EcoVue® and EcoVue® HV Ultrasound Gel Symbols Glossary

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DEFINITIONS:

- *SafeWrap*™—A sterile pouch in which the individual ultrasound gel packet is placed. *SafeWrap* is a registered trademark of HR Pharmaceuticals, Inc.

- *FlexPac*®—A multi-use flexible packaging container, that is similar to a bottle of ultrasound gel. FlexPac® is a registered trademark of HR Pharmaceuticals, Inc., its subsidiaries or divisions.

- *Medical Device*—any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
  - — diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
  - — diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
  - — investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
  - — providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

  and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

- *Sterile Barrier System*—minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at point of use.

GLOSSARY OF SYMBOLS

United States' Title 21 of the Code of Federal Regulations (CFR) Section 801.109(b)(1)			
Symbol	**Reference**	**Title of Symbol**	**Description or Meaning**
Rx ONLY	21 CFR Section 801.109 (b) (1) and United States Food and Drug Administration Guidance for Industry – Alternative to Certain Prescription Device Labeling Requirements, Issued on January 21, 2000	Prescription Use Only	CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner
ISO 15223-1:2016 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements			
Symbol	**Reference**	**Title of Symbol**	**Description or Meaning**
	5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC, and 98/79/EC
	5.1.3	Date of Manufacture	Indicates the date when the medical device was manufactured
	5.2.8	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	5.4.2	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.
	5.4.4	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.
	5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	5.1.5	Batch number	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	5.2.4	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.

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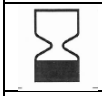
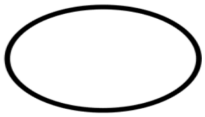
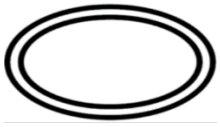
Symbol	Reference	Title of Symbol	Description or Meaning
	5.2.7	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process
	5.4.5 and Annex B.2 and Guidance for Industry and US Food and Drug Administration Staff - Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex; Issued on December 2, 2014	Not made with natural rubber latex	Indicates that neither the medical device nor the packaging of the medical device contains the presence of natural rubber latex.
	5.3.2	Keep away from sunlight	Indicates a medical device that needs protection from light sources.
	5.1.4	Use-by date	Indicates the date after which the medical device is not be used.
	5.3.7	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	5.1.2	Authorized Representative in the European Community	Indicates the authorized representative in the European Community.
European Medical Device Directive 93/42/EEC / European Medical Device Regulation 2017/745			
Symbol	**Reference**	**Title of Symbol**	**Description or Meaning**
	Article 17	CE Conformity Marking and Notified Body Number	Product conforms to the applicable requirements for a medical device as set forth in the regulation and assessed by the certifying notified body.
	Article 17	CE Conformity Marking	Product conforms to the applicable requirements for medical device as set forth in the regulation and assessed by the certifying notified body
	Annex 1, 23.3(a)	Single Sterile Barrier System	Sterile barrier system
	Annex 1, 23.3(a)	Double Sterile Barrier System	Double entry package with two sterile barrier systems
	Annex 1, 23.2(q)	Medical Device	Designation that the item is classified as a Medical Device
Union of Orthodox Jewish Congregations of America (the "Orthodox Union") certification requirements for kosher products			
Symbol	**Reference**	**Title of Symbol**	**Description or Meaning**
	Kosher Requirements per Union of Orthodox Jewish Congregations of America	Certified Kosher	Certified Kosher per the Union of Orthodox Jewish Congregations of America as Pareve (contains neither milk or meat ingredients)

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Federal Trade Commission Guidance on Compliance with "Made in USA"			
Symbol	**Reference**	**Title of Symbol**	**Description or Meaning**
	N/A	Made in USA	All or virtually all significant parts and processing of this product are of U.S. origin.
Therapeutic Goods Medical Device Regulation			
	N/A	Australian Sponsor	Indicates the authorized sponsor in the Australian market.