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 15223-1:2012		5.1.1	**Manufacturer**	Indicates the medical device manufacturer as defined in applicable medical device regulations
ISO 15223-1:2012		5.1.2	**Authorized representative in the European Community**	Indicates the Authorized representative in the European Community.
ISO 15223-1:2012 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 15223-1:2012 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 15223-1:2012		5.1.5	**Batch code**	Indicates the manufacture's batch code so that the batch or lot can be identified.
ISO 15223-1:2012		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 15223-1:2012		5.2.1	**Sterile**	Indicates a medical device that has been subjected to a sterilization process.
ISO 15223-1:2012		5.2.4	**Sterilized using irradiation**	Indicates a medical device that has been sterilized using irradiation.
ISO 15223-1:2012		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 15223-1:2012		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.
ISO 15223-1:2012		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.
ISO 15223-1:2012		5.4.3	**Consult instructions for use**	Indicates the need for the user to consult the instructions for use.

* Standard title and reference number (FDA recognition):
5-90: ISO 15223-1:2012 Second Edition 2012-07-01, Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements. (General I (QS/RM))