PARKER LABORATORIES, INC.

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
- ISO 20417:2021 Medical Devices – Information to be Supplied by the Manufacturer
- ISO 15223-1-2021 Medical Devices – Symbols to be used with information to be supplied by the manufacturer
- 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 10993-10:2021 Biological evaluation of medical devices – Part 10: Test for 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:

Candy Beck

Candy Beck, Regulatory Specialist
for and on behalf of Parker Laboratories, Inc.
Fairfield NJ 07004 USA

Nov 12, 2024
Date

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Product List – Non-sterile Ultrasound Products

Product Description	Product Refs	Basic UDI
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	03-20	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

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