



LABORATORIES, INC.

Declaration of Conformity

- Manufacturer:** Parker Laboratories, Inc.
286 Eldridge Road
Fairfield, NJ 07004 USA
- 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
- 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 conform to the Essential Requirements of EC Directive (EU) 2017/745.

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

26 Feb 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	03-34	085568300601003GR
Aquasonic Clear Ultrasound Transmission Gel	03-50	085568300601003GR
Aquasonic Clear Ultrasound Transmission Gel	03-54	085568300601003GR
Aquasonic Clear Ultrasound Transmission Gel	03-54	085568300601003GR
Aquasonic Clear Ultrasound Transmission Gel	03-08	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