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SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	ISO 15223-1 Reference no. 5.1.1. (ISO 7000-3082) FDA Recognition # 5-117	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 Reference no. 5.1.3. (ISO 7000-2497) FDA Recognition # 5-117	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 Reference no. 5.1.4. (ISO 7000-2607) FDA Recognition # 5-117	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 Reference no. 5.1.5. (ISO 7000-2492) FDA Recognition # 5-117	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 Reference no. 5.1.6. (ISO 7000-2493) FDA Recognition # 5-117	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 Reference no. 5.2.3. (ISO 7000-2501) FDA Recognition # 5-117	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 Reference no. 5.2.6. (ISO 7000- 2608) FDA Recognition # 5-117	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 Reference no. 5.2.9 (A.12, NOTE 1) (ISO 7000-3084) FDA Recognition #5-117	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Sterile fluid path	A.12 Examples of use of symbol 5.2.9 for "Sterile fluid path": Medical device contains a sterile fluid path that has been sterilized using ethylene oxide.
	ISO 15223-1 Reference no. 5.3.2. (ISO 7000-0624) FDA Recognition # 5-117	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 Reference no. 5.3.4. (ISO 7000-0626) FDA Recognition # 5-117	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 Reference no. 5.2.8. (ISO 7000-2606) FDA Recognition # 5-117	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 damage	To indicate that the device must not be used if the package holding the device is damaged, for example on packaging of medical devices.
	ISO 15223-1 Reference no. 5.4.2. (ISO 7000- 1051)FDA Recognition # 5-117	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 Reference no. 5.4.3. (A.16, NOTE 2) (ISO 7000-1641) FDA Recognition # 5-117	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	To identify the location where the operator's manual is stored or to identify information that relates to the operating instructions. To indicate that the operating instructions should be considered when operating the device or control close to where the symbol is placed.

FRESENIUS KABI
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US Symbol Glossary

	ISO 15223-1 Reference no. 5.4.4. (ISO 7000-0434A) FDA Recognition # 5-117	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 Reference no. 5.4.5. (ISO 700-2725) FDA Recognition # 5-117	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Contains or presence of natural rubber latex	To indicate the presence of dry natural rubber or natural rubber latex as a material of construction within the medical device or the packaging of a medical device.
	ISO 15223-1 Reference no. 5.6.3. (ISO 7000-2724) FDA Recognition # 5-117	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Non-pyrogenic	On medical devices: to indicate that the product is non-pyrogenic.
	ISO 15223-1 Reference no. 5.6.2 + 5.6.3 (ISO 7000-2723)FDA Recognition # 5-117	Graphic symbols for use on electrical equipment.	Non-pyrogenic fluid path. (combined symbol)	On medical devices: to indicate that the fluid path is non-pyrogenic.
	ISO 15223-1 Reference no. 5.6.4. (ISO 7000-2726) FDA Recognition # 5-117	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Drops per milliliter	On medical devices: to indicate the number of drops per milliliter. That means the design of the drip tube in the drip chamber of the system. NOTE: The number of drops per millilitre is specified; 20 is shown as an example and will be replaced by the appropriate number of drops per millilitre.
	ISO 15223-1 Reference no. 5.6.5. (ISO 7000-2727) FDA Recognition # 5-117	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Liquid filter with pore size	On medical devices: to indicate that the infusion or transfusion system contains a liquid filter in various sizes. NOTE: The nominal pore size of the filter is specified; 15 is shown as an example and will be replaced by the appropriate pore size.
	n/a	n/a	Inline Filter with pore size	Indicates the nominal pore size of the inline filter.
	ISO 15223-1 Reference no. 5.6.5. (ISO 7000-2728) FDA Recognition #5-117	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	One-way valve	On medical devices: to indicate a product with check valve in the fluid path (one way only). For the user it is important to know that the administration is only possible one way. No possibiltiy in aspiration or withdrawal of solution.
	ISO 15223-1 Reference no. 5.7.7	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
	EU 2017-745 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 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.

FRESENIUS KABI
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US Symbol Glossary

CE 0123	EU 2017-745 Reference no. Article 18	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 (TÜV)	(18.5) Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedure set out in article 48.
VOL	ISO 8536-8:2015 FDA Recognition #6-358	Infusion equipment for medical use — Part 8: Infusion sets for single use with pressure infusion apparatus	storage capacity of a 1m long hose.	Bolus volumen; storage capacity of a 1m long tube
MOD	EU 2017-745 ANNEX I (GSPR 23.2 (a))	ANNEX I: GENERAL SAFETY AND PERFORMANCE REQUIREMENTS - Requirements regarding the information supplied with the Device.	Model	23.2 a) the name or trade name of the device.
PHT DEHP	EN 15986:2011 Reference no. A.4	Symbol for use in the labeling of medical devices — Requirements for labeling of medical devices containing phthalates.	Contains or presence of phthalates: Diethylhexylphtalate (DEHP)	Medical device is derived from or manufactured from products containing phthalate: bis (2- ethylhexyl) phthalate (DEHP).
G	n/a	n/a	For gravity use only	Symbol was created based on the requirement in ISO 8536-4:2015 (E) Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed (10.2.h and 10.3.f): the letter "G", which stands for gravity and whose type high shall stand out clearly from surrounding text
P	ISO 8536-10:2015 FDA Recognition #3-360	n/a	For pressure Use	Symbol was created based on the requirement in ISO 8536-8:2015 (E) Infusion equipment for medical use — Part 8: Infusion sets for single use with pressure infusion apparatus (10.2 j and 10.3 f): the letter "P", which stands for pressure, and whose type height shall stand out clearly from surrounding text.
P SAFE	ISO 8536-10:2015 FDA Recognition #3-360	Infusion equipment for medical use — Part 10: Accessories for fluid lines for single use with pressure infusion equipment.	Safe for use with pressure infusion equipment.	Symbol was created based on the requirement in ISO 8536-10:2015 (E) Infusion equipment for medical use — Part 10: Accessories for fluid lines for single use with pressure infusion equipment (8.3 e): the wording "Safe for use with pressure infusion equipment"; f) the letter "P" which stands for pressure and the type, the height of which shall stand out clearly from surrounding text.
	ISO 15223-1 Reference no. 5.2.11. (ISO 7000-3707) FDA Recognition #5-117	Medical Devices — Symbols to be used with medical device labels, labeling, and information to be supplied — Part 1: General requirements.	Single sterile barrier system	To indicate a single sterile barrier system. NOTE: This symbol shall be placed adjacent to or in combination with symbol 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.9 or 5.2.10
	ISO 15223-1 Reference no. 5.2.14 (ISO 7000-3709) FDA Recognition #5-117	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Single sterile barrier system with protective packaging outside	To indicate that there is a single sterile barrier system with protective packaging outside. NOTE This symbol shall be placed adjacent to or in combination with symbol 5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.9 or 5.2.10.

FRESENIUS KABI
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US Symbol Glossary

	ISO 15223-1 Reference no. 5.2.11. + 5.2.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	Single sterile barrier system. Sterilized by ethylene oxide. (combined symbol)	To indicate a single sterile barrier system which is sterilized by ethylene oxide.
	ISO 15223-1 Reference no. 5.2.14 + 5.2.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Single sterile barrier system with protective packaging outside. Sterilized by ethylene oxide. (combined symbol)	To indicate that there is a single sterile barrier system with protective packaging outside which is sterilized by ethylene oxide.
	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.
	n/a	n/a	Priming volume	To indicate the amount of fluid required to fill the fluid path to eliminate all air.
	n/a	n/a	Set length	To indicate the length of the complete set without drip chamber.
	ASTM F2503	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.	The medical device is MR safe	To indicted the product is safe to use in a MR enviroment.