SAM Medical Symbol Glossary

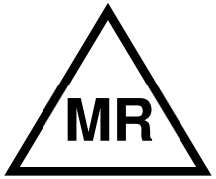
General Requirements for Use

Symbols that are registered with ISO 7000 or other Standards Development Organization must comply with the graphical representation especially with respect to relative dimensions, including line thickness, orientation and the absence or presence of filled or shaded areas.

Title of Symbol	Symbol	Source Reference #	ISO 7000 #	Description	Requirements	Notes
Manufacturer		EN ISO 15223-1:2012 – 5.1.1 EN 980:2008 – 5.12	3082	Indicates the medical device manufacturer as defined in 93/42/EEC	Symbol shall be accompanied by the name and address of the manufacturer adjacent to the symbol	Symbol used to indicate info required in EU. Date of manufacture as well as the name and address of the manufacturer can be combined into one symbol. The relative size of the symbol and the size of the name and address are not specified.
EU Authorized Representative		EN ISO 15223-1:2012 – 5.1.2 EN 980:2008 – 5.13	N/A	Indicates the Authorized Representative in the European Community.	This symbol shall be accompanied by the name and address of the AR in the EC, adjacent to the symbol.	Symbol used to indicate info required in EU.
CE Mark		93/42/EEC	N/A	Mark of conformance with the relevant European essential requirements.	The symbol must be included on the label of products sold in the EU. If the device is Class IIa to Class III, the notified body identifier must be included.	If the marking is reduced or enlarged the proportions must be respected. The vertical dimension may not be less than 5mm.
Date of Manufacture		EN ISO 15223-1:2012 – 5.1.3 EN 980:2008 – 5.6	2497	Indicates the date when the medical device was manufactured.	This symbol shall be accompanied by a date to indicate the date of manufacture. This shall be expressed as in ISO 8601 as four digits for the year and, where appropriate, two digits for the month and two digits for the day. The date shall be located adjacent to the symbol.	This symbol can be filled or unfilled. If filled (5.1.1), the date of manufacture as well as the name and address of the manufacture can be combined in one symbol.

Title of Symbol	Symbol	Source Reference #	ISO 7000 #	Description	Requirements	Notes
Use-by Date	 YYYY – MM – DD	EN ISO 15223-1:2012 – 5.1.4 EN 980:2008 – 5.3	2607	Indicates the date after which the medical device is not to be used.	The date shall be expressed as in ISO 8601 as four digits for the year and, where appropriate, two digits for the month and two digits for the day. The date shall be located adjacent to the symbol.	Synonym is “Expiration Date”
Batch Code		EN ISO 15223-1:2012 – 5.1.5 EN 980:2008 – 5.4	2492	Indicates the manufacturer's batch code so that the batch or lot can be identified.	This symbol shall be accompanied by the manufacturer's batch code. The batch code shall be adjacent to the symbol.	Synonyms are “lot number” and “batch number”.
Catalog Number		EN ISO 15223-1:2012 – 5.1.6 EN 980:2008 – 5.10	2493	Indicates manufacturer’s catalog number so that the medical device can be identified.	The manufacturer’s catalog number shall be adjacent to the symbol.	The relative size of the symbol and the catalog number are not specified. Synonyms are reference number and reorder number.
Serial Number		EN ISO 15223-1:2012 – 5.1.7 EN 980:2008 – 5.5	2498	Indicates the manufacturer's serial number so that a specific medical device can be identified.	This symbol shall be accompanied by the manufacturer's serial number. The serial number shall be adjacent to the symbol.	The relative size of the symbol and the serial number are not specified.
Sterilized using Irradiation		EN ISO 15223-1:2012 – 5.2.4 EN 980:2008 – 5.8.3	2502	Indicates a medical device that has been sterilized using irradiation.	None	This symbol can be used to indicate that the product has been subjected to irradiation processes.
Non-Sterile		EN ISO 15223-1:2012 – 5.2.7 EN 980:2008 – 5.23	2609	Indicates a medical device that has not been subjected to a sterilization process.	None	This symbol should only be used to distinguish between identical or similar medical devices sold in both sterile and non-sterile conditions.
Do Not Resterilize		EN ISO 15223-1:2012 – 5.2.6 EN 980:2008 – 5.22	2608	Indicates a medical device that is not to be resterilized.	None	None

Title of Symbol	Symbol	Source Reference #	ISO 7000 #	Description	Requirements	Notes
Do Not Reuse		EN ISO 15223-1:2012 – 5.4.2 EN 980:2008 – 5.2	1051	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	None	Synonyms are Single Use and Use Only Once
Do Not Use if Package is Open or Damaged		EN ISO 15223-1:2012 – 5.2.8 EN 980:2008 – 6.3	2606	Indicates a medical device that should not be used if the package has been damaged or opened.	None	This symbol may also mean "Do not use if the product sterile barrier system or its packaging is compromised".
Fragile, Handle With Care		EN ISO 15223-1:2012 – 5.3.1	0621	Indicates a medical device that can be broken or damaged if not handled carefully.	None	None
Keep Dry		EN ISO 15223-1:2012 -	0626	Indicates a medical device that needs to be protected from moisture.	None	This symbol can also mean “Keep away from rain” as referenced in ISO 7000.
Keep Away from Sunlight		EN ISO 15223-1:2012 – 5.3.2 EN 980:2008 – 5.20	0624	Indicates a medical device that needs protection from light sources.	None	This symbol can also mean “Keep away from heat”, as referenced in ISO 7000:1989.
Temperature Limit		EN ISO 15223-1:2012 – 5.3.7 EN 980:2008 – 5.17.3	0632	Indicates the temperature limits to which the medical device can be safely exposed.	The upper and lower limits of temperature shall be indicated adjacent to the upper and lower horizontal lines.	None
Upper Limit of Temperature		EN ISO 15223-1:2012 – 5.3.7 EN 980:2008 – 5.17.3	0533	Indicates the maximum temperature limit to which the medical device can be safely exposed.	The upper limits of temperature shall be indicated adjacent to the upper and lower horizontal lines.	None

Title of Symbol	Symbol	Source Reference #	ISO 7000 #	Description	Requirements	Notes
Consult Instructions For Use		EN ISO 15223-1:2012 – 5.4.3 EN 980:2008 – 5.18	1641	Indicates the need for the user to consult the instructions for use.	None	Synonym is Consult Operating Instructions Consider the difference between the description of this symbol and that of symbol 5.4.4.
Caution, Consult Instructions for Use		EN ISO 15223-1:2012 – 5.4.4 EN 980:2008 – 5.11	0434A	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.	The symbol variant ISO 7000-0434B (“Caution”) may be used.	Consider the difference between the description of this symbol and that of symbol 5.4.3. This symbol is essentially a cautionary symbol and should be used to highlight that there are specific warnings or precautions which are not otherwise found on the label.
Time		IEC60417	5184	Used on labels to indicate time, such as the time of tourniquet application.	None	This is one adaption of the ISO 7000 symbol which can also indicate timer, clock or timer switch.
Prescription Only		21 CFR 801	N/A	US FDA Prescription Labeling Statement	Use of an appropriate symbol or the wording “Rx Only” to appear on the label of prescription medical devices.	FDA Guidance “Alternative to Certain Prescription Device Labeling Requirements”, January 2000 allows the use of the symbol or the words “Rx Only” to convey the prescription legend statement.
X-Ray Radiolucent		N/A	N/A	A symbol that indicates the medical device is radiolucent to x-rays and will not impact the diagnostic nature of the radiograph.	***Not a standard symbol, text “Radiolucent” should be provided on label and in labeling to describe symbol meaning.***	ASTM F640-12 Standard Test Methods for Determining Radiopacity for Medical Use can be used to determine radiolucency.
MR Conditional		ASTM F2503-13	N/A	Magnetic resonance conditional indicates the device has been demonstrated as safe for operation in the MR environment under defined conditions	Place description of the conditions under which the device would be safe (field strength, i.e., 3 Tesla (3T); spatial gradient; RF fields; specific absorption rate active)	ASTM F2503-13 Standard Practice for Marking Medical Devices for Safety in the Magnetic Resonance Environment.

Title of Symbol	Symbol	Source Reference #	ISO 7000 #	Description	Requirements	Notes
Contains (or Presence) of Natural Latex Rubber		EN ISO 15223-1:2012 – 5.4.5 EN 980:2008 – 6.2	N/A	Indicates the presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device.	This symbol should not be used for medical devices containing "synthetic rubber". In Europe, this symbol shall be explained in the information supplied by the manufacturer.	This symbol is intended to warn those people who may have allergic reactions to certain proteins in latex.
Not Made With Natural Rubber Latex		EN 80416-3:2002	N/A	Indicates that natural rubber latex was not used in the manufacture of the product, product container or packaging.	Two diagonal bars 2 mm in thickness at right angles that extend to the horizontal and vertical dimensions and is centered on the symbol.	This symbol is intended to convey to individuals who may have allergic reactions to certain proteins in latex that the product and its packaging was not manufactured with natural rubber latex.

Use of general prohibition symbol and negation symbol

The general prohibition symbol (as used in ISO 3864-1), a red circle with the red negation bar is intended to indicate a prohibited action and in SAM Medical device labeling it is used as an active direction to mean "do not".

SAM Medical communicates the meaning of "does not" or "is not" where a symbol expressing this meaning does not exist and follows the method set out in Clause 7 of EN 80416-3 (the "negation symbol") in which two crossed diagonal bars (X) are placed over the symbol.

Providing MR Safety Information in Labeling (from FDA Guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment

The MR terminology and symbols in ASTM F2503-13, *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*, are used in SAM Medical device labeling as appropriate. Labeling for MR Conditional devices should indicate the parameters under which the device can be safely used in the MR environment.

Use of Dates in SAM Medical Labeling

When dates are included in SAM Medical labeling, the FDA Unique Device Identifier convention (based on ISO 8601 Data elements and interchange formats – Information exchange – Representation of Dates) is utilized. The convention is four (4) digits for the year followed by a dash (-), then two (2) digits for the month followed by a dash (-), then two (2) digits for the day (YYYY – MM – DD). Example: 2016-11-01 indicates the 1st day of November in 2016. The day will always be present in the date, and the first day of the month (01) will be the standard unless a more specific date is recorded in device manufacturing records.