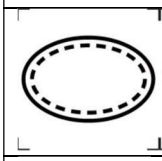
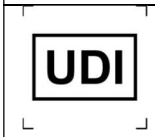
BUSA®

SYMBOLS GLOSSARY

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	EXPLANATORY TEXT
	ISO 15223-1, Reference no. 5.1.1 (ISO 7000-3082)	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 no. 5.1.2	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Authorised representative in the European Community	Indicates the authorised representative in the European Community / European Union
	ISO 15223-1, Reference no. 5.1.3 (ISO 7000-2497)	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 no. 5.4.3 (ISO 7000-1641)	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.
	ISO 15223-1, Reference no. 5.4.4 (ISO 7000-0434A)	Medical Devices — Symbols to be used with medical device labels, labelling, 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
	21 CFR 801.15(c)(1)(i)F	Labelling-Medical devices; prominence of required label statements.	Prescription only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.
	ISO 15223-1, Reference no. 5.3.1. (ISO 7000-0621)	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 correctly.
	ISO 15223-1, Reference no. 5.3.4. (ISO 7000-0626)	Medical devices — Symbols to be used with medical device labels, labeling, 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 no. 5.3.7. (ISO 7000-0632)	Medical devices — Symbols to be used with medical device labels, labeling, and information to be supplied – Part 1: General requirements.	Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed.
	IEC 60417-5032	Graphical Symbols for Use on Equipment.	Alternating Current	To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.
	IEC 60417- 5031	Graphical Symbols for Use on Equipment.	Direct Current	To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals.

	IEC 60417-5172	Graphical Symbols for Use on Equipment.	Class II equipment	To identify equipment meeting the safety requirements specified for Class II equipment according to IEC 61140.
	IEC 60417-5957	Graphical Symbols for Use on Equipment.	For indoor use only	To identify electrical equipment designed primarily for indoor use.
	DIRECTIVE 2012/19/ EU	Graphical Symbols for Use on Equipment.	Collect Separately	Separate collection for waste of electrical and electronic equipment. Do not dispose of battery in municipal waste. The symbol indicates separate collection for battery is required.
			ETL Listed Mark	The ETL Mark is proof of product compliance to North American safety standards.
	ISO 7000	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Distributor	To indicate the entity distributing the medical device into the locale.
	Internal Symbol		Li-Ion Battery	To indicate that a Lithium battery must be recycled
	ISO 15223-1, Reference no. 5.1.4 (ISO 7000-2607)	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Use by date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1, Reference no. 5.1.5 (ISO 7000-2492)	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 no. 5.1.6 (ISO 7000- 2493)	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Catalogue number Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified ISO 15223 Catalogue number ISO 7000 Catalogue number
	ISO 15223-1, Reference no. 5.2.1 (ISO 7000-2499)	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Product subjected to a sterilisation process	Indicates a medical device that has been subjected to a sterilisation process.
	ISO 15223-1, Reference no. 5.2.4 (ISO 7000-2502)	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Sterilised using irradiation	Indicates a medical device that has been sterilised using irradiation.
	ISO 15223-1, Reference no. 5.2.6 (ISO 7000-2608)	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Do not resterilise	Indicates a medical device that is not to be resterilised.

	ISO 15223-1, Reference no. 5.2.7 (ISO 7000-2609)	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 sterilisation process.
	ISO 15223-1, Reference no. 5.2.8 (ISO 7000-2606)	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/DIS 15223-1:2020(E) DRAFT Reference no. 5.2.13 (ISO 7000-3708)	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 inside	Indicates a single sterile barrier system with protective packaging inside
	ISO 15223-1, Reference no. 5.4.1 (ISO 7000-0659)	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 15223-1, Reference no. 5.4.2 (ISO 7000-1051)	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	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/DIS 15223-1:2020(E) DRAFT Reference no. 5.7.7	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Medical device	Indicates the item is a medical device.
	ISO/DIS 15223-1:2020(E) DRAFT Reference no. 5.7.10	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information.
	ISO 15223-1, Reference no. A.15	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Consult instructions for use or consult electronic instructions for use	Indicates consult instructions for use for an electronic instruction for use (eIFU)
	21 CFR 801.109	Labelling-Prescription devices.		
	EU 2017-745 EU 2017-746 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	(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
	N/A	N/A	Global Trade Item Number	Custom symbol denoting global trade item number.

	N/A	N/A	Quantity	Custom symbol denoting number of medical devices units within a package
	ISO 15223-1, Reference no. 5.7.8 (ISO 7000-3728)	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Translation	Indicates that the original medical device information has undergone a translation which supplements or replaces the original information
	ISO 15223-1, Reference no. 5.1.8 (ISO 7000-3725)	Medical Devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 1: General requirements.	Importer	Indicates the entity importing the *medical device* into the locale
	N/A	N/A	Authorised representative in the United Kingdom	Indicates the authorised representative in the United Kingdom