

Declaration of Conformity

Parker Labs: Parker Laboratories
286 Eldridge Road
Fairfield, NJ 07004 USA

Product Name: Aquasonic 100 Sterile Ultrasound Gel

Description: The Aquasonic 100 Sterile 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 Community Directive 93/42/EEC as amended Concerning Medical Devices

EC Representative MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

Parker Laboratories, being a manufacturer/distributor within the European Union hereby declare that the products covered by the declaration conform with 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, carrying the Notified Body Number 0086.

This declaration is valid for all devices described in this document.

The declaration is supported by EC Certificate of Quality Assurance issued by:

BSI
Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP
Satnav postcode: MK5 8PP

Notified Body Number 0086
Certificate Number CE615075

Signed 

6/18/2018
Date

Monte Nelson
QA Manager, Parker Laboratories