Standard References:

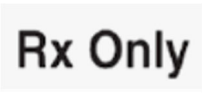
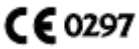
- ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
- REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- Title 21 Code of Federal Regulations Parts 801.109

Symbol Legend:

Symbol Graphic & Ref number	**Symbol Title**	**Symbol Description (Explanatory Text)**	**Standard, Title, and Applicable FDA Recognition Number**
5.1.1. 	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1:2021 (E) Medical Devices – Symbols to be used with information to be supplied by manufacturer FDA Recognition Number: 5-134
5.1.2 	Authorized representative in the European Community / European Union	Indicates the authorized representative in the European Community / European Union	ISO 15223-1:2021 (E) Medical Devices – Symbols to be used with information to be supplied by manufacturer FDA Recognition Number: 5-134
5.1.4. 	Use-by date	Indicates the date after which the medical device is not to be used	ISO 15223-1:2021 (E) Medical Devices – Symbols to be used with information to be supplied by manufacturer FDA Recognition Number: 5-134
5.1.5. 	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified	ISO 15223-1:2021 (E) Medical Devices – Symbols to be used with information to be supplied by manufacturer FDA Recognition Number: 5-134
5.1.6. 	Catalog number	Indicates the manunfacturer's catalogue number so that the medical device can be identified	ISO 15223-1:2021 (E) Medical Devices – Symbols to be used with information to be supplied by manufacturer FDA Recognition Number: 5-134

5.1.9. 	Distributor	Indicates the entity distributing the medical device into the locale	ISO 15223-1:2021 (E) Medical Devices – Symbols to be used with information to be supplied by manufacturer FDA Recognition Number: 5-134
5.1.11. 	Country of manufacture	To identify the country of manufacture of products	ISO 15223-1:2021 (E) Medical Devices – Symbols to be used with information to be supplied by manufacturer FDA Recognition Number: 5-134
5.2.3. 	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide	ISO 15223-1:2021 (E) Medical Devices – Symbols to be used with information to be supplied by manufacturer FDA Recognition Number: 5-134
5.2.6. 	Do not resterilize	Indicates a medical device that is not to be resterilized	ISO 15223-1:2021 (E) Medical Devices – Symbols to be used with information to be supplied by manufacturer FDA Recognition Number: 5-134
5.2.8. 	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.	ISO 15223-1:2021 (E) Medical Devices – Symbols to be used with information to be supplied by manufacturer FDA Recognition Number: 5-134
5.2.13. 	Single sterile barrier system with protective packaging inside	Indicates a single sterile barrier system with protective packaging inside.	ISO 15223-1:2021 (E) Medical Devices – Symbols to be used with information to be supplied by manufacturer FDA Recognition Number: 5-134
5.2.11 	Single sterile barrier system	Indicates a single sterile barrier system	ISO 15223-1:2021 (E) Medical Devices – Symbols to be used with information to be supplied by manufacturer FDA Recognition Number: 5-134
5.2.12 	Double sterile barrier system	Indicates two sterile barrier systems	ISO 15223-1:2021 (E) Medical Devices – Symbols to be used with information to be supplied by manufacturer

			FDA Recognition Number: 5-134
5.3.7. 	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1:2021 (E) Medical Devices – Symbols to be used with information to be supplied by manufacturer FDA Recognition Number: 5-134
5.4.2. 	Do not reuse	Indicates medical device that is intended for one single use only	ISO 15223-1:2021 (E) Medical Devices – Symbols to be used with information to be supplied by manufacturer FDA Recognition Number: 5-134
5.4.3. 	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15223-1:2021 (E) Medical Devices – Symbols to be used with information to be supplied by manufacturer FDA Recognition Number: 5-134
5.4.4. 	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	ISO 15223-1:2021 (E) Medical Devices – Symbols to be used with information to be supplied by manufacturer FDA Recognition Number: 5-134
5.4.5. 	Product is not made with natural rubber latex	Indicates that natural rubber latex was not used in the manufacturing of the product, its container, or its packaging.	ISO 15223-1:2021 (E) Medical Devices – Symbols to be used with information to be supplied by manufacturer Reference Annex B for the general prohibition symbol and negation symbol FDA Recognition Number: 5-134
5.7.7. 	Medical device	Indicates the item is a medical device	ISO 15223-1:2021 (E) Medical Devices – Symbols to be used with information to be supplied by manufacturer FDA Recognition Number: 5-134
5.7.10. 	Unique device identifier	Indicates a carrier that contains unique device identifier information	ISO 15223-1:2021 (E) Medical Devices – Symbols to be used with information to be supplied by manufacturer

			FDA Recognition Number: 5-134
5.1.8 	Importer	Indicates the entity importing the medical device into the locale	ISO 15223-1:2021 (E) Medical Devices – Symbols to be used with information to be supplied by manufacturer FDA Recognition Number: 5-134
	Rx Only	Symbol to be used in place of the statement “Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.”	Title 21 Code of Federal Regulations Parts 801.109
	CE Marking: CE Mark of DQS Medizinprodukte GmbH	Symbol is mandatory for marking devices entering the European market to indicate conformity with the essential health and safety requirements set out in European Directives/Regulations. The symbol may be accompanied by a 4-digit identification number of the notified body.	Regulation (EU) 2017/745 MDR, Annex V