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Glossary of Symbols

United States' Title 21 of the Code of Federal Regulations (CFR) Section 801.109(b)(1)			
Symbol	**Reference**	**Title of Symbol**	**Description**
Rx ONLY	21 CFR Section 801.109 (b) (1) and United States Food and Drug Administration Guidance for Industry – Alternative to Certain Prescription Device Labeling Requirements, Issued on January 21, 2000	Prescription Use Only	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner
ISO 15223-1:2016 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements			
Symbol	**Reference**	**Title of Symbol**	**Description**
REF	5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
	5.2.8	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use
	5.3.4	Keep Dry	Indicates a medical device needs to be protected from moisture.
	5.4.2	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
STERILE EO	5.2.3	Sterilized by ethylene oxide treatment	Indicates a medical device that has been sterilized using ethylene oxide.
	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	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.
	5.2.6	Do Not Re-sterilize	Indicates a medical device that is not to be re-sterilized.
LOT	5.1.5	Batch number	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	5.1.4	Use-by date	Indicates the date after which the medical device is not be used.
BS EN 15986:2011 – Medical devices – 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	Does not contain DEHP	Indicates a medical device that does not contain the phthalate plasticizers DEHP
	BS EN 15986:2011 Reference no. A.5	Contains or presence of phthalate DEHP	Indicates presence of Bis (2-ethylexyl) phthalate (DEHP)