Symbols Glossary

MANI

Symbol	Symbol Title	Description of Symbol	Standard Reference
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1:2016 5.1.1 ISO 15223-1:2021 5.1.1
	Authorized representative in the European Community/ European Union	Indicates the authorized representative in the European Community/ European Union	ISO 15223-1:2016 5.1.2 ISO 15223-1:2021 5.1.2
	Date of manufacture	Indicates the date when the medical device was manufactured	ISO 15223-1:2016 5.1.3 ISO 15223-1:2021 5.1.3
	Use-by date	Indicates the date after which the medical device is not to be used	ISO 15223-1:2016 5.1.4 ISO 15223-1:2021 5.1.4
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1:2016 5.1.5 ISO 15223-1:2021 5.1.5
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1:2016 5.1.6 ISO 15223-1:2021 5.1.6

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Symbol	Symbol Title	Description of Symbol	Standard Reference
	Importer	Indicates the entity importing the medical device into the locale	ISO 15223-1:2021 5.1.8
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide	ISO 15223-1:2016 5.2.3 ISO 15223-1:2021 5.2.3
	Do not resterilize	Indicates a medical device that is not to be resterilized	ISO 15223-1:2016 5.2.6 ISO 15223-1:2021 5.2.6
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process	ISO 15223-1:2016 5.2.7 ISO 15223-1:2021 5.2.7
	Do not use if package is damaged and consult instructions for use	Indicates that 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 15223-1:2016 5.2.8 ISO 15223-1:2021 5.2.8
	Single sterile barrier system	Indicates a single sterile barrier system	ISO 15223-1:2021 5.2.11

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Symbol	Symbol Title	Description of Symbol	Standard Reference
	Do not re-use	Indicates a medical device that is intended for one single use only	ISO 15223-1:2016 5.4.2 ISO 15223-1:2021 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	ISO 15223-1:2016 5.4.3 ISO 15223-1:2021 5.4.3
	Contains hazardous substances	Indicates a medical device that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties	ISO 15223-1:2016 5.4.10 ISO 15223-1:2021 5.4.10
	Medical device	Indicates the item is a medical device	ISO 15223-1:2021 5.7.7
	Unique device identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1:2021 5.7.10
Rx Only Or Rx Only	Prescription use only	Caution: Federal law restricts this device to sale by or on the order of a physician	21 CFR 801.109

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Symbol	Symbol Title	Description of Symbol	Standard Reference
CE	CE mark	European conformity	The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Directive & Medical Device Regulation.
CE 0197 Or CE 0197	CE mark with Notified Body Number	European conformity	The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Directive & Medical Device Regulation.