






















# Summit Medical | Symbols Glossary

Symbol	Symbol Title	Explanatory Text	Standard Title	Standard Reference
	Catalog number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 7000-3082 ISO 15223-1:2021 Reference no. 5.1.6
	Lot Number	Indicates the manufacturer's batch code so that the batch or lot can be identified.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 7000-2607 ISO 15223-1:2021 Reference no. 5.1.5
	Manufactured by	Indicates the medical device manufacturer.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 7000-3082 ISO 15223-1:2021 Reference no. 5.1.1
	Date of Manufacture	Indicates the date when the medical device was manufactured.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 7000-2607 ISO 15223-1:2021 Reference no. 5.1.3
	Country of manufacture. "Made in USA"	Indicates the origin of manufacture.	Graphical Symbols for Use on Equipment	IEC 60417-6049 ISO 15223-1:2021 Reference no. 5.1.11
	Quantity	Indicates the number of unit(s) per package.	N/A	Custom Symbol
	Rx Only	Indicates the product is defined as a Medical Device, defined by 21CFR 820.3(l) and federal US law. The sale is restricted to or by the order of a physician.	801.109 Prescription Devices	21 CFR 801.109.
	For US audiences Only	Indicates the symbol directly next to this symbol applies to US audiences only.	N/A	Custom Symbol









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	Use By	Indicates the date after which the medical device is not to be used.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 7000-2607 ISO 15223-1:2021 Reference no. 5.1.4
	Unique Device identifier	Indicates a carrier that contains unique device identifier information.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 15223-1:2021 Reference no. 5.7.10
	Single Use only	Indicates a medical device that is intended for one single use only.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 7000-1051 ISO 15223-1:2021 Reference no. 5.4.2
	Keep Dry	Indicates a medical device that needs to be protected from moisture.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 7000-0626 ISO 15223-1:2021 Reference no. 5.3.4
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 7000-0624 ISO 15223-1:2021 Reference no. 5.3.2
	Do not use if damaged	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.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 7000-2606 ISO 15223-1:2021 Reference no. 5.2.8
“Not Made with Natural Rubber Latex”	Not made with natural rubber latex	Indicates that natural rubber latex was not used in the manufacturing of the product, its container, or its packaging.	N/A	Custom Symbol








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	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 7000-0434A ISO 15223-1:2021 Reference no. 5.4.4
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 7000-1641 ISO 15223-1:2021 Reference no. 5.4.3
	Medical Device	Indicates the item is a medical device.	MDR 2017/745	ISO 15223-1:2021 Reference no. 5.7.7
	CE-Mark	Indicates the manufacturers declaration that their product conforms with performance and safety requirements of the European medical device, health, safety and environment legislations.	European Medical Devices Directive 93/42/EEC  European Medical Device Regulation 2017/745	N/A
	CE-Mark with BSI Notified Body Number	Indicates conformity of products where the notified body performed conformity assessment. Notified body reference # is displayed.	European Medical Devices Directive 93/42/EEC  European Medical Device Regulation 2017/745	N/A
	Distributor	Indicates the entity distributing the medical device into the locale.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 7000-3724 ISO 15223-1:2021 Reference no. 5.1.9
	Patient Identification	Indicates the indication data of the patient	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	IEC 60417-5664 ISO 15223-1:2021 Reference no. 5.7.3









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	Date	Indicates the data that information was entered or a medical procedure took place.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	IEC 60417-5662 ISO 15223-1:2021 Reference no. 5.7.6
	Health care center or doctor	Indicates the address of the healthcare center or doctor where, medical information about the patient may be found.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 7001 PI PF 044 ISO 15223-1:2021 Reference no. 5.7.5
	Patient information website	Indicates a website where a patient can obtain additional information on the medical product.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 7000-3705 ISO 15223-1:2021 Reference no. 5.7.4
	Single Sterile Barrier system with protective packaging inside	Indicates a single sterile barrier system with protective packaging inside.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 7000-3708 ISO 15223-1:2021 Reference no. 5.2.13
	Single sterile barrier system with protective packaging outside	Indicates a single sterile barrier system with protective packaging outside.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 7000-3709 ISO 15223-1:2021 Reference no. 5.2.14
	Double Sterile barrier system	Indicates two sterile barrier systems.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 7000-3704 ISO 15223-1:2021 Reference no. 5.2.12
	Single Sterile Barrier	Indicates a single sterile barrier system.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 7000-3707 ISO 15223-1:2021 Reference no. 5.2.11
	Do not re-sterilize	Indicates a medical device that is not to be re-sterilized.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 7000-2608 ISO 15223-1:2021 Reference no. 5.2.6

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	Sterilized using Ethylene Oxide	Indicates a medical device that has been sterilized using ethylene oxide.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 7000-2501 ISO 15223-1:2021 Reference no. 5.2.3
	Sterilized using Radiation	Indicates a medical device that has been sterilized using radiation.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 7000-2502 ISO 15223-1:2021 Reference no. 5.2.4
	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 7000-2609 ISO 15223-1:2021 Reference no. 5.2.7
	MR Conditional	Indicates the product has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use.	N/A	ASTM F2503
	MR Safe	Indicates the product poses no safety hazards in the MR environment and may be placed anywhere in the MR Environment.	N/A	ASTM F2503
	Peelable Label	Indicates a part of the label that can be peeled off the original label.	N/A	Custom Symbol
	Importer	Indicates the importer of the medical product.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 7000-2498 ISO 15223-1:2021 Reference No. 5.1.8

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	CH Rep	Indicates the Swiss Authorized representative.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 15223-1:2021 Reference no. 5.1.2
	EC Rep	Indicates the Authorized representative in the European Community.	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 15223-1:2021 Reference no. 5.1.2
	Equipment not suitable for use in the presence of a flammable anesthetic mixture	Indicates the equipment should not be used in the presence of a flammable anesthetic mixture.	Custom Symbol	N/A
	Ingress Protection Rating IP22	Protected against solid objects over 12.5mm (e.g., a finger) and protected against falling drops of water, if the case is exposed at any angle up to 15 degrees from vertical.	N/A	N/A
	Direct Current	Indicates the required current type of the device.	Graphical Symbols for Use on Equipment	IEC 60417 – 5031
	Device requires AAA batteries	Indicates the device requires AAA Batteries. The quantity of batteries required for operation may appear next to the symbol.	Custom Symbol	N/A
	Dispose of device and battery according to national or local regulations	Indicates the user should consult national or local regulations before disposing of the product / device.	Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE)	BS EN 50419
	Type BF Applied Part	Indicates the device makes conductive contact with the patient.	Graphical Symbols for Use on Equipment	IEC 60417-5333

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<b>FP</b>	Fluoroplastic Product	Indicates the product is made out of fluoroplastic: ETFE or PTFE	Custom Symbol	N/A
<b>PTFE</b>	PTFE Product	Indicates the product is made out of Polytetrafluoroethylene.	Custom Symbol	N/A
<b>SI</b>	Silicone Product	Indicates the product is made out of Silicone.	Custom Symbol	N/A
<b>TI</b>	Titanium Product	Indicates the product is made out of Titanium.	Custom Symbol	N/A
<b>ID</b>	Inner Diameter	Indicates the products inner diameter.	Custom Symbol	N/A