# **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 |
|  | **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 |