

Design History File

**001-094 EcoVue Non-Sterile Ultrasound Gel EU Declaration  
of Conformity**

Version 1

June 30, 2021

**Awaiting Approval**

Colby Wiesman	_____	_____
President	_____	Date
Jessica Steckbeck	_____	7/1/2021
Author	_____	Date
Rande Dettinger	_____	_____
Chief Operating Officer	_____	Date
Stacey Benser	_____	_____
Senior Quality/Regulatory Manager	_____	Date

Version	Version Date	Change Description
1	6/30/2021	Update to remove MDD references; Add SRN #
0	6/7/2021	Initial Upload



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## EU DECLARATION OF CONFORMITY

Manufacturer: HR Pharmaceuticals, INC.  
2600 Eastern Boulevard, Suite 201  
York, Pennsylvania 17402 USA  
Tel: (717)-252-1110  
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SRN: US-MF-000008639

Device Family: EcoVue® Non-Sterile Ultrasound Gel (GMDN-15321)

Basic UDI-DI: 851809002ECOVUEDC

Description: EcoVue® Non-Sterile Ultrasound Gel is an ultrasound coupling gel intended for non-invasive procedures which contact intact skin only.

EC Product Class: Class I (Annex VIII, Rule 1) Medical Device (Non-Sterile)

### Declaration of Conformity

HR Pharmaceuticals, Inc. declares this EU declaration of conformity is issued under the sole responsibility of the manufacturer and the products described herein conform to the provisions of Annex IX, EC Medical Device Regulation 2017/745.

HR Pharmaceuticals, Inc. has appointed Emergo as our EU Authorized Representative of:

Emergo Europe  
Prinsessegracht 20  
2514 AP The Hague  
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SRN: NL-AR-000000116

Issued: June 30 2021



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**PRODUCT LIST**

MFR #	Product
281	EcoVue® Ultrasound Gel 20g Non-Sterile Packet
283	EcoVue® Ultrasound Gel 32g Non-Sterile Packet
284	EcoVue® Ultrasound Gel 60g Non-Sterile Tube
285	EcoVue® Ultrasound Gel 250g Non-Sterile FlexPac®
286	EcoVue® Ultrasound Gel 250mL Non-Sterile Bottle

*Stacey Benser*

HR Pharmaceuticals, Inc.  
Stacey Benser  
Senior Quality/Regulatory Manager

Awaiting Approval Version

