











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: 2016: Medical devices-symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General Requirements | | | |
|  | Manufacturer | 5.1.1 | Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC |
|  | Authorised Rep – European community | 5.1.2 | Indicates the Authorized 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 |
|  | 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 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 |
| 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 |