



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](http://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**

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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 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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**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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