.3.2
	MR conditional- safety in MR environment	ASTM F 2503
	MR unsafe	ASTM F 2503
	Biohazard risk	EN 980, 5.19 ISO 7000-0659 ISO 15223 5.4.1
	Keep away from heat and radioactive sources.	ISO 15223-1
	Read Operator Manual	IEC 60601-1, Table D.2, Symbol 10
	Sterilized using vaporized hydrogen peroxide	MDR, Annex I, 23.2, l.

Symbol	Definition	Reference
	Class II device	IEC 60417-5172 (2003-02)
	Keep dry	EN 980, Clause 5.2.1 ISO 7000-0626 ISO 15223-1, Clause 5.3.4
	Type B applied part, Shock protection	IEC 60417-5840 IEC 60601-1, Table D.1
	Type BF applied part Shock protection	IEC 60417-5333 IEC 60601-1, Table D.1
	Fragile, handle carefully	ISO 7000-0621 ISO 15223-1, Clause 5.3.1
	Recycle	ISO PI PF 066
	WEEE—Subject to waste electrical and electronic equipment regulations, i.e. not for general waste	BS EN 50419: 2006 2012/19/EU
	Shipping box is made of corrugated cardboard and should be recycled accordingly	NA
	Quantity in package	Salter symbol
	Quantity per box/package	ISO 7000-2794 (2009-02)
	FCC Declaration of Conformity	FCC Part 18
	Medical Device	MDR, Annex 1, 23.2, q.
	Single Patient- Multiple Use	ISO/DIS 20417 2019 Section 3.26

*US Federal Law restricts this device to sale by or on the order of a physician

References:

1. ISO 7000:2014 Graphical Symbols for Use on Equipment - Registered Symbols
2. BS EN ISO 15223-1:2012 Medical devices- symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General Requirements
3. IEC 60601-1 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance FDA Guidance for Industry: Alternative to Certain Prescription Device Labeling Requirements
4. Waste Electrical and Electronic Equipment (WEEE) Directive 2002/96/EC of the European Parliament, Annex IV
5. ASTM F2503 Standard practice for marking medical devices and other items for safety in magnetic resonance environment.
6. ISO/DIS 20417 2019 Section 3.26: definition of *single patient reuse*
7. IMDRF draft on ''Principles of Labelling for Medical Devices and IVD Medical Devices'', GRRP WG (PD1)/N52: July 2018), Art. 5.2.17.
8. ISO 15223-2:2010-01 Medical Devices – Symbols to be used with medical device labels, labelling, and information to be supplied – Part 2: Symbol development, selection and validation.
9. 21 CFR Parts 660, 801, and 809. Use of Symbols in Labeling. 2016. FDA.