Symbols glossary

IFU-000288
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SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD TITLE	STANDARD REFERENCE
	Manufacturer	Indicates the medical device manufacturer	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	ISO 15223-1 Reference No. 5.1.1 ISO 7000 Reference No. 3082
	Authorized representative in the European Union	Indicates the Authorized representative in the European Union	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	ISO 15223-1 Reference No. 5.1.2
	Date of manufacture	Indicates the date when the medical device was manufactured.	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	ISO 15223-1 Reference No. 5.1.3 ISO 7000 Reference No. 2497
	Use-by date	Indicates the date after which the medical device is not to be used.	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	ISO 15223-1 Reference No. 5.1.4 ISO 7000 Reference No. 2607
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	ISO 15223-1 Reference No. 5.1.5 ISO 7000 Reference No. 2492
	Catalogue number / Part number	Indicates the manufacturer's catalogue number/part number so that the medical device can be identified.	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	ISO 15223-1 Reference No. 5.1.6 ISO 7000 Reference No. 2493
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	ISO 15223-1 Reference No. 5.1.7 ISO 7000 Reference No. 2498
	Importer	Indicates the entity importing the medical device into the European Union	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	ISO 15223-1 Reference No. 5.1.8. ISO 7000 Reference No. 3725
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	ISO 15223-1 Reference No. 5.3.1 ISO 7000 Reference No. 0621
	Keep away from sunlight and/or heat	Indicates a medical device that needs protection from light sources and/or heat.	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	ISO 15223-1 Reference No. 5.3.2 ISO 7000 Reference No. 0624
	Keep dry	Indicates a medical device that needs to be protected from moisture.	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	ISO 15223-1 Reference No. 5.3.4 ISO 7000 Reference No. 0626
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	ISO 15223-1 Reference No. 5.3.7 ISO 7000 Reference No. 0632
	Do not re-use / Single use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	ISO 15223-1 Reference No. 5.4.2 ISO 7000 Reference No. 1051
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	ISO 15223-1 Reference No. 5.4.3 ISO 7000 Reference No. 1641
 eIFU Indicator	Consult electric instructions for use	Indicates the need for the user to consult the instructions for use and where the electronic instructions for use (eIFU) can be found. The eIFU indicator can be a manufacturer's website URL or some other appropriate indication that the instructions for use are available in an electronic format.	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	ISO 15223-1 Reference No. 5.4.3. ISO 7000 Reference No. 1641
	Contains natural rubber latex	Indicates natural rubber latex as a material of construction within the product	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	ISO 15223-1 Reference No. 5.4.5 ISO 7000 Reference No. 2725

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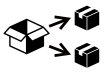
SYMBOL	SYMBOL TITLE	EXPLANATORY TEXT	STANDARD TITLE	STANDARD REFERENCE
	Medical device	Indicates the item is a medical device	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	ISO 15223-1 Reference No. 5.7.7 ISO 7000 Reference No. 2725
	Translation	Indicates that the original medical device information has undergone a translation which supplements or replaces the original information	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	ISO 15223-1 Reference No. 5.7.8. ISO 7000 Reference No. 3728
	Repackaging	Indicates that a modification to the original medical device packaging configuration has occurred	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	ISO 15223-1 Reference No. 5.7.9. ISO 7000 Reference No. 3727
	Unique device identifier	Indicates a carrier that contains unique device identifier information. This symbol may be used when multiple data carriers are present on the label. If used, this symbol is placed adjacent to the unique device identifier carrier.	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements	ISO 15223-1 Reference No. 5.7.10.
	CE Mark	Indicates that a product complies with applicable European Union regulations	New approach directive Medical Devices Directive 93/42/EEC Medical Device Regulation (EU) 2017/745	New approach directive Medical Devices Directive 93/42/EEC Medical Device Regulation (EU) 2017/745
	Prescription Device	Indicates that the product is a medical device and Federal Law (USA) restricts this device to sale by or on the order of a dental professional	21 CFR 801.109 Prescription Devices	21 CFR 801.109 Prescription Devices
	Light-curing time	Indicates the light source and time for light-curing of the material.	N/A	N/A