

**MDSAP**

Medical Device Single Audit Program



America

CERTIFICATE

No. QS6 015373 0004 Rev. 01

Certificate Holder:**Erbe Elektromedizin GmbH**

Waldhoernlestrasse 17

72072 Tuebingen

GERMANY

Certification Mark:**Scope of Certificate:****See Page 2 for Overall Scope Statement.****Standard(s):****ISO 13485:2016****Regulatory Authority(ies):****Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:QS6_015373_0004_Rev_01

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID:**F008338****Report No.:****713375699****Effective Date:****2025-09-16****Expiry Date:****2026-07-01**

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(Renee Walker)
Director, US Certification Body, MHS



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Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 – Vigilance

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Overall Scope Statement:

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 Switches, Adapter for Endoscopes), Water Jet Surgery Units, Applicators, Probes and Accessories for Water Jet Surgery (Pump Cartridges, Foot Switches), Suction Units, Cryosurgery Units, Cryo Probes and Accessories for Cryosurgery (Carts, Foot Switches, Extension Cables, Gas Bottle Adapters, Valves, Filters)

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Facility(ies):**Erbe Elektromedizin GmbH**

Waldhoernlestrasse 17, 72072 Tuebingen, GERMANY

Erbe Elektromedizin GmbH

Rudolf-Diesel-Strasse 29, 72414 Rangendingen, GERMANY

Erbe Elektromedizin GmbH

Waldhoernlestrasse 18, 72072 Tuebingen, GERMANY

Erbe Elektromedizin GmbH

Ernst-Simon-Straße 10, 72072 Tuebingen, GERMANY

Facility Scopes:**Erbe Elektromedizin GmbH**

Waldhoernlestrasse 17, 72072 Tuebingen, GERMANY

Production and Servicing of Reusable Medical Devices:
Electrosurgical Generators, Smoke Evacuation Units, Cables,
Adapters, Accessories for Electro Surgery (Carts, Foot Switches),
Argon Plasma Coagulation Units, Irrigation Pump and Irrigation Pump
Accessories (Foot Switches), Water Jet Surgery Units and
Accessories for Water Jet Surgery (Foot Switches), Suction Units,
Cryosurgery Units and Accessories for Cryosurgery (Carts, Foot
Switches, Extension Cables)

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Erbe Elektromedizin GmbH

Rudolf-Diesel-Strasse 29, 72414 Rangendingen, GERMANY

Design, Development and Production of Reusable and Disposable
Medical Devices: Electrosurgical Instruments, Adapters, Patient
Plates, Electrodes, Handles and Accessories for Electro Surgery
(Fastening Sets), Argon Plasma Coagulation Probes and Applicators,
Irrigation Pump Accessories (Tubing Sets, Suction Containers,
Adapter for Endoscopes), Applicators, Probes and Accessories for
Water Jet Surgery (Pump Cartridges), Cryo Probes and Accessories

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Director, US Certification Body, MHS

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for Cryosurgery (Gas Bottle Adapters, Valves, Filters)

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Erbe Elektromedizin GmbH

Waldhoernlestrasse 18, 72072 Tuebingen, GERMANY

Design and Development of Reusable Medical Devices:
Electrosurgical Generators, Smoke Evacuation Units, Cables,
Adapters, Accessories for Electro Surgery (Carts, Foot Switches),
Argon Plasma Coagulation Units, Irrigation Pump and Irrigation Pump
Accessories (Foot Switches), Water Jet Surgery Units and
Accessories for Water Jet Surgery (Foot Switches), Suction Units,
Cryosurgery Units and Accessories for Cryosurgery (Carts, Foot
Switches, Extension Cables)

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Erbe Elektromedizin GmbH

Ernst-Simon-Straße 10, 72072 Tuebingen, GERMANY

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 Switches, Adapter
for Endoscopes), Water Jet Surgery Units, Applicators, Probes and
Accessories for Water Jet Surgery (Pump Cartridges, Foot Switches),
Suction Units, Cryosurgery Units, Cryo Probes and Accessories for
Cryosurgery (Carts, Foot Switches, Extension Cables, Gas Bottle
Adapters, Valves, Filters)

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