










Commonly Used Symbols

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



symbol	explanatory text	standard reference	standard title
	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.
		ISO 7000-2493	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
Catalogue or model number			Graphical symbols for use on equipment.
	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.
		ISO 7000-2492	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
Batch code			Graphical symbols for use on equipment.
	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.
		ISO 7000-2498	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
Serial number			Graphical symbols for use on equipment.
	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.
		ISO 7000-0626	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
Keep dry			Graphical symbols for use on equipment.
	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.
		ISO 7000-0624	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
Keep away from sunlight			Graphical symbols for use on equipment.
	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.
		ISO 7000-3082	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
Manufacturer			Graphical symbols for use on equipment.
	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.
		ISO 7000-2497	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
Date of manufacture			Graphical symbols for use on equipment.
	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.
		ISO 7000-3724	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
Distributor			Graphical symbols for use on equipment.
	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.
		ISO 7000-3725	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
EU Importer			Graphical symbols for use on equipment.
	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.
Prescription only			
	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.
Do not use if package is damaged			



Commonly Used Symbols

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



symbol	explanatory text	standard reference	standard title
	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.
Fragile, handle with care			Graphical symbols for use on equipment.
	Indicates a medical device that contains a battery.	IEC 60417-5001B	Graphical symbols for use on equipment.
Battery			
	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.
Contains natural rubber latex			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
	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.
Not made with natural rubber latex			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied
	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.
Use by		ISO 7000-2607	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
	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.
Consult instructions for use		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.
	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.
Caution		IEC 60601-1, Table D.1, Symbol 10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
	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.
Do not reuse		ISO 7000-1051	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
	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.
Follow instructions for use			
	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.
CE marking			
	Signifies UK (United Kingdom) technical conformity	Regulation 765/2008	The requirements for accreditation and market surveillance relating to marketing of products.
UKCA Marking			



Commonly Used Symbols

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



symbol	explanatory text	standard reference	standard title
	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.
Authorized European representative			Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
	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.
Storage temperature range		ISO 7000-0632	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
	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.
Lower limit of storage temperature		ISO 7000-0534	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
	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.
Upper limit of storage temperature		ISO 7000-0533	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
	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.
Humidity Limitation		ISO 7000-2620	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
	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.
Atmospheric Pressure		ISO 7000-2621	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
	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.
Do not resterilize		ISO 7000-2608	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
	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.
Non sterile		ISO 7000-2609	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
	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.
Product subjected to a sterilization process		ISO 7000-2499	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
	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.
Sterilized using irradiation		ISO 7000-2502	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
	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.
Sterilized using aseptic techniques		ISO 7000-2500	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.



Commonly Used Symbols

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



symbol	explanatory text	standard reference	standard title
	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.
Sterilized by ethylene oxide treatment		ISO 7000-2501	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
	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.
Sterilized using steam or dry heat		ISO 7000-2503	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
	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.
Biological Risks		ISO 7000-0659	Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied.
	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.
Protected Earth; Protected Ground			
	Double insulated appliance	IEC 60417-5172	Graphical symbols for use on equipment.
Double insulated appliance			
	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.
EE Class III			
	Type B applied part complying with IEC 60601-1.	IEC 60417-5840	Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance.
Type B applied part		IEC 60878 IEC 60601-1	
	Type BF applied part.	IEC 60417-5333	Graphical symbols for use on equipment.
Type BF applied part			
	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*	Graphical symbols for use on equipment.
IP code, International Protection Marking		*(does not have a reference number per 60601-1 [2005] p.645)	
	Magnetic resonance safe	ASTM F2503	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.
MR Safe			



Commonly Used Symbols

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





symbol	explanatory text	standard reference	standard title
	Magnetic resonance conditional	ASTM F2503	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.
MR Conditional			
	Magnetic resonance unsafe	ASTM F2503	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.
MR Unsafe			
	Defibrillation-Proof	IEC 60417-5336	Graphical symbols for use on equipment. Type CF of applied part.
Defibrillation-proof			
	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.
EE Type CF			
	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
WEEE			
	Non-ionizing electromagnetic radiation	IEC 60417 REF 5140	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.
Non-ionizing Radiation			
	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.
Does not contain DEHP			
	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.
Medical Device			
	Indicates a single sterile barrier system.	ISO 7000-3707	Graphical symbols for use on equipment.
Single Sterile Barrier System			
	Indicates two sterile barrier systems.	ISO 7000-3704	Graphical symbols for use on equipment.
Double Sterile Barrier System			
	Indicates a single sterile barrier system with protective packaging inside.	ISO 7000-3708	Graphical symbols for use on equipment.
Single Sterile Barrier System with Protective Packaging Inside			
	Indicates a single sterile barrier system with protective packaging outside.	ISO 7000-3709	Graphical symbols for use on equipment.
Single Sterile Barrier System with Protective Packaging Outside			



Commonly Used Symbols

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



symbol	explanatory text	standard reference	standard title
 <p>Benchmark Product Certification</p>	<p>Benchmark mark is a registered certification mark owned and operated by BSI.</p>	N/A	N/A
 <p>Accreditation Recognition Mark</p>	<p>Compliance with AS/NZS (Australia/New Zealand) requirements.</p>	N/A	N/A