KINAMED INCORPORATED

Symbol Glossary Definitions

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	ISO 15223-1, Clause 5.1.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1, Clause 5.1.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Authorized European Representative	Indicates the Authorized representative in the European Community (EC).
	ISO 15223-1, Clause 5.1.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Date of Manufacture	Indicates the date when the medical device was manufactured.
	ISO 15223-1, Clause 5.1.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Use-by date: YYYY-MM or YYYY-MM-DD	Indicates the date after which the medical device is not to be used.
	ISO 15223-1, Clause 5.1.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1, Clause 5.1.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Catalog number	Indicates the manufacturer's catalog number, or part number, so that the medical device can be identified.
	ISO 15223-1, Clause 5.2.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Sterile	Indicates a medical device that has been subjected to a sterilization process.
	ISO 15223-1, Clause 5.2.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.

KINAMED INCORPORATED

Symbol Glossary Definitions

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	ISO 15223-1, Clause 5.2.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Sterilized using gamma irradiation	Indicates a medical device that has been sterilized using irradiation.
	ISO 15223-1, Clause 5.2.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Do not resterilize	Indicates a medical device that is not to be resterilized.
	ISO 15223-1, Clause 5.2.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	ISO 15223-1, Clause 5.2.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	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), Clause 5.2.11	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	Single sterile barrier system	Indicates single sterile barrier system
	ISO-DIS 15223-1-2020(E), Clause 5.2.14	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	Indicates a single sterile barrier system with protective packaging outside
	ISO 15223-1, Clause 5.4.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

KINAMED INCORPORATED

Symbol Glossary Definitions

Symbol	Standard Reference	Standard Title	Symbol Title	Explanatory Text
	ISO-DIS 15223-1-2020(E), Clause 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 or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1, Clause 5.4.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied.	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information, such as warning, contraindications, precautions, etc. that cannot be present on the medical device itself.
	ISO-DIS 15223-1-2020(E), Clause 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), Clause 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.
	EN 15986, Clause 4.2	Symbol for use in the labelling of medical devices. Requirements for labelling of medical devices containing phthalates.	CONTAINS OR PRESENCE OF PHTHALATE DEHP di(2-ethylexyl) phthalate	Indicates presence of di (2-ethylhexyl Phthalate (DEHP).

KINAMED INCORPORATED

Symbol Glossary Definitions

SYMBOLS NOT FROM STANDARDS

Symbol	Regulation Reference	Regulation Title	Symbol Title	Explanatory Text
	21 CFR 801.15(c)(1)(i)F	Labeling-Medical devices; prominence of required label statements; use of symbols in labeling.	Prescription Only	Requires prescription in the United States.
	21 CFR 801.109	Labeling-Prescription devices.		
	765/2008/EC 768/2008/EC MDD 93/42/EEC Articles 4,11,12,17, Annex II	The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Directive.	CE Marking	Signifies European technical conformity.
	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		(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
0086 or 2797	765/2008/EC 768/2008/EC MDD 93/42/EEC Articles 4,11,12,17, Annex II)	The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Directive.	Notified Body Number	Notified Body Number for BSI
QTY	21CFR801.5(b)	Labeling-Medical Devices; adequate directions for use	Quantity	Quantity of devices contained inside the commercial packaging

KINAMED INCORPORATED

Symbol Glossary Definitions

Symbol	Regulation Reference	Regulation Title	Symbol Title	Explanatory Text
CAT	N/A	N/A	Catalog number	Indicates the manufacturer's catalog number, or part number, so that the medical device can be identified.