



Declaration of Conformity

- Manufacturer:** Parker Laboratories, Inc.
286 Eldridge Road
Fairfield, NJ 07004 USA
Single Registration Number (SRN): US-MF-000013857
- Description:** Nonsterile ultrasound gels, creams, lotions
- Classification:** Class I Non-measuring, non-sterile per REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 Annex VIII Chapter 3 Rule 1
- EC Representative:** Parker Laboratories BV
Bedrijvenpark Twente 305
7602 KL Almelo
The Netherlands
Single Registration Number (SRN): NL-AR-000012618
- Products:** See attached product list
- Intended Use:** Non-sterile ultrasound products are intended for use with commercially available ultrasound devices to couple sound waves between a patient and an ultrasound transducer. They are intended for use on intact skin for noninvasive diagnostic and therapeutic ultrasound procedures.

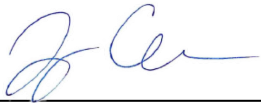
These products are manufactured in compliance with the following standards:

- ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- EN 1041:2008 Information Supplied by the Manufacturer with Medical Devices
- ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices
- ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Test for in vitro cytotoxicity
- ISO 10993-10:2012 Biological evaluation of medical devices – Part 10: Test for irritation and skin sensitization

Parker Laboratories, Inc., being a manufacturer of medical devices sold within the European Union, hereby declares that the products covered by this declaration meet the relevant provisions of the European Regulation (EU) 2017/745 for Medical Devices and the General Safety and Performance Requirements listed in Annex I.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer, Parker Laboratories, Inc.

Signature:



Larry Elisca, Quality Manager
for and on behalf of Parker Laboratories, Inc.
Fairfield NJ 07004 USA

15 Oct 2021

Date

Product List – Non-sterile Ultrasound Products

Product Description	Product Refs	Basic UDI-DI
Aquaflex Ultrasound Gel Pad	04-02	085568300604000H8
Aquasonic 100 Ultrasound Transmission Gel	01-34	085568300601003GR
Aquasonic 100 Ultrasound Transmission Gel	01-50	085568300601003GR
Aquasonic 100 Ultrasound Transmission Gel	01-02	085568300601003GR
Aquasonic 100 Ultrasound Transmission Gel	01-08	085568300601003GR
Aquasonic 100 Ultrasound Transmission Gel	01-20	085568300601003GR
Aquasonic Clear Ultrasound Transmission Gel	03-02	085568300601003GR
Aquasonic Clear Ultrasound Transmission Gel	03-08	085568300601003GR
Aquasonic Clear Ultrasound Transmission Gel	03-20	085568300601003GR
Aquasonic Clear Ultrasound Transmission Gel	03-34	085568300601003GR
Aquasonic Clear Ultrasound Transmission Gel	03-50	085568300601003GR
Aquasonic Clear Ultrasound Transmission Gel	03-54	085568300601003GR
Polysonic Ultrasound Lotion	21-08	085568300620021HA
Polysonic Ultrasound Lotion	21-28	085568300620021HA
Polysonic Ultrasound Lotion (Polypac)	21-50	085568300620021HA
Polysonic Ultrasound Lotion with Aloe	20-08	085568300620021HA
Polysonic Ultrasound Lotion with Aloe	20-28	085568300620021HA
Polysonic Ultrasound Lotion with Aloe	20-50	085568300620021HA
Scan Ultrasound Gel	11-08	085568300601003GR
Scan Ultrasound Gel	11-28	085568300601003GR
Scan Ultrasound Gel (Scanpac)	11-28S	085568300601003GR