Declaration of Conformity

Manufacturer Parker Laboratories
286 Eldridge Road
Fairfield NJ 07004 USA

Parker Laboratories Inc. declares with sole responsibility that the CE marked products specified in the attached list meet the provisions of the Council Directive 93/42/EEC Concerning Medical Devices, including amendments through 2007/47EC.

Device Classification	Class I Non-Measuring, Non Sterile
Conformity Assessment Route	Annex VII
EU Authorized Representative	Medical Device Safety Services (MDSS) GmbH Schiffgraben 41 D-30175 Hannover Germany

Signed _____ 11 Jul 2019
Date

Larry Elisca

Quality Assurance Manager/ Management Representative
Fairfield, NJ USA

Parker Laboratories Inc.

Notified Medical Device & UMDNS Description	UMDNS Code	Product	Part Numbers
Lubricating Jellies	12-401	Aquagel® Lubricating Gel	57-05, 57-20
Gel, Electrode	11-425	Spectra® 360 Electrode Gel	12-02, 12-08
		Signagel® Electrode Gel	15-60, 15-25
		Tensive® Conductive Adhesive Gel	22-60
		Redux® Electrolyte Gel	65-04
Media, Electroconductive		Signacreme® Electrode Cream	17-05, 17-20
		Signaspray® Electrode Solution and Skin Prep	18-25, 18-28, 18-04, 18-50
		Redux® Electrolyte Cream	66-04
		Redux® Electrolyte Paste	67-05
Gel, Ultrasonic Coupling	15-321	Aquasonic® 100 Ultrasound Transmission Gel	01-02, 01-08, 01-20, 01-34, 01-50
		Aquasonic® Clear Ultrasound Gel	03-02, 03-08, 03-34, 03-50, 03-54, 03-20
		Aquaflex® Ultrasound Gel Pad	04-02
		Scan® Ultrasound Gel	11-08, 11-28, 11-28S
Ultrasonic Coupling Lotion		Polysonic® Ultrasound Lotion	21-08, 21-28, 21-50
		Polysonic® Ultrasound Lotion with Aloe Vera	20-08, 20-28, 20-50
Covers	15-571	Eclipse® Probe Cover	38-01, 38-03

PARKER LABORATORIES, INC.
286 ELDRIDGE ROAD, FAIRFIELD, NEW JERSEY 07004 U.S.A.

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. The Parker Laboratories EC Certificate was transferred from BSI Notified Body 0086 to BSI Notified Body 2797 on 2019-02-04.

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

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

BSI
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

Notified Body Number 2797
Certificate Number CE 615075

Signed _____ 20 Mar 2019
Date

Larry Elisca
QA Manager, Parker Laboratories

PARKER LABORATORIES, INC.
286 ELDRIDGE ROAD, FAIRFIELD, NEW JERSEY 07004 U.S.A.

Declaration of Conformity

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

Product Name: Ultradrape

Description: Ultradrape is a sterile ultrasound guided peripheral intravenous barrier and securement device.

Classification: Class Is (Annex IX, Rule 1) 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 of medical devices sold 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. The Parker Laboratories EC Certificate was transferred from BSI Notified Body 0086 to BSI Notified Body 2797 on 2019-02-04.

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Date

Larry Elisca
QA Manager, Parker Laboratories