






























































# Symbols Glossary

## Full explanation of symbols used on Premier Packaging, Instructions for Use (IFU) and Safety Data Sheets (SDS)

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
<b>Symbols Derived from Standards</b>				
	ISO 15223-1, Reference 5.1.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1, Reference 5.1.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Authorized European representative	Indicates the Authorized representative in the European Community.
	ISO 20417 Reference no. 6.1.2 d)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Authorized Representative in the United Kingdom	Indicates the authorized representative in United Kingdom
	ISO 20417 Reference no. 6.1.2 d)	Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	Authorized Representative in Switzerland	Indicates the authorized representative in Switzerland
	ISO 15223-1, Reference 5.1.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Date of manufacture	Indicates the date when the medical device was manufactured.
	ISO 15223-1, Reference 5.1.11	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Country of manufacture	To identify the country of manufacture of products.
	ISO 15223-1, Reference 5.1.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Use by	Indicates the date after which the medical device is not to be used.
	ISO 15223-1, Reference 5.1.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1, Reference 5.1.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Catalogue or model number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1, Reference 5.7.10	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier Information.
	ISO 15223-1, Reference 5.1.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	ISO 15223-1, Reference 5.2.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Product subjected to a sterilization process	Indicates a medical device that has been subjected to a sterilization process.
	ISO 15223-1, Reference 5.2.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Sterilized using aseptic processing techniques	Indicates a medical device that has been manufactured using accepted aseptic techniques
	ISO 15223-1, Reference 5.2.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Sterilized by ethylene oxide treatment	Indicates a medical device that has been sterilized using ethylene oxide.
	ISO 15223-1, Reference 5.2.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.
	ISO 15223-1, Reference 5.2.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Sterilized using steam or dry heat	Indicates a medical device that has been sterilized using steam or dry heat.
	ISO 15223-1, Reference 5.2.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process. (Note: This symbol should only be used to distinguish between identical or similar medical devices sold in both sterile and non-sterile conditions)
	ISO 15223-1, Reference 5.2.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Do not re-sterilize	Indicates a medical device that is not to be resterilized
	ISO 15223-1, Reference 5.2.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	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, Reference 5.3.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Keep away from sunlight	Indicates a medical device that needs protection from light sources
	ISO 15223-1 Reference #5.3.1 FDA Recognition # 5-117 ISO 7000 Reference #0621 FDA Recognition # 5-103	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.

	ISO 15223-1, Reference 5.3.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Keep dry	Indicates a medical device that needs to be protected from moisture.
	ISO 15223-1, Reference 5.3.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Lower limit of temperature	Indicates the lower limit of temperature to which the medical device can be safely exposed.
	ISO 15223-1, Reference 5.3.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Upper limit of temperature	Indicates the upper limit of temperature to which the medical device can be safely exposed.
	ISO 15223-1, Reference 5.3.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223-1, Reference 5.3.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.
	ISO 15223-1, Reference 5.3.9	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	ISO 15223-1, Reference 5.4.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Do not reuse or single patient use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 7001: 2007 Reference number PI PF 066	Graphical symbols—Public information symbols	Recycling	To indicate the location of a recycling bin or container
	ISO 15223-1, Reference 5.4.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	IEC 60601-1, Table D.2, Symbol 10; ISO 7010 Reference M002	IEC 60601-1 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance; ISO 7010 — Graphical symbols -- Safety colours and safety signs -- Registered safety signs	Refer to instruction manual/booklet	To signify that the instruction manual/booklet must be read
	ISO 15223-1, Reference 5.4.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	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, Reference 5.4.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Contains natural rubber or latex	Indicates the presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device.
	ISO 15223-1, Reference 5.7.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Patient number	Indicates a unique number associated with an individual patient.
	ISO 15223-1, Reference 5.4.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.	Biological Risks	Indicates that there are potential biological risks associated with the medical device.
	ISO 7000, Reference 0010	Graphical symbols for use on equipment - Registered Symbols	Number of revolutions per minute; rotational speed	To indicate continuous rotation speed in revolutions per minute of a machine component or element.
	ISO 7000, Reference 2403	Graphical symbols for use on equipment - Registered Symbols	Stacking limit by number	To indicate that the items shall not be vertically stacked beyond the specified number, either because of the nature of the transport packaging or because of the nature of the items themselves.
	ISO 7000, Reference 2784	Graphical symbols for use on equipment - Registered Symbols	Ultrasonic bath	To indicate that the instrument can be cleaned in an ultrasonic bath.
	ISO 7000, Reference 2785	Graphical symbols for use on equipment - Registered Symbols	Washer-disinfector for thermal disinfection	On dental instruments: to indicate that the instrument can be used with a washer-disinfector for thermal disinfection. To indicate that the dental instrument can be used with a washer-disinfector for thermal disinfection.
	ISO 7000, Reference 2794	Graphical symbols for use on equipment - Registered Symbols	Packaging unit	To indicate the number of pieces in the package.
	ISO 7000, Reference 2868	Graphical symbols for use on equipment - Registered Symbols	Sterilizable in a steam sterilizer (autoclave) at temperature specified	To indicate that the instrument is sterilizable in a steam sterilizer (autoclave) at temperature specified (Note: the temperature limit of 132°C/270°F is shown only as an example).
	IEC 60417 & ISO 7000 Reference 5140	IEC 60417-5140 — Graphical Symbols for Use on Equipment; ISO 7000 Graphical symbols for use on equipment - Registered Symbols	Non-ionizing electromagnetic radiation	To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.
<b>IPX3</b>	IEC 60529	Degrees of protection provided by enclosures (IP Code)	Protected against spraying water	Protected against spraying water up to a 60 degree angle.
<b>IPX0</b>	IEC 60529	Degrees of Protection Provided by Enclosures (IP Code)	Not protected from fluid ingress	Indicates that protection from fluid ingress is not provided.
	ISO 7000/IEC 60417 Reference 5840	Graphical symbols for use on equipment - Registered Symbols	Type B applied part	To identify a type B applied part complying with IEC 60601-1

	IEC 60601-1 Reference no. Table D.1, Symbol 4 (IEC 60417- 5031)	Medical electrical equipment — Part 1: General requirements. for basic safety and essential performance	Direct current	To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals
	ISO 60417: 2004 Reference number 6042	Graphical symbols for use on equipment	Caution, risk of electric shock	To identify equipment, for example, the welding power source, that has risk of electric shock.
	IEC 60417 Reference no. Table D.1, Symbol 9 (IEC 60417- 5172)	Graphic symbols for use on electrical equipment	Class II equipment	To identify equipment meeting the safety requirements specified for Class II equipment according to IEC 61140
	U.S. DoE Level VI efficiency standard	N/A	Energy Efficiency Level VI	To indicate the Energy efficiency level.
	BS EN 15986, Reference 4.2	Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates.	Contains phthalates	To indicate the presence of phthalates as a material of construction within the medical device. The type of phthalate is indicated next to the symbol. (Note: DEHP is shown only as an example).
	BS EN 15986, Reference 4.2	Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates.	Contains phthalates	To indicate the presence of phthalates as a material of construction within the medical device. The type of phthalate is indicated next to the symbol. (Note: BBP is shown only as an example).
	ASTM D7611	Standard Practice for Coding Plastic Manufactured Articles for Resin Identification	Package contains other recyclable material	Other resin
<b>Symbols Not Derived from Standards</b>				
<b>Rx only</b>	21 CFR 801.15 21 CFR 801.109	Labeling; Prescription devices	Prescription use only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
	MDD 93/42/EEC MDR 2017/745 Regulation (EC) 765/2008	The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Directive and Medical Device Regulation.	European conformity	European conformity (CE) mark for Class I medical devices.
	MDR 2017/745 Annex 1 23.2(q)	The requirements for indicating that a device is a medical device; Medical Device Regulation.	Medical device	Indicates that the device is a medical device.
	Part 4, Chapter 1, Section 16 (1) (f)	Medicines and Medical Devices Act 2021	UKCA marking	Signifies Great Britain technical conformity.
	MDD 93/42/EEC MDR 2017/745 Regulation (EC) 765/2008	Guide to the implementation of directives based on new approach and global approach	CE mark with Notified Body Reference # ###	Signifies European conformity (CE) mark.  Indicates conformity of products where the notified body performed conformity assessment. Notified body reference # is displayed.
	Title 47 United States Code of Federal Regulations Part 15.19	N/A	FCC Compliance Mark	Complies with limits for Class B digital device established by FCC Rules, Part 15
	N/A	N/A	N/A	UL—Underwriters Laboratories Recognized Component certification mark
	N/A	N/A	N/A	UL—Underwriters Laboratories Recognized Component certification mark in Canada and the United States
	N/A	N/A	N/A	UL—Underwriters Laboratories Certification mark for electrical shock, fire, and mechanical hazards only
	Directive 2002/96/EC (WEEE)	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)	Waste stream disposal status	Do not dispose of electronic products in the general waste stream.
	N/A	South Korea - Act on the Promotion of Saving and Recycling of Resources	Package contains other recyclable material	Other resin (Korean recycling symbol)
	N/A	Taiwan Waste Disposal Act	Package contains other recyclable material	Other resin (Taiwan recycling symbol)
	Regulation (EC) No. 1272/2008	Classification, labelling and packaging of substances and mixtures (CLP)	GHS02 flame	Warning. Flammable liquid and vapor. (Note: signal word and warning phrase may be accompanied by additional precautionary statements as required.)
	Regulation (EC) No. 1272/2008	Classification, labelling and packaging of substances and mixtures (CLP)	GHS07 Exclamation mark	Warning. Causes serious eye irritation (Note: signal word and warning phrase may be accompanied by additional precautionary statements as required.)

	Regulation (EC) No. 1272/2009	Classification, labelling and packaging of substances and mixtures (CLP)	GHS05 Corrosion	Danger. Causes serious eye damage (Note: signal word and warning phrase may be accompanied by additional precautionary statements as required.)
	Regulation (EC) No. 1272/2010	Classification, labelling and packaging of substances and mixtures (CLP)	GHS08 Health Hazard	Danger. May cause allergy or asthma symptoms or breathing difficulties if inhaled (Note: signal word and warning phrase may be accompanied by additional precautionary statements as required.)
	Regulation (EC) No. 1272/2010	Classification, labelling and packaging of substances and mixtures (CLP)	GHS06 Skull and Crossbones	Indicates the presence of acute toxicity.
	Regulation (EC) No. 1272/2010	Classification, labelling and packaging of substances and mixtures (CLP)	GHS03 Flame Over Circle	Indicated the presence of a oxidizer
	Regulation (EC) No. 1272/2010	Classification, labelling and packaging of substances and mixtures (CLP)	GHS04 Warning, Compressed gas	Indicated the presence of a compressed gas (Gas cylinder)
	Regulation (EC) No. 1272/2010	Classification, labelling and packaging of substances and mixtures (CLP)	GHS01 Danger, Unstable, Explosive	Indicated the presence of Exploding bomb
	Regulation (EC) No. 1272/2010	Classification, labelling and packaging of substances and mixtures (CLP)	GHS09 Environment	Indicated "Hazardous to the Environment"

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