US Symbol Glossary

SYMBOL	STANDARD REFERANCE	STANDARD TITEL	SYMBOL TITEL	EXPLANATORY TEXT
	ISO 15223-1:2021 Reference no. 5.1.1. (FDA Recognition number #5-134)	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Manufacturer	To identify the manufacturer of a product.
	ISO 15223-1:2021 Reference no. 5.1.3. (FDA Recognition number #5-134)	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Date of manufacture	To indicate the date on which a product was manufactured.
	ISO 15223-1:2021 Reference no. 5.1.4. (FDA Recognition number #5-134)	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Use-by date	To indicate that the device should not be used after the date accompanying the symbol.
	ISO 15223-1:2021 Reference no. 5.1.5. (FDA Recognition number #5-134)	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Batch code	To identify the manufacturer's batch or lot code, for example on a medical device or the corresponding packaging. The code shall be placed adjacent to the symbol.
	ISO 15223-1:2021 Reference no. 5.1.6. (FDA Recognition number #5-134)	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Catalogue number	To identify the manufacturer's catalogue number, for example on a medical device or the corresponding packaging. The catalogue number shall be placed adjacent to the symbol.
	ISO 15223-1:2021 Reference no. 5.2.1. (FDA Recognition number #5-134)	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Sterile	Indicates a medical device that has been subjected to a sterilization procedure.
	ISO 15223-1:2021 Reference no. 5.2.2. (FDA Recognition number #5-134)	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Sterilized using ethylene oxide	To indicate that the device is provided sterile and has been sterilized using ethylene oxide
	ISO 15223-1:2021 Reference no. 5.2.6 (FDA Recognition number #5-134)	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — 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. 5.2.7 (FDA Recognition number #5-134)	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	ISO 15223-1:2021 Reference no. 5.2.8 (FDA Recognition number #5-134)	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Do not use if package is damaged and follow the instructions for use	To indicate that the device must not be used if the package holding the device is damaged, for example on packaging of medical devices, and and that the user should read the instructions for use for additional information
	ISO 15223-1:2021 Reference no. 5.2.11 (FDA Recognition number #5-134)	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Single sterile barrier system	Indicates a single sterile barrier system

SYMBOL	STANDARD REFERANCE	STANDARD TITEL	SYMBOL TITEL	EXPLANATORY TEXT
	ISO 15223-1:2021 Reference no. 5.2.13 (FDA Recognition number #5-134)	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Simple sterile barrier system with internal protective packaging	Indicates a single-sterile barrier system with internal protective packaging
	ISO 15223-1:2021 Reference no. 5.3.2 (FDA Recognition number #5-134)	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Keep away from sunlight	To indicate that transport package shall not be exposed to sunlight.
	ISO 15223-1:2021 Reference no. 5.3.4 (FDA Recognition number #5-134)	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Keep away from rain	To indicate that the transport package shall be kept away from rain and in dry conditions.
	ISO 15223-1:2021 Reference no. 5.4.2 (FDA Recognition number #5-134)	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Do not re-use	To indicate that the item is for single use only and must not be used more than once, for example on packages of medical disposables.
	ISO 15223-1:2021 Reference no. 5.4.3 (FDA Recognition number #5-134)	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Operator's manual; operating instructions	Indicates to the user that it is necessary to follow the instructions for use.
	ISO 15223-1:2021 Reference no. 5.4.4 (FDA Recognition number #5-134)	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Caution	To indicate 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. 5.4.12 (FDA Recognition number #5-134)	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	For reuse on a single patient	Indicates a medical device that may be used multiple times (for multiple procedures) on a single patient.
	ISO 15223-1:2021 Reference no. 5.7.7 (FDA Recognition number #5-134)	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Medical Device	Indicates the item is a medical device
	MDR Medical Device Regulation EU 2017-745	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 marking (class 1 devices without notified body)	(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
	MDR Medical Device Regulation EU 2017-745	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on	CE marking (TÜV Nord)	(18.5) Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity

SYMBOL	STANDARD REFERANCE	STANDARD TITEL	SYMBOL TITEL	EXPLANATORY TEXT
		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.		assessment procedure set out in article 48.
MR	ASTM F2503-20 (FDA recognition number #8-528)	Standard practice for Making Medical Devices and other item for safety in the magnetic resonance environment	Magnetic Resonance (MR) safe	To indicate the product is safe to use in a MR environment.
Rx Only	21 CFR 801.109	Code of Federal Regulations Title 21 - Food and Drugs; Subchapter H Medical Devices Part 801 Labeling – Prescription devices.	For prescription use only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
LATEX	n.a.	n.a.	Not made with natural rubber latex	Indicates that the product was not made with natural rubber latex.
PVC	n.a.	n.a.	Not made with PVC	Indicates that the product was not made with PVC.
DEHP	n.a.	n.a.	Not made with DEHP	Indicates that the product was not made with DEHP.
BPA	n.a.	n.a.	Not made with BPA	Indicates that the product was not made with BPA.
ENFit®	ISO 80369-3 (FDA Recognition number #5-123)	Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications	ENFit - enteral feeding connector	Indicates that the product has an ENFit connector. The new ENFit® connectors reduce the risk of incorrect connections between enteral and other systems and thus significantly improve patient safety. The ENFit ensures, by design, non-interconnectivity of connectors of different applications in the care environment.
ENSwivel	ISO 80369-3 (FDA Recognition number #5-123)	Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications	ENSwivel®	ENSwivel® stands for an ENFit® connector with a rotating ring, which allows for effortless connection and disconnection of ENFit® devices. Even very tight connections can be easily released. This feature avoids any twisting of the enteral tube which is both painful for the patient and inconvenient for the user.