



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:

- 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



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Parker Laboratories, Inc., being a manufacturer of medical devices 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 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
Candy Beck, Regulatory Specialist
for and on behalf of Parker Laboratories, Inc.
Fairfield NJ 07004 USA

July 12, 2023
Date

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