



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.
Aquage® 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						
Signage® 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 Ultrasonic Transmission Gel, 01-02, 01-08, 01-20, 01-34, 01-50						
Aquasonic® Clear Ultrasonic Gel, 03-02, 03-08, 03-34, 03-50, 03-54, 03-20						
Aquaflex® Ultrasonic Gel Pad, 04-02, 04-15, 04-20, 04-35, 04-40						
Scan® Ultrasonic Gel, 11-08, 11-28, 11-28S						
Gel, Ultrasonic Coupling	15-321	Ila	00	DE/CA09/0170/P05/005-02	2797/CE 615075	2024-05-26
Aquasonic® 100 Sterile Ultrasonic Gel						
Aquasonic® 100 Sterile Ultrasonic Gel, 01-01						
Ultrasonic Coupling Lotion	---	I	00	DE/CA09/0170/P05/002-01	N.A.	N.A.
Polysonic® Ultrasonic Lotion, 21-08, 21-28, 21-50						
Polysonic® Ultrasonic 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
Ultradrape						
Ultradrape Guided Peripheral Intravenous Barrier and Securement Device						

PMA

