



## 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.



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

Signature:

Candy  
Beck

Digitally signed by  
Candy Beck  
Date: 2026.04.01  
14:37:51 -04'00'

---

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

**Product List – Electromedical Products**

| <b>Product Name</b>                          | <b>Product Numbers</b> | <b>Basic UDI-DI</b> |
|--|------------------------|---------------------|
| 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   |

## 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          | 085568300657001KN |
| Aquagel 1.9 L Bottle | 57-20          | 085568300657001KN |

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.

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

Signature:

Candy Beck

Digitally signed by  
Candy Beck  
Date: 2026.07.06  
14:30:18 -04'00'

---

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., 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:

Digitally signed by  
Candy Beck  
Date: 2026.02.19  
13:37:24 -05'00'

---

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

### 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 |



## 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., 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:

Digitally signed by  
Candy Beck  
Date: 2026.04.01  
14:37:03 -04'00'

---

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

**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



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