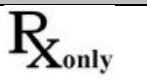
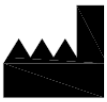
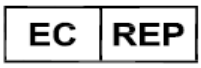
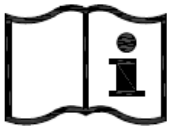
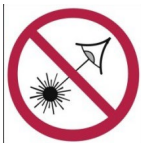
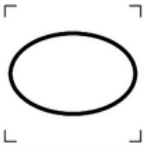
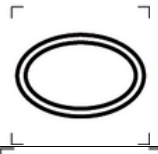
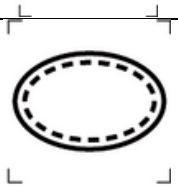
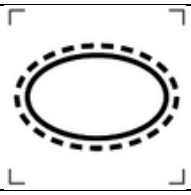
Standard*/ Source	Symbol	Reference Number	Title of Symbol	Description of Symbol per Standard
Code of Federal Regulations Title 21		21 CFR 801.15(c)(1)(i)F 21 CFR 801.109	Prescription use only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
European Medical Device Regulation 2017/745		Annex V	CE marking	Signified European technical conformity
GOV.UK		None	UK CA Mark	Signified United Kingdom Competent Authority technical conformity
SWISSMEDIC.CH		None	Switzerland Authorized Representative	Signified Switzerland Authorized Representative contact information
EN ISO 15223-1: 2021		5.1.1	Manufacturer	Indicates the medical device manufacturer.
EN ISO 15223-1: 2021		5.1.2	Authorized representative in the European Community	Indicates the Authorized representative in the European Community.
EN ISO 15223-1: 2021		5.1.3	Date of manufacture	Indicates the date when the medical device was manufactured.
EN ISO 15223-1: 2021		5.1.4	Use-by date	Indicates the date after which the medical device is not to be used.
EN ISO 15223-1: 2021		5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
EN ISO 15223-1: 2021		5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
EN ISO 15223-1: 2021		5.1.7	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
EN ISO 15223-1: 2021		5.2.1	Sterile	Indicates a medical device that has been subjected to a sterilization process.
EN ISO 15223-1: 2021		5.2.2	Sterilized using aseptic processing techniques	Indicates a medical device that has been manufactured using accepted aseptic techniques.
EN ISO 15223-1: 2021		5.2.3	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.

Standard*/ Source	Symbol	Reference Number	Title of Symbol	Description of Symbol per Standard
EN ISO 15223-1: 2021		5.2.4	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.
EN ISO 15223-1: 2021		5.2.6	Do not resterilize	Indicates a medical device that is not to be resterilized.
EN ISO 15223-1: 2021		5.2.7	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
EN ISO 15223-1: 2021		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.
EN ISO 15223-1: 2021		5.3.4	Keep dry	Indications a medical device that needs to be protected from moisture
EN ISO 15223-1: 2021		5.3.5	Lower limit of temperature	Indicates the lower limit of temperature to which the medical device can be safely exposed.
EN ISO 15223-1: 2021		5.3.6	Upper limit of temperature	Indicates the upper limit of temperature to which the medical device can be safely exposed.
EN ISO 15223-1: 2021		5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
EN ISO 15223-1: 2021		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.
EN ISO 15223-1: 2021		5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
EN ISO 15223-1: 2021		5.4.4	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

Standard*/ Source	Symbol	Reference Number	Title of Symbol	Description of Symbol per Standard
EN ISO 15223-1: 2021		5.6.3	Non-pyrogenic	Indicates a medical device that is non-pyrogenic
EN 60601-1: 2006		Table D.2, Symbol 10	Refer to instruction manual/booklet	Follow instructions for use
EN 60601-1: 2006		Table D.1, Symbol 4	Direct current	The medical electric device is powered through direct current
EN 60601-1: 2006		Table D.1, Symbol 9	Class II equipment	The medical electric device is contains Class II equipment
IEC 60825-1: 2014		Section 7.4, Figure 9	Laser radiation	Warning label serves as a hazard symbol signifying that the device emits laser light
IEC 60825-1: 2014		Section 7.4, Figure 9	Do not expose users of telescopic optics	Warning label that the laser radiation could be harmful if magnified through telescopic optics
IEC 60825-1: 2014		Section 7.4, Figure 9	Do not stare into beam	Warning label not to look into the laser beam
EN ISO 15223-1: 2021		Table 1, Figure 5.7.7	Medical Device	Indicates the item is a medical device
ASTM 2503-20: 2020		Table 1, Figure 7.3.1	MR Safe	An item that poses no known hazards in all MR imaging environments
ASTM 2503-20: 2020		Table 1, Figure 7.3.2.2	MR Conditional	An item that has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use
EN ISO 15223-1: 2021		Table 23.3 (a), Figure 5.2.11	Single sterile barrier system	Indicates a single sterile barrier system

Standard*/ Source	Symbol	Reference Number	Title of Symbol	Description of Symbol per Standard
EN ISO 15223-1: 2021		Table 23.3 (a), Figure 5.2.12	Double sterile barrier system	Indicates two sterile barrier systems
EN ISO 15223-1: 2021		Table 23.3 (a), Figure 5.2.13	Single sterile barrier system with protective packaging inside	Indicates a single sterile barrier system with protective packaging inside
EN ISO 15223-1: 2021		Table 23.3 (a), Figure 5.2.14	Single sterile barrier system with protective packaging outside	Indicates a single sterile barrier system with protective packaging outside

* Standard title and reference number (FDA recognition)

EN ISO 15223-1:2021 - *Medical Devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements (FDA recognition number: 5-134)*

EN 60825-1:2014 - *Safety of Laser Products - Part 1: Equipment Classification, And Requirements (Incorporating corrigenda December 2017 and March 2021) (FDA recognition number: 12-273)*

EN 60601-1:2006 – *Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance (FDA recognition number: 19-4)*

ASTM 2503-20 – *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment (FDA recognition number: 8-528)*

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