



America

CERTIFICATE

No. QS6 015373 0004 Rev. 00

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.00

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

REPs Facility ID: F008338
Report No.: 713363099
Effective Date: 2025-05-30
Expiry Date: 2026-07-01

Page 1 of 3

Date of Issue: 2025-05-30

(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 Sterile and Non-Sterile 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

Page 2 of 3

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Facility(ies):

Erbe Elektromedizin GmbH
Waldhoernlestrasse 17, 72072 Tuebingen, GERMANY

Erbe Elektromedizin GmbH
Rudolf-Diesel-Strasse 29, 72414 Rangendingen, GERMANY

Facility Scopes:

Erbe Elektromedizin GmbH
Waldhoernlestrasse 17, 72072 Tuebingen, GERMANY

Design and Development, Production, Servicing and Distribution of Sterile and Non-Sterile 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
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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, 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)
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Page 3 of 3

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Director, US Certification Body, MHS