Symbols Glossary

Symbol	Title	Description	Standard or Regulation	Reference Number
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/E	ISO 15223-1:2016	5.1.1 NOTE The date of manufacture, as well as the name and address of the manufacturer, can be combined in one symbol.
			ISO 15223-1:2021	
	Authorized Representative in the European Community	Indicates the Authorized Representative in the European Community	ISO 15223-1:2016	
	Authorized Representative in the European Community/European Union	Indicates the Authorized Representative in the European Community/European Union	ISO 15223-1:2021	
	Date of Manufacture	Indicates the date when the medical device was manufactured	ISO 15223-1:2021	5.1.3
	Use-by Date	Indicates the date after which the medical device is not to be used	ISO 15223-1:2021	5.1.4
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1:2021	5.1.5
	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified	ISO 15223-1:2021	5.1.6

Symbol	Title	Description	Standard or Regulation	Reference Number
	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified	ISO 15223-1:2021	5.1.7
	Importer	Indicates the entity importing the medical device into the locale	ISO 15223-1:2021	5.1.8
	Distributor	Indicates the entity distributing the medical device into the locale	ISO 15223-1:2021	5.1.9
	Model Number	Indicates the model number or type number of a product	ISO 15223-1:2021	5.1.10
	Country of Manufacture	To identify the country of manufacture of products	ISO 15223-1:2021	5.1.11
	Sterile	Indicates a medical device that has been subjected to a sterilization process	ISO 15223-1:2021	5.2.1
	Sterilized Using Aseptic Processing Techniques	Indicates a medical device that has been sterilized using aseptic processing techniques	ISO 15223-1:2021	5.2.2
	Sterilized Using Ethylene Oxide	Indicates a medical device that has been sterilized using ethylene oxide	ISO 15223-1:2021	5.2.3
	Sterilized Using Irradiation	Indicates a medical device that has been sterilized using irradiation	ISO 15223-1:2021	5.2.4
	Sterilized using steam or dry heat	Indicates a medical device that has been sterilized using steam or dry heat	ISO 15223-1:2021	5.2.5

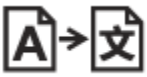
Symbol		Description	Standard or Regulation	Reference Number
		Indicates a medical device that is not to be resterilized	ISO 15223-1:2021	5.2.6
		Indicates a medical device that has not been subjected to a sterilization process	ISO 15223-1:2021	5.2.7
	Do Not Use if Package is Damaged	Indicates a medical device that should not be used if the package has been damaged or opened	ISO 15223-1:2016	5.2.8
	Do Not Use if Package is Damaged and consult instructions for use	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	ISO 15223-1:2021	
	Sterile fluid path	Indicates the presence of a sterile fluid path within the medical device in cases when other parts of the medical device, including the exterior, might not be supplied sterile	ISO 15223-1:2021	5.2.9
	Sterilized using vaporized hydrogen peroxide	Indicates a medical device that has been sterilized using vaporized hydrogen peroxide	ISO 15223-1:2021	5.2.10
	Single sterile barrier system	Indicates a single sterile barrier system	ISO 15223-1:2021	5.2.11
	Double sterile barrier system	Indicates two sterile barrier systems	ISO 15223-1:2021	5.2.12

Symbol	Title	Description	Standard or Regulation	Reference Number
	Single sterile barrier system with protective packaging inside	Indicates a single sterile barrier system with protective packaging inside	ISO 15223-1:2021	5.2.13
	Single sterile barrier system with protective packaging outside	Indicates a single sterile barrier system with protective packaging outside	ISO 15223-1:2021	5.2.14
	Double sterile barrier system with protective packaging outside	Indicates a double sterile barrier system with protective packaging outside	NA, Resolve-created symbol based on similar symbols within ISO 15223-1:2021 to indicate a packaging configuration not represented in the standard	
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully	ISO 15223-1:2021	5.3.1
	Keep Away from Sunlight	Indicates a medical device that needs protection from light sources	ISO 15223-1:2021	5.3.2
	Protect from heat and radioactive sources	Indicates a medical device that needs protection from heat and radioactive sources	ISO 15223-1:2021	5.3.3
	Keep Dry	Indicates a medical device that needs to be protected from moisture	ISO 15223-1:2021	5.3.4
	Lower Limit of Temperature	Indicates the lower limit of temperature to which the medical device can be safely exposed	ISO 15223-1:2021	5.3.5

Symbol	Title	Description	Standard or Regulation	Reference Number
	Upper Limit of Temperature	Indicates the upper limit of temperature to which the medical device can be safely exposed	ISO 15223-1:2021	5.3.6
	Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed	ISO 15223-1:2021	5.3.7
	Humidity limitation	The humidity limitation shall be indicated adjacent to the upper and lower horizontal lines.	ISO 15223-1:2016	5.3.8
		Indicates the range of humidity to which the medical device can be safely exposed	ISO 15223-1:2021	
	Atmospheric pressure limitation	The atmospheric pressure limitations shall be indicated adjacent to the upper and lower horizontal lines.	ISO 15223-1:2016	5.3.9
		Indicates the range of atmospheric pressure to which the medical device can be safely exposed	ISO 15223-1:2021	
	Biological risks	Indicates that there are potential biological risks associated with the medical device	ISO 15223-1:2021	5.4.1
	Do Not Reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure	ISO 15223-1:2021	5.4.2

Symbol	Title	Description	Standard or Regulation	Reference Number
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use	ISO 15223-1:2016	5.4.3
	Consult Instructions for Use or consult electronic instructions for use		ISO 15223-1:2021	
	Caution	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	ISO 15223-1:2016	5.4.4
		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	ISO 15223-1:2021	
	Contains or presence of natural rubber latex	Indicates 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 15223-1:2021	5.4.5
	Contains human blood or plasma derivatives	Indicates a medical device that contains or incorporates human blood or plasma derivatives	ISO 15223-1:2021	5.4.6
	Contains a medicinal substance	Indicates a medical device that contains or incorporates a medicinal substance	ISO 15223-1:2021	5.4.7

Symbol	Title	Description		Reference Number
	Contains biological material of animal origin	Indicates a medical device that contains biological tissue, cells, or their derivatives, of animal origin		5.4.8
	Contains biological material of human origin	Indicates a medical device that contains biological tissue, cells, or their derivatives, of human origin		5.4.9
	Contains hazardous substances	Indicates a medical device that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties		5.4.10
	Contains nano materials	Indicates a medical device that contains nano materials	ISO 15223-1:2021	5.5.11
	Single patient multiple use	Indicates a medical device that may be used multiple times (multiple procedures) on a single patient	ISO 15223-1:2021	5.6.12
	Patient Number	Indicates a unique number associated with an individual patient	ISO 15223-1:2021	5.7.1
	Patient name	Indicates the name of the patient	ISO 15223-1:2021	5.7.2
	Patient identification	Indicates the identification data of the patient	ISO 15223-1:2021	5.7.3

Symbol	Title	Description	Standard or Regulation	Reference Number
	Patient information website	Indicates a website where a patient can obtain additional information on the medical product	ISO 15223-1:2021	5.7.4
	Health care centre or doctor	Indicates the address of the health care centre or doctor where medical information about the patient may be found	ISO 15223-1:2021	5.7.5
	Date	Indicates the date that information was entered, or a medical procedure took place	ISO 15223-1:2021	5.7.6
	Medical device	Indicates the item is a medical device	ISO 15223-1:2021	5.7.7
	Translation	Indicates that the original medical device information has undergone a translation which supplements or replaces the original information	ISO 15223-1:2021	5.7.8
	Repackaging	Indicates that a modification to the original medical device packaging configuration has occurred	ISO 15223-1:2021	5.7.9
	Unique device identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1:2021	5.7.10
	Contains or Presence Of	To indicate that the equipment contains the identified product or substance	ISO 7000/IEC 60417 Graphical Symbols for Use on Equipment	2725
	Sterilizable in a steam sterilizer (autoclave) at temperature specified	To indicate that the device is sterilizable in a steam sterilizer (autoclave) at temperature specified	ISO 7000/IEC 60417 Graphical Symbols for Use on Equipment	2868

Symbol	Title	Description	Standard or Regulation	Reference Number
x1	Limit one-time	To indicate one-time limit	N/A NOTE: When combined in one symbol with 2868 (above), indicates limit of one-time resterilization	
Rx only	Caution: Federal law restricts this device to sale by or on the order of a physician	To indicate that U.S. federal law restricts this device to sale by or on the order of a physician	21 CFR	Sec. 801.15 (c)(1)(i)(F)
CE	CE marking	To indicate device conformity with the provisions of the Directives (see adjacent column) NOTE: may be accompanied by the identification number of the notified body	MDD 93/42/EEC	Article 17
			MDR 2017/745	Article 20

- NOTE: ISO 15223-1:2021 *Medical devices — Symbols to be used with information to be supplied by the manufacturer* replaced ISO 15223-1:2016 in September 2021. Until all labeling is updated, descriptions of symbols in the Symbols Glossaries within specific IFUs may vary, as shown above.