Symbols Glossary

Symbol	Symbol Title	Explanatory Text	Standard Title	Standard Reference
	Manufacturer	Indicates the medical device manufacturer	Medical devices – symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.1.1 FDA Recognition #5-117 ISO 7000 Reference #3082 FDA Recognition #5-103
	Date of Manufacture	Indicates the date when the medical device was manufactured	Medical devices – symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.1.3 FDA Recognition #5-117 ISO 7000 Reference #2497 FDA Recognition #5-103
LOT	**Batch code**	Indicates the manufacturer's batch code so that the batch or lot can be identified	Medical devices – symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.1.5 FDA Recognition #5-117 ISO 7000 Reference #2492 FDA Recognition #5-103
REF	**Catalog Number**	Indicates the manufacturer's catalog number so that the medical device can be identified	Medical devices – symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.1.6 FDA Recognition #5-117 ISO 7000 Reference #2493 FDA Recognition #5-103
NON STERILE	**Non-sterile**	Indicates a medical device that has not been subjected to a sterilization process	Medical devices – symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.2.7 FDA Recognition #5-117 ISO 7000 Reference #2609 FDA Recognition #5-103
	Do Not Reuse	Indicates the device is single use only.	Medical devices – symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.4.2 FDA Recognition #5-117 ISO 7000 Reference #1051 FDA Recognition #5-103
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use.	Medical devices – symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements	ISO 15223-1 Reference #5.4.3 FDA Recognition #5-117 ISO 7000 Reference #1641 FDA Recognition #5-103
Rx Only	**Rx Only**	Caution: Federal (USA) law restricts this device to sale by or on the order or a physician.	Guidance for Industry and FDA on Alternative to certain Prescription Device Labeling Requirements	N/A
QTY	**Quantity**	Indicates the amount of product included per package	N/A	N/A

Symbols will appear on packaging, labeling, and/or instructions for use where applicable.

In accordance with 21CFR801
C400_QF_1305.1