Labeling Symbols Glossary

Manufacturer:
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℞ ONLY
Caution: Federal Law restricts this device to sale by or on the order of a physician.

The following is an explanation of symbols that may be used on Caldera Medical's product packaging:

Symbol	Title/ Meaning/ Referent	Function/ Description	ISO 7000 Reg. no.	ISO 15223-1 or Other
Manufacture				
	**Manufacturer**	Indicates the medical device manufacturer.	3082	5.1.1
	**EU Authorized Representative**	Indicates the authorized representative in the European community.	N/A	5.1.2
	**Date of Manufacture**	Indicates the date when the medical device was manufactured.	2497	5.1.3
	**Use by Date**	Indicates the date after which the medical device is not to be used.	2607	5.1.4
	**Batch Code**	Indicates the manufacturer's batch code so that the batch or lot can be identified.	2492	5.1.5
	**Catalogue number**	Indicates the manufacturer's catalogue number so that the medical device can be identified.	2493	5.1.6
Sterility				
	**Sterilized Using Ethylene Oxide**	Indicates a medical device that has been sterilized using ethylene oxide.	2501	5.2.3
	**Do Not Resterilize**	Indicates a medical device that is not to be resterilized.	2608	5.2.6
	**Do Not Use If Package Is Damaged**	Indicates a medical device that should not be used if the package has been damaged or opened.	2606	5.2.8
	**Non-sterile**	Indicates a medical device that has not been subjected to a sterilization process.	2609	5.2.7
Storage				
	**Keep Dry**	Indicates a medical device that needs to be protected from moisture.	0626	5.3.4
Safe Use				
	**Do Not Re-use**	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	1051	5.4.2
	**Consult Instructions for Use**	Indicates the need for the user to consult the instructions for use.	1641	5.4.3
 [IFU URL]	**Consult Instructions for Use, or For Instructions for Use Refer to**	Indicates the need for the user to consult the instructions for use and where the electronic instructions for use (eIFU) and symbols glossary can be found.	1641	5.4.3
	**Caution**	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.	0434A	5.4.4

Symbol	Title/ Meaning/ Referent	Function/ Description	ISO 7000 Reg. no.	ISO 15223-1 or Other
Other				
	**Packaging Unit**	Indicates the number of pieces in the package.	2794	N/A
	**Prescription Only**	Requires prescription in the United States of America.	N/A	21 CFR 801.109
	**CE Marking of Conformity**	Signifies European technical conformity – Class I (sterile, measuring), IIa, IIb, III devices	N/A	93/42/EEC, Annex XII
	**CE Marking of Conformity**	Signifies European technical conformity – Class I (non-sterile, non-measuring)	N/A	93/42/EEC, Annex XII

The most current version of the Labeling Symbols Glossary is available for viewing or download here: www.calderamedical.com/medical-professionals/product-instructions-for-use

All Caldera Medical Instruction for Use (IFU) documents are available in print form at no additional cost upon request. If you would like to request a copy please contact us at 818.879.6555, fax 818.879.6556, or email info@calderamedical.com.

To learn more about our products, please contact Caldera Medical at 818.879.6555 or visit our website at www.calderamedical.com.