
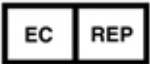

















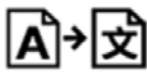







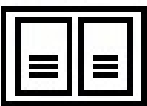


Ref. No. & Symbol	Title	Description	Reference Document
5.1.1 	Manufacturer	Indicates the medical device manufacturer, as defined in EU Regulation 2017/745.	ISO 15223-1 ISO 7000-3082
5.1.2 	Authorized representative in the EC / EU	Indicates the Authorized representative in the European Community / European Union	ISO 15223-1
5.1.3 	Date of manufacture	Indicated the date when the medical device was manufactured.	ISO 15223-1 ISO 7000-2497
5.1.4 	Use-by date	Indicates the date after which the medical device is not to be used. The date shall be expressed in accordance with ISO 8601-1.	ISO 15223-1 ISO 7000-2607
5.1.5 	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1 ISO 7000-2492
5.1.6 	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1 ISO 7000-2493
5.1.11 	Country of manufacture	To identify the country of manufacturer of products. The "CC" shall be replaced by either the two or three letter country code per ISO 3166-1.	ISO 15223-1 IEC 60417-6049
5.2.3 	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1 ISO 7000-2501
5.2.6 	Do not resterilize	Indicates a medical device that is not to be resterilized.	ISO 15223-1 ISO 7000-2608
5.2.7 	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	ISO 15223-1 ISO 7000-2609

Ref. No. & Symbol	Title	Description	Reference Document
5.2.8 	Do not use if package is damaged and consult instruction 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 ISO 7000-2606
5.2.11 	Single sterile barrier system with 5.2.3	Indicates a single sterile barrier system in combination with symbol 5.2.3.	ISO 15223-1 ISO 7000-3707
5.3.2 	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	ISO 15223-1 ISO 7000-0624
5.3.4 	Keep dry	Indicates a medical device that needs to be protected from moisture.	ISO 15223-1 ISO 7000-0626
5.4.1 	Biological risks	Indicates that there are potential biological risks associated with the medical device.	ISO 15223-1 ISO 7000-0659
5.4.2 	Do not re-use	Indicates a medical device that is intended for one single use only.	ISO 15223-1 ISO 7000-0659
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 ISO 7000-1051
5.4.4 	Caution	Indicates that caution is necessary when operating the device or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	ISO 15223-1 ISO 7000-0434A
5.7.7 	Medical device	Indicates the item is a medical device.	ISO 15223-1

Ref. No. & Symbol	Title	Description	Reference Document
5.7.8 	Translation	Indicates that the original medical device information has undergone a translation which supplements or replaces the original information. <b>Shall only be used when translation activity was undertaken by someone other than the manufacturer.</b>	ISO 15223-1 ISO 7000-3728
5.7.10 	Unique device identifier	Indicates a carrier that contains unique device identifier information.	ISO 15223-1 ISO 7000-3727
801.109 (b)(1) 	Prescription only	Indicates the Federal Law (USA) restricts this device to sale by or on the order of a physician.	21 CFR 801 81 FR 38911
Article 20 Annex V 	European Conformity	Indicates that the product may be legally placed on the market in the European Union.	MDR (EU) 2017/745
	Product number	Indicates the universal product number or code.	–
	No Phthalate	Indicates the product is not made with Phthalate	–
	No Latex	Indicates the product is not made with Latex.	–
	Dispenser quantity	Indicates the quantity of units in dispenser.	–
	Case quantity	Indicates the quantity of units in a case.	–

Primary source: ISO 15223-: Medical devices – Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements