PARKER LABORATORIES, INC.

Declaration of Conformity

Product Name	Product Numbers
Aquagel® Lubricating Gel	57-05, 57-20

Manufacturer: Parker Laboratories, Inc.
286 Eldridge Road
Fairfield, NJ 07004 USA

Description: Non-sterile lubricating gel

Classification: Class I Non-measuring, non-sterile per Annex IX, Rule 5 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

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.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer, Parker Laboratories, Inc.

Signature:

Larry Elisca, Quality Manager
for and on behalf of Parker Laboratories, Inc.
Fairfield NJ 07004 USA

26 Feb 2020
Date

PARKER LABORATORIES, INC.

Declaration of Conformity

Manufacturer: Parker Laboratories, Inc.
286 Eldridge Road
Fairfield, NJ 07004 USA

Product Name: Ultradrape® UGPIV Barrier and Securement

Product Code: 34-15

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

Classification: Class Is (Annex IX, Rule 1) 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

Parker Laboratories, Inc., being a manufacturer of medical devices sold within the European Union, hereby declares that the products covered by the 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:

Larry Elisca, Quality Manager
for and on behalf of Parker Laboratories, Inc.
Fairfield NJ 07004 USA

18 Feb 2020
Date

phone: 973.276.9500 · fax: 973.276.9510 · email: parker@parkerlabs.com · website: www.parkerlabs.com

PARKER LABORATORIES, INC.

Declaration of Conformity

Manufacturer:	Parker Laboratories, Inc. 286 Eldridge Road Fairfield, NJ 07004 USA
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

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Fairfield NJ 07004 USA

18 Feb 2020
Date

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PARKER LABORATORIES, INC.

Declaration of Conformity

Manufacturer:	Parker Laboratories, Inc. 286 Eldridge Road Fairfield, NJ 07004 USA
Product Names:	Protex® Pro Disinfectant Spray and Wipes
Product Codes:	Product Code 43-32, Protex Pro Disinfectant Spray Product Code 47-44, Protex Pro Disinfectant Wipes
Description:	Disinfectant intended for the cleaning and disinfection of non-critical hard non-porous surfaces of non-invasive, non-lumened medical devices.
Classification:	Class IIa (Annex IX, Rule 15) 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

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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:

Larry Elisca, Quality Manager
for and on behalf of Parker Laboratories, Inc.
Fairfield NJ 07004 USA

28 Apr 2020
Date

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PARKER LABORATORIES, INC.

Declaration of Conformity

Product Names and Descriptions	Product Numbers
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
Polysonic® Ultrasound Lotion	21-08, 21-28, 21-50
Polysonic® Ultrasound Lotion with Aloe Vera	20-08, 20-28, 20-50

Manufacturer: Parker Laboratories, Inc.
286 Eldridge Road
Fairfield, NJ 07004 USA

Description: Gels, creams, and lotions for medical ultrasound procedures

Classification: Class I Non-measuring, non-sterile per Annex IX, Rule 1 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

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Signature:

Larry Elisca, Quality Manager
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Fairfield NJ 07004 USA

26 Feb 2020
Date

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PARKER LABORATORIES, INC.

Declaration of Conformity

Product Name	Product Numbers
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
Redux® Electrolyte Gel	65-04
Spectra® 360 Electrode Gel	12-02, 12-08
Signagel® Electrode Gel	15-60, 15-25
Tensive® Conductive Adhesive Gel	22-60

Manufacturer: Parker Laboratories, Inc.
286 Eldridge Road
Fairfield, NJ 07004 USA

Description: Gels, creams, pastes and solutions for electromedical procedures

Classification: Class I Non-measuring, non-sterile per Annex IX, Rule 1 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
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Signature:

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

26 Feb 2020
Date

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PARKER LABORATORIES, INC.

Declaration of Conformity

Product Name	Product Numbers
Eclipse® Probe Cover	38-01
Eclipse® 3D Probe Cover	38-03

Manufacturer: Parker Laboratories, Inc.
286 Eldridge Road
Fairfield, NJ 07004 USA

Description: Soft, latex-free, disposable probe cover for medical ultrasound probes/transducers, pre-gelled

Classification: Class I Non-measuring, non-sterile per Annex IX, Rule 5 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
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