















PRODUCT LABELING – SYMBOLS GLOSSARY

Caution: the following symbols key is for reference only – some symbols listed may not apply. Please see main product label affixed to product for applicable symbols.

SYMBOL	TITLE	REF NO.	DESCRIPTION
ISO 15223-1: 2021 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1 General Requirements			
	Manufacturer	5.1.1	Indicates the medical device manufacturer, as defined in Regulation (EU) 2017/745
	Authorised Rep – European community	5.1.2	Indicates the Authorised Representative in the European Community
	Date of manufacture	5.1.3	Indicates the date when the medical device was manufactured
	Batch code	5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Catalogue number	5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified
	Importer	5.1.8	Indicates the entity importing the medical device into the locale
	Distributor	5.1.9	Indicates the entity distributing the medical device into the locale
	Non-sterile	5.2.7	Indicates a medical device that has not been subjected to a sterilization process
	Do not re-use	5.4.2	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
	Consult instructions for use	5.4.3	Indicates the need for the user to consult the instructions for use
	Caution	5.4.4	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
	Medical Device	5.7.7	Indicates the item is a medical device
21 CFR 801.109 Labeling: Prescription devices			
Rx only	Prescription use only	n/a	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
Regulation (EU) 2017/745: Medical Device Regulations			
	CE marking	Annex V	CE marking of conformity
MedDO, SR 812.213: Switzerland Medical Devices Ordinance			
	Authorised Rep – Switzerland	n/a	Indicates the Authorised Representative in Switzerland