



Certificate of CE-Registration

This is to certify that, in accordance with the Medical Device Directive 93/42/EEC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

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

as stipulated and demanded by the aforementioned Directive. The German Competent Authority has allocated the medical devices of the Manufacturer registration numbers as foreseen in:

Annex A dated September 19, 2019

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the medical devices fulfill the applicable requirements of Directive 93/42/EEC. In compliance with German law, a safety officer has been appointed for Germany.

2019-09-19

Dr. Philipp Hohenbrink
Senior Consultant
MDSS GmbH

Annex A dated September 19, 2019

Manufacturer: Parker Laboratories, Inc.

UMDNS Description & Notified Medical Device	UMDNS Code	Risk Class	Cat. Code	Registration Number	NB No. / NB Certificate No.	NB Cert. Valid Until YYYY-MM-DD
Lubricating Jellies	12-401	I	00	DE/CA09/0170/P05/006-01	N.A.	N.A.
Aquagel® Lubricating Gel, 57-05, 57-20						
Gel, Electrode	11-425	I	00	DE/CA09/0170/P05/007-01	N.A.	N.A.
Spectra® 360 Electrode Gel, 12-02, 12-08						
Signagel® Electrode Gel, 15-60, 15-25						
Tensive® Conductive Adhesive Gel, 22-60						
Redux® Electrolyte Gel, 65-04						
Electroconductive Media	---	I	00	DE/CA09/0170/P05/004	N.A.	N.A.
Signacreme® Electrode Cream, 17-05, 17-20						
Signaspray® Electrode Solution and Skin Prep, 18-25, 18-28, 18-04, 18-50						
Redux® Electrolyte Creme, 66-04						
Redux® Electrolyte Paste, 67-05						
Gel, Ultrasonic Coupling	15-321	I	00	DE/CA09/0170/P05/003	N.A.	N.A.
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, 04-15, 04-20, 04-35, 04-40						
Scan® Ultrasound Gel, 11-08, 11-28, 11-28S						
Gel, Ultrasonic Coupling	15-321	IIa	00	DE/CA09/0170/P05/005-02	2797/CE 615075	2024-05-26
Aquasonic® 100 Sterile Ultrasound Gel						
Aquasonic® 100 Sterile Ultrasound Gel, 01-01						
Ultrasonic Coupling Lotion	---	I	00	DE/CA09/0170/P05/002-01	N.A.	N.A.
Polysonic® Ultrasound Lotion, 21-08, 21-28, 21-50						
Polysonic® Ultrasound Lotion with Aloe, 20-08, 20-28, 20-50						
Covers	15-571	I	10	DE/CA09/0170/P05/001	N.A.	N.A.
Eclipse® Probe Cover, 38-01, 38-03						
Self-adherent Bandage	10-288	Is	10	DE/CA09/0170/P05/008-01	2797/CE 615075	2024-05-26
Ultradraper						
Ultradraper Guided Peripheral Intravenous Barrier and Securement Device						

PJA