Symbol Glossary

Symbol	Title	Explanatory Text	Standard Reference	Standard Title
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1: 2021 Reference no. 5.1.1. (ISO 7000-3082)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
	Manufacturing date	Indicates the date when the medical device was manufactured	ISO 15223-1: 2021 Reference no. 5.1.3. (ISO 7000-2497)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
	Country of Manufacture	To identify the country of manufacture of products	ISO 15223-1: 2021 Reference no. 5.1.11. (IEC 60417-6049)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
	Batch number	Indicates the manufacturer's batch number so that the batch or lot can be identified	ISO 15223-1: 2021 Reference no. 5.1.5. (ISO 7000-2492)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
	Sterilized using Ethylene Oxide	Indicates a medical device that has been sterilized using ethylene oxide	ISO 15223-1: 2021 Reference no. 5.2.3. (ISO 7000-2501)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
	MR Unsafe	An item that is known to pose hazards in all MRI environments	ASTM F2503-20	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

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	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	ISO 15223-1: 2021 Reference no. 5.4.4. (ISO 7000-0434A)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
	Consult instructions for use	Indicates the need for the user to consult the instructions for use iso_15223 Consult instructions for use iso_grs_7000_1641 Operator's manual; operating instructions	ISO 15223-1: 2021 Reference no. 5.4.3. (ISO 7000-1641)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
	Refer to instruction manual/booklet	To signify that the instruction manual/booklet must be read	IEC 60601-1, Reference no. Table D.2, Safety sign 10 (ISO 7010-M002)	Medical electrical equipment — Part 1: General requirements. for basic safety and essential performance
	Medical Device	Indicates the item is a medical device	ISO 15223-1: 2021 Reference no. 5.7.7.	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
RxOnly	To sale by or on the order of a physician.	Caution: Federal (US) law restricts this device to sale by or on the order of a physician.	c) (1) (i) (F) (b) (1)	21 CFR 801.15 21 CFR 801.109
	Do not re-use	Indicates a medical device that is intended for one single use only	ISO 15223-1: 2021 Reference no. 5.4.2. (ISO 7000-1051)	Medical devices — Symbols to be used with information to be

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				supplied by the manufacturer – Part 1: General requirements.
	Do not resterilize	To indicate that the device should not be re-sterilized after it once has been sterilized.	ISO 15223-1: 2021 Reference no. 5.2.6. (ISO 7000-2608)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
	Single patient multiple use	Indicates a medical device that may be used multiple times (multiple procedures) on a single patient	ISO 15223-1: 2021 Reference no. 5.4.12. (ISO 7000-3706)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
	Single sterile barrier system	Indicates a single sterile barrier system	ISO 15223-1: 2021 Reference no. 5.2.11. (ISO 7000-3707)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
	Single sterile barrier system with protective packaging outside	Indicates a single sterile barrier system with protective packaging outside	ISO 15223-1: 2021 Reference no. 5.2.14. (ISO 7000-3709)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
	Does not contain or has presence of natural rubber	Indicates the medical device is not made of natural rubber or dry natural rubber latex as a material of construction within the medical device or its packaging	ISO 15223-1: 2021 Reference no. 5.4.5. (ISO 7000-2725). Annex B for the general prohibition symbol and negation symbol.	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.

Symbol	Title	Explanatory Text	Standard Reference	Standard Title
	Does not contain or has presence of natural rubber	Indicates the medical device is not made of natural rubber or dry natural rubber latex as a material of construction within the medical device or its packaging	N/A	N/A
	Does not contain DEHP	Indicates the medical device does not contain di(2-ethylhexyl) phthalate (DEHP) or may contain a minimum amount within acceptable or undetectable levels.	ISO 3864-1 (ISO 7000-2725)	Graphical symbols — Safety colours and safety signs — Part 1: Design principles for safety signs and safety markings
	Does not contain DEHP	Indicates the medical device does not contain di(2-ethylhexyl) phthalate (DEHP) or may contain a minimum amount within acceptable or undetectable levels.	N/A	N/A
	Non-pyrogenic	Indicates a medical device that is non-pyrogenic	ISO 15223-1: 2021 Reference no. 5.6.3. (ISO 7000-2724)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
	Fluid Path	Indicates the presence of a fluid path	ISO 15223-1: 2021 Reference no. 5.6.2. (ISO 7000-2722)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
	Drops per millilitre	Indicates the number of drops per millilitre	ISO 15223-1: 2021 Reference no. 5.6.4. (ISO 7000-2726)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.

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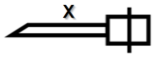
	Liquid filter with pore size	Indicates an infusion or transfusion system of the medical device that contains a filter of a particular nominal pore size	ISO 15223-1: 2021 Reference no. 5.6.5. (ISO 7000-2727)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
	Upper limit of temperature	Indicates the upper temperature limits to which the medical device can be safely exposed.	ISO 15223-1: 2021 Reference no. 5.3.6. (ISO 7000-0632)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
	Lower limit of temperature	Indicates the lower temperature limits to which the medical device can be safely exposed.	ISO 15223-1: 2021 Reference no. 5.3.5. (ISO 7000-0632)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
	Temperature limit	Indicates the lower temperature limits to which the medical device can be safely exposed.	ISO 15223-1: 2021 Reference no. 5.3.7. (ISO 7000-0632)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
	Don’t use if the product sterile barrier system or its packaging is compromised and consult instructions for use	Indicates that a medical device that should not be used if the product sterile barrier system or its packaging has been damaged or opened and that the user should consult the instructions for use for additional information.	ISO 15223-1: 2021 Reference no. 5.2.8. (ISO 7000-2606)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.

Symbol	Title	Explanatory Text	Standard Reference	Standard Title
CE	CE Mark	(43) 'CE marking of conformity' or 'CE marking' means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing	EU 2017-745 EU 2017-746 Reference no. ANNEX V	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/ EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/ EEC and 93/42/EEC
CE xxxx CE xxxx	CE Mark with Notified Body Reference # ###	Indicates the CE Marking with Notified Body reference # displayed. (43) 'CE marking of conformity' or 'CE marking' means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing	EU 2017-745 EU 2017-746 Reference no. ANNEX V	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/ EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/ EEC and 93/42/EEC
REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1: 2021 Reference no. 5.1.6. (ISO 7000-2493)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
SN	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	ISO 15223-1: 2021 Reference no. 5.1.7. (ISO 7000-2498)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.

Symbol	Title	Explanatory Text	Standard Reference	Standard Title
GTIN	Global trade item number	The GS1 identification key used to identify trade items. The key comprises a GS1 Company Prefix, an item reference and check digit.	N/A	N/A
UDI	Unique device identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1: 2021 Reference no. 5.7.10.	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
	Importer	Indicates the entity importing the medical device into the locale	ISO 15223-1: 2021 Reference no. 5.1.8. (ISO 7000-3725)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
EC REP	Authorized Representative in the European Community / European Union	Indicates the Authorized Representative in the European Community / European Union	ISO 15223-1: 2021 Reference no. 5.1.2.	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
	Use-by date	Indicates the date after which the medical device is not to be used	ISO 15223-1: 2021 Reference no. 5.1.4. (ISO 7000-2607)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
	Quantity	Indicates the number of units in the package.	N/A	N/A
	Packaging unit	To indicate the number of pieces in the package.	ISO 7000-2794	Graphical symbols for use on equipment — Registered symbols

Symbol	Title	Explanatory Text	Standard Reference	Standard Title
	Length	Indicates medical device length.	N/A	N/A
	Number of needles	Number of needles present in the infusion set. X is replaced by the number of needles.	N/A	N/A
	Approximate priming volume	Approximate amount of fluid or medication remaining in the administration set after the drug volume is infused.	N/A	N/A
	Distributor	Indicates manufacturer's approved distributor of products.	ISO 15223-1: 2021 Reference no. 5.1.9. (ISO 7000-3724)	Medical devices — Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements.
	Telephone	Indicates manufacturer's phone number.	N/A	N/A
	Website	Indicates manufacturer's website.	N/A	N/A
	Address	Indicates manufacturer's physical address.	N/A	N/A
	Peel Down	Indicates the location that can be used to open medical device pouch.	N/A	N/A