

# CERTIFICATE

Number: 2247808

The management system of the organization(s) and locations mentioned on the addendum belonging to:

## ERBE Elektromedizin GmbH

Waldhornlestrasse 17  
72072 Tübingen  
Germany

Manufacturer Facility Identifier F004323

Conforms with the following standard and regulatory requirements:

## ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure  
Brazil: RDC ANVISA n. 665/2022, 551/2021 and 67/2009  
Canada: Medical Devices Regulations - Part 1- SOR 98/282  
Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act  
United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

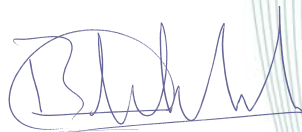
### Scope:

Design and development, production, servicing and distribution of reusable and disposable medical devices: Electrosurgical generators, smoke evacuation units, electrosurgical instruments, cables, adapters, patient plates, electrodes, handles and accessories for electro surgery (carts, foot switches, fastening sets), argon plasma coagulation units, argon plasma coagulation probes and applicators, irrigation pump and irrigation pump accessories (tubing sets, suction containers, foot switch, adapter for endoscopes), water jet surgery units, suction units, applicators, probes and accessories for water jet surgery (pump cartridges, foot switches), cryosurgery units, cryo probes and accessories for cryosurgery (carts, foot switches, extension cables, gas bottle adapters, valves, filters), physical therapy units.

Certificate expiry date: 2026-07-01  
Certificate effective date: 2023-07-21  
Certified since: 2020-07-13

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus  
Managing Director



J.M.A. McKenzie  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:  
<https://www.dekra-product-safety.com/en/certified-organizations>

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.



# ADDENDUM

To certificate: 2247808

The management system of the organization(s) and/or location(s) of:

## ERBE Elektromedizin GmbH

Waldhornlestrasse 17  
72072 Tübingen  
Germany

Certified organization(s) and/or locations:

Different scope

ERBE Elektromedizin GmbH  
Rudolf-Diesel-Str. 29  
72414 Rangendingen  
Germany  
Facility Identifier F004324

Design, development and production of reusable and disposable medical devices: Electrosurgical instruments, electrodes, handles and accessories for electro surgery (carts, foot switches, fastening sets), argon plasma coagulation probes and applicators, irrigation pump accessories (tubing sets, suction containers, foot switch, adapter for endoscopes), applicators, probes and accessories for water jet surgery (pump cartridges, foot switches), probes and accessories for cryosurgery (carts, foot switches, extension cables, gas bottle adapters, valves, filters).

Addendum expiry date: 2026-07-01

Addendum effective date: 2023-07-21