Commonly Used Symbols

Glossary of symbols commonly used on
DeRoyal Medical Device Packaging and Labeling

DeRoyal®

symbol	explanatory text	standard reference	standard title
REF Catalogue or model number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1, Clause 5.1.6	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		ISO 7000- 2493	Graphical symbols for use on equipment.
LOT Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1, Clause 5.1.5	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		ISO 7000-2492	Graphical symbols for use on equipment.
SN Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO 15223-1, Clause 5.1.7	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		ISO 7000-2498	Graphical symbols for use on equipment.
Keep dry	Indicates a medical device that needs to be protected from moisture.	ISO 15223-1, Clause 5.3.4	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		ISO 7000-0626	Graphical symbols for use on equipment.
Keep away from sunlight	Indicates a medical device that needs protection from light sources.	ISO 15223-1, Clause 53.2	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		ISO 7000-0624	Graphical symbols for use on equipment.
Manufacturer	Indicates the medical device manufacturer.	ISO 15223-1, Clause 5.1.1	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		ISO 7000-3082	Graphical symbols for use on equipment.
Date of manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1, Clause 5.1.3	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		ISO 7000-2497	Graphical symbols for use on equipment.
Distributor	Indicates the entity distributing the medical device into the locale.	ISO 15223-1, Clause 5.1.9	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		ISO 7000-3724	Graphical symbols for use on equipment.
EU Importer	Indicates the entity importing the device into the locale.	ISO 15223-1, Clause 5.1.8	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		ISO 7000-3725	Graphical symbols for use on equipment.
R$_X$ Only Prescription only	Requires prescription in the United States.	21 CFR 801.15(c)(1)(i)F	Labeling-Medical devices; prominence of required label statements.
		21 CFR 801.109	Labeling-Prescription devices.
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, Clause 5.2.8	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		ISO 7000-2606	Graphical symbols for use on equipment.

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Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.	ISO 7000-0621, 2014-06-04	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
			Graphical symbols for use on equipment.
Battery	Indicates a medical device that contains a battery.	IEC 60417-5001B	Graphical symbols for use on equipment.
Contains natural rubber 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, Clause 5.4.5	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
Not made with natural rubber latex	Indicates the materials of construction of the device or its packaging were not manufactured with natural rubber or dry natural rubber latex.	ISO 15223-1, Clause 5.4.5, Reference Annex B for negation symbol	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied
Use by	Indicates the date after which the medical device is not to be used.	ISO 15223-1, Clause 5.1.4	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		ISO 7000-2607	Graphical symbols for use on equipment.
Consult instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1, Clause 5.4.3	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		IEC 60601-1, Table D.1, Symbol 11	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
		ISO 7000-1641	Graphical symbols for use on equipment.
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, Clause 5.4.4	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		IEC 60601-1, Table D.1, Symbol 10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
Do not reuse	Indicates a medical device that is intended for one use or for use on a single patient during a single procedure. NOTE: Synonyms for "Do not re-use" are "single use" and "use only once".	ISO 15223-1, Clause 5.4.2	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		ISO 7000-1051	Graphical symbols for use on equipment.
Follow instructions for use	Refer to instruction manual/ booklet.	IEC 60601-1, Table D.2, Symbol 10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
CE marking	Signifies European technical conformity.	765/2008/EC 768/2008/EC MDD 9 3/42/EEC Articles 4,11,12,17, Annex II)	The requirements for accreditation and market surveillance relating to the marketing of products; Medical Device Directive.
UKCA Marking	Signifies UK (United Kingdom) technical conformity	Regulation 765/2008	The requirements for accreditation and market surveillance relating to marketing of products.

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EC | REP **Authorized European representative**	Indicates the authorized representative in the European Community.	ISO 15223-1, Clause 5.1.2	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
Storage temperature range	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1, Clause 5.3.7	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		ISO 7000-0632	Graphical symbols for use on equipment.
Lower limit of storage temperature	Indicates the lower limit of temperature to which the medical device can be safely exposed.	ISO 15223-1, Clause 5.3.5	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		ISO 7000-0534	Graphical symbols for use on equipment.
Upper limit of storage temperature	Indicates the upper limit of temperature to which the medical device can be safely exposed.	ISO 15223-1, Clause 5.3.6	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		ISO 7000-0533	Graphical symbols for use on equipment.
Humidity Limitation	Indicates the range of humidity to which the medical device can be safely exposed.	ISO 15223-1, Clause 5.3.8	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
		ISO 7000-2620	Graphical symbols for use on equipment.
Atmospheric Pressure	To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage.	ISO 15223-1, Clause 5.3.9	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
		ISO 7000-2621	Graphical symbols for use on equipment.
Do not resterilize	Indicates a medical device that is not to be re-sterilized.	ISO 15223-1, Clause 5.2.6	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		ISO 7000-2608	Graphical symbols for use on equipment.
Non sterile	Indicates a medical device that has not been subjected to a sterilization process.	ISO 15223-1, Clause 5.2.7	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		ISO 7000-2609	Graphical symbols for use on equipment.
STERILE **Product subjected to a sterilization process**	Indicates a medical device that has been subjected to a sterilization process.	ISO 15223-1, Clause 5.2.1	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		ISO 7000-2499	Graphical symbols for use on equipment.
STERILE | R **Sterilized using irradiation**	Indicates a medical device that has been sterilized using irradiation.	ISO 15223-1, Clause 5.2.4	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		ISO 7000-2502	Graphical symbols for use on equipment.
STERILE | A **Sterilized using aseptic techniques**	Indicates a medical device that has been sterilized using aseptic techniques.	ISO 15223-1, Clause 5.2.2	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		ISO 7000-2500	Graphical symbols for use on equipment.

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STERILE EO — Sterilized by ethylene oxide treatment	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1, Clause 5.2.3	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		ISO 7000-2501	Graphical symbols for use on equipment.
STERILE — Sterilized using steam or dry heat	Indicates a medical device that has been sterilized using steam or dry heat.	ISO 15223-1, Clause 5.2.5	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		ISO 7000-2503	Graphical symbols for use on equipment.
Biological Risks	Indicates there are potential biological risks associated with the medical device.	ISO 15223 5.4.1	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
		ISO 7000-0659	Graphical symbols for use on equipment.
Protected Earth; Protected Ground	Any terminal which is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode.	IEC 60417-5019	Graphical symbols for use on equipment. Used to mark the Protective Earthing Conductor terminal of Class I equipment.
Double insulated appliance	Double insulated appliance	IEC 60417-5172	Graphical symbols for use on equipment.
EE Class III	A Class III appliance is designed to be supplied from a separated extra-low voltage (SELV) power source. The voltage from a SELV supply is low enough that under normal conditions a person can safely come into contact with it without risk of electrical shock.	IEC 60417-5180	Graphical symbols for use on equipment meeting the safety requirements specified for class III according to IEC 61140: Protection against electric shock — Common aspects for installation and equipment.
Type B applied part	Type B applied part complying with IE 60601-1.	IEC 60417-5840	Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance.
		IEC 60878	
		IEC 60601-1	
Type BF applied part	Type BF applied part	IEC 60417-5333	Graphical symbols for use on equipment.
IP22 — IP code, International Protection Marking	Classifies and rates the degree of protection provided by casing/enclosure of electrical device. • **PROTECTION** against solid objects > 12.5 mm; • **PROTECTION** against water sprayed up to 15 from vertical	IEC 60529* *(does not have a reference number per 60601-1 [2005] p.645)	Graphical symbols for use on equipment.

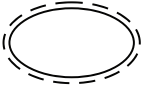| symbol	explanatory text	standard reference	standard title
MR / MR Safe	Magnetic resonance safe	ASTM F2503	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.
MR Conditional	Magnetic resonance conditional	ASTM F2503	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.
MR Unsafe	Magnetic resonance unsafe	ASTM F2503	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.
Defibrillation-proof	Defibrillation-Proof	IEC 60417-5336	Graphical symbols for use on equipment. Type CF of applied part.
EE Type CF	Indicates part complies with higher degree of protection against electric shock as defined by IEC 60601-1.	IEC 60601-1 / IEC 60878	Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance.
WEEE	To indicate that separate collection for waste electric and electronic equipment (WEEE) is required.	ISO 7000-6414 / 2012/19/EU	Graphical symbols for use on equipment. / Waste Electrical and Electronic Equipment Directive
Non-ionizing Radiation	Non-ionizing electromagnetic radiation	IEC 60417 / REF 5140	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.
PHT DEHP / Does not contain DEHP	Indicates the materials of construction do not include the phthalate plasticizer DEHP	BS EN 15986 Annex B	Symbol for use in the labeling of medical devices – Requirements for labeling of medical devices containing phthalates.
MD / Medical Device	Indicates the item is a medical device.	ISO 15223 – 1, Clause 5.7.7	Medical Devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General Requirements.
Single Sterile Barrier System	Indicates a single sterile barrier system.	ISO 7000-3707	Graphical symbols for use on equipment.
Double Sterile Barrier System	Indicates two sterile barrier systems.	ISO 7000-3704	Graphical symbols for use on equipment.
Single Sterile Barrier System with Protective Packaging Inside	Indicates a single sterile barrier system with protective packaging inside.	ISO 7000-3708	Graphical symbols for use on equipment.

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Single Sterile Barrier System with Protective Packaging Outside	Indicates a single sterile barrier system with protective packaging outside.	ISO 7000-3709	Graphical symbols for use on equipment.
Benchmark Product Certification	Benchmark mark is a registered certification mark owned and operated by BSI.	N/A	N/A
Accreditation Recognition Mark	Compliance with AS/NZS (Australia/New Zealand) requirements	N/A	N/A
NFPA 704 Hazard Diamond	Provides a general idea of the hazards of a material and the severity of the hazards as they relate to emergency response. • **RED:** Fire Hazard 0 - Will not burn • **BLUE:** Health Hazard 0 - Hazard no greater than ordinary material • **YELLOW:** Reactivity Hazard 0 - Stable • **WHITE:** Special - Eye Safety	NFPA 704: 2022	National Fire Protection Association (NFPA): Standard System for the Identification of the Hazards of Materials for Emergency Response.