



Declaration of Conformity

Manufacturer: Parker Laboratories, Inc.
286 Eldridge Road
Fairfield, NJ 07004 USA
Single Registration Number (SRN): US-MF-000013857

Description: Non-Sterile Lubricating Gel

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 5

EC Representative: Parker Laboratories BV
Bedrijvenpark Twente 305
7602 KL Almelo
The Netherlands
Single Registration Number (SRN): NL-AR-000012618

Intended Use: Aquagel is a non-sterile, water-soluble non-irritating lubricating gel

Products: See table below

Product Name	Product Number	Basic UDI
Aquagel 142 g Tube	57-05	085568300657000KL
Aquagel 1.9 L Bottle	57-20	085568300657000KL

This product is 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

Standards (cont.):

- 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 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:

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

October 2, 2024
Date