PARKER LABORATORIES, INC.

Declaration of Conformity

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

Description: Eclipse® and Eclipse® 3D Ultrasound Probe Covers

Classification: Class I transient, invasive, non-active, 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: Eclipse® and Eclipse® 3D Probe Covers are disposable probe covers for use with medical ultrasound probes/transducers.

Products: See table below

Product Description	Product Refs	Basic UDI-DI
Eclipse Ultrasound Probe Covers	38-01	085568300638000K5
Eclipse 3D Ultrasound Probe Covers	38-03	085568300638000K5
Eclipse Ultrasound Probe Cover (Single)	38-01-1	085568300638000K5

These products are manufactured in compliance with the following standards:

- EN ISO 13485:2016 / A11:2021, Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- EN ISO 14971:2019, Medical Devices – Application of Risk Management to Medical Devices
- EN IEC 62366:2015 + A1 2020 Medical devices; Application of usability engineering to medical devices
- EN ISO 10993-1:2025, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

PARKER LABORATORIES, INC.

Parker Laboratories, Inc., being a manufacturer of medical device accessories 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 Accessory 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, Sr. Regulatory Specialist
for and on behalf of Parker Laboratories, Inc.
Fairfield NJ 07004 USA

PARKER LABORATORIES, INC.

Declaration of Conformity

Manufacturer:	Parker Laboratories, Inc. 286 Eldridge Road Fairfield, NJ 07004 USA Single Registration Number (SRN): US-MF-000013857
Description:	Gels, creams, pastes and solutions for electromedical procedures
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 1
EC Representative:	Parker Laboratories BV Bedrijvenpark Twente 305 7602 KL Almelo The Netherlands Single Registration Number (SRN): NL-AR-000012618
Products:	See attached product list
Intended Use:	Electromedical products are non-sterile, electrically conductive gels, creams, pastes and solutions for electromedical procedures. They are intended for external use only on intact, unbroken skin.

These products are manufactured in compliance with the following standards:

- EN ISO 13485:2016 / A11:2021, Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- EN ISO 14971:2019, Medical Devices – Application of Risk Management to Medical Devices
- EN IEC 62366:2015 + A1 2020 Medical devices; Application of usability engineering to medical devices
- EN ISO 10993-1:2025, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

Parker Laboratories, Inc., being a manufacturer of medical device accessories 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 Accessory and the General Safety and Performance Requirements listed in Annex I.

PARKER LABORATORIES, INC.

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

Signature:

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

PARKER LABORATORIES, INC.

Product List – Electromedical Products

Product Name	Product Numbers	Basic UDI-DI
Signacreme® Electrode Cream	17-05	085568300666017L9
Signacreme® Electrode Cream	17-20	085568300666017L9
Signaspray® Electrode Solution and Skin Prep	18-25	085568300618000JF
Signaspray® Electrode Solution and Skin Prep	18-28	085568300618000JF
Signaspray® Electrode Solution and Skin Prep	18-50	085568300618000JF
Redux® Electrolyte Cream	66-04	085568300666017L9
Redux® Electrolyte Paste	67-05	085568300667000KX
Redux® Electrolyte Gel	65-04	085568300612015HJ
Spectra® 360 Electrode Gel	12-02	085568300612015HJ
Spectra® 360 Electrode Gel	12-08	085568300612015HJ
Signagel® Electrode Gel	15-60	085568300612015HJ
Signagel® Electrode Gel	15-25	085568300612015HJ
Tensive® Conductive Adhesive Gel	22-60	085568300612015HJ

PARKER LABORATORIES, INC.

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-DI
Aquagel 142 g Tube	57-05	085568300657000KL
Aquagel 1.9 L Bottle	57-20	085568300657000KL

These products are manufactured in compliance with the following standards:

- EN ISO 13485:2016 / A11:2021, Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- EN ISO 14971:2019, Medical Devices – Application of Risk Management to Medical Devices
- EN IEC 62366:2015 + A1 2020 Medical devices; Application of usability engineering to medical devices
- EN ISO 10993-1:2025, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

PARKER LABORATORIES, INC.

Parker Laboratories, Inc., being a manufacturer of medical device accessories 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 Accessory 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, Sr. Regulatory Specialist
for and on behalf of Parker Laboratories, Inc.
Fairfield NJ 07004 USA

LABORATORIES, INC.

Declaration of Conformity

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

Description: Nonsterile ultrasound gels, creams, lotions

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 1

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

Products: See attached product list

Intended Use: Non-sterile ultrasound products are intended for use with commercially available ultrasound devices to couple sound waves between a patient and an ultrasound transducer. They are intended for use on intact skin for noninvasive diagnostic and therapeutic ultrasound procedures.

These products are manufactured in compliance with the following standards:

- EN ISO 13485:2016 /A11:2021, Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- EN ISO 14971:2019, Medical Devices – Application of Risk Management to Medical Devices
- EN IEC 62366:2015 + A1 2020 Medical devices; Application of usability engineering to medical devices
- EN ISO 10993-1:2025, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

PARKER LABORATORIES, INC.

Parker Laboratories, Inc., being a manufacturer of medical device accessories 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 Accessory 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
Regulatory Specialist
for and on behalf of Parker Laboratories, Inc.
Fairfield NJ 07004 USA

PARKER LABORATORIES, INC.

Product List – Non-sterile Ultrasound Products

Product Description	Product Refs	Basic UDI-DI
Aquaflex Ultrasound Gel Pad	04-02	085568300604000H8
Aquasonic 100 Ultrasound Transmission Gel	01-34	085568300601003GR
Aquasonic 100 Ultrasound Transmission Gel	01-50	085568300601003GR
Aquasonic 100 Ultrasound Transmission Gel	01-02	085568300601003GR
Aquasonic 100 Ultrasound Transmission Gel	01-08	085568300601003GR
Aquasonic 100 Ultrasound Transmission Gel	01-20	085568300601003GR
Aquasonic Clear Ultrasound Transmission Gel	03-34	085568300601003GR
Aquasonic Clear Ultrasound Transmission Gel	03-50	085568300601003GR
Aquasonic Clear Ultrasound Transmission Gel	03-54	085568300601003GR
Aquasonic Clear Ultrasound Transmission Gel	03-02	085568300601003GR
Aquasonic Clear Ultrasound Transmission Gel	03-20	085568300601003GR
Aquasonic Clear Ultrasound Transmission Gel	03-08	085568300601003GR
Polysonic Ultrasound Lotion	21-08	085568300620021HA
Polysonic Ultrasound Lotion	21-28	085568300620021HA
Polysonic Ultrasound Lotion (Polypac)	21-50	085568300620021HA
Polysonic Ultrasound Lotion with Aloe	20-08	085568300620021HA
Polysonic Ultrasound Lotion with Aloe	20-28	085568300620021HA
Polysonic Ultrasound Lotion with Aloe	20-50	085568300620021HA
Scan Ultrasound Gel	11-08	085568300601003GR
Scan Ultrasound Gel	11-28	085568300601003GR
Scan Ultrasound Gel (Scanpac)	11-28S	085568300601003GR

PARKER 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
And Person Responsible for Regulatory Compliance
for and on behalf of Parker Laboratories, Inc.
Fairfield NJ 07004 USA

May 2, 2024
Date

PARKER LABORATORIES, INC.

Declaration of Conformity

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

Product Name: Ultradrape® and Ultradrape® II UGPIV Barrier and Securement

Product Codes: 34-15 (Ultradrape®) and 34-10 (Ultradrape® II)

Description: 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:

Candy Beck

Candy Beck, Regulatory Specialist
And Person Responsible for Regulatory Compliance
for and on behalf of Parker Laboratories, Inc.
Fairfield NJ 07004 USA

May 2, 2024
Date

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