



LABORATORIES, INC.

Declaration of Conformity

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

Product Name: Sterile Aquasonic® 100 Ultrasound Transmission Gel

Product Codes: 01-01 and 01-01-4

Description: Sterile Aquasonic 100 Ultrasound Transmission Gel is a sterile, water soluble and non-staining gel intended for sterile ultrasound procedures and where sterility is indicated.

Classification: Class IIa (Annex IX, Rule 6) of European Council (EC) Directive 93/42/EEC - Medical Device Directive (MDD) as amended via 2007/47/EEC under Annex VII

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

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 93/42/EEC and have been subject to the Conformity Assessment procedures defined in Annex V under the supervision of BSI, a Notified Body authorized by the Competent Authority.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer, Parker Laboratories, Inc. It is supported by the EC Certificate of Production Quality Assurance issued by:

BSI
Say Building, John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands
Notified Body Number 2797

BSI EC Certificate Number CE 615075 was transferred from Notified Body BSI 0086 to Notified Body BSI 2797 on 2019-02-04.

Signature:

Candy Beck

Candy Beck, Regulatory Specialist

for and on behalf of Parker Laboratories, Inc.

Fairfield NJ 07004 USA

April 17, 2023
Date