Graphical Symbols for Medical Device Labeling

Standard*/ Source	Symbol	Reference number	Title of Symbol	Description of Symbol per Standard
FDA Guidance "Alternative to Certain Prescription Device Labeling Requirements", issued 1/21/2000		N/A	N/A	Caution**:** Federal (USA) law restricts this device to sale by or on the order of a physician.
ISO 15223-1:2021		5.1.1	**Manufacturer**	Indicates the medical device manufacturer as defined in applicable medical device regulations
ISO 15223-1:2021		5.1.2	**Authorized representative in the European Community**	Indicates the Authorized representative in the European Community.
ISO 15223-1:2021 21 CFR Part 801.18 (applies to date format)		5.1.3	**Date of manufacture**	Indicates the date when the medical device was manufactured.
ISO 15223-1:2021 21 CFR Part 801.18 (applies to date format)		5.1.4	**Use-by date**	Indicates the date after which the medical device is not to be used.
ISO 15223-1:2021		5.1.5	**Batch code**	Indicates the manufacture's batch code so that the batch or lot can be identified.
ISO 15223-1:2021		5.1.6	**Catalogue Number**	Indicates the manufacturer's catalogue number so that the medical device can be identified.

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Standard*/ Source	Symbol	Reference number	Title of Symbol	Description of Symbol per Standard
ISO 15223-1:2021		5.1.7	**Serial number**	Indicates the manufacturer's serial number so that a specific medical device can be identified
ISO 15223-1:2021		5.2.1	**Sterile**	Indicates a medical device that has been subjected to a sterilization process.
ISO 15223-1:2021		5.2.4	**Sterilized using irradiation**	Indicates a medical device that has been sterilized using irradiation.
ISO 15223-1:2021		5.2.3	**Sterilized using Ethylene Oxide**	Indicates a medical device that has been sterilized using Ethylene Oxide.
ISO 15223-1:2021		5.2.7	**Non-sterile**	Indicates a medical device that has not been subjected to a sterilization process. This symbol should only be used to distinguish between identical or similar medical devices sold in both sterile and non-sterile conditions.
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 and that the user should consult the instructions for use for additional information.
ISO 15223-1:2021		5.4.2	**Do not re-use**	Indicates a medical device that is intended for one single use only.

Graphical Symbols for Medical Device Labeling

Standard*/ Source	Symbol	Reference number	Title of Symbol	Description of Symbol per Standard
ASTM F2503-20		N/A	**MR Unsafe**	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.
ISO 15223-1:2021		5.4.5	**Does not Contain natural rubber latex**	Indicates that natural rubber latex was not used in the manufacturing of the product, its container, or its packaging.
ISO 15223-1:2021		5.4.3	**Consult instructions for use**	Indicates the need for the user to consult the instructions for use.
ISO 15223-1:2021		5.1.8	**Importer**	Indicates the entity importing the *medical device* into the locale.

* Standard title and reference number (FDA recognition):
5-134: ISO 15223-1 Fourth edition 2021-07 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
8-528: ASTM F2503-20 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment