







Product Service

Certificate

No. Q5 015373 0009 Rev. 00

Holder of Certificate: Erbe Elektromedizin GmbH

Waldhoernlestrasse 17 72072 Tuebingen GERMANY

Certification Mark:



Scope of Certificate:

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).

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 015373 0009 Rev. 00

Report No.: 713360866

 Valid from:
 2025-09-16

 Valid until:
 2026-09-06

Date. 2025-09-16 Christoph Dicks

Head of Certification/Notified Body





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Applied Standard(s): ISO 13485:2016

(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)

Medical devices - Quality management systems -

Requirements for regulatory purposes

Facility(ies): 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).

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).

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).

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,







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irrigation pump accessories (tubing sets, suction containers, adapter for endoscopes), applicators, probes and accessories for water jet surgery (pump cartridges), cryo probes and accessories for cryosurgery (gas bottle adapters, valves, filters).