



## Declaration of Conformity

- 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 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
- 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:

- ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
- EN 1041:2008 Information Supplied by the Manufacturer with Medical Devices
- ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices
- ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Test for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Test for irritation and skin sensitization

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 (EU) 2017/745.



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

Signature:

A handwritten signature in blue ink, appearing to read "L. Elisca", is written above a horizontal line.

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

08 Mar 2021

Date

**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
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