ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 015373 0007 Rev. 00

Manufacturer: **Erbe Elektromedizin GmbH**
Waldhoernlestrasse 17
72072 Tuebingen
GERMANY

SRN Manufacturer - DE-MF-000005498

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective aspects relating to
- establishing, securing, and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

If class IIa or class IIb devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class III or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

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:G15 015373 0007 Rev. 00

Report No.: 713360866
Valid from: 2025-05-31
Valid until: 2026-07-12

Issue date: 2025-05-30

Christoph Dicks
Head of Certification/Notified Body

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Classification:	Class IIb
Device Group:	Z12010902 - ELECTROSURGICAL UNITS (ESU) FOR GENERAL USE
Intended Purpose:	The electrosurgical unit with instruments and accessories is designed to deliver high frequency (HF) current for cutting, ablation, coagulation of tissue and sealing of vessels. The footswitch is intended for connection to the electrosurgical units used to activate the devices.
Classification:	Class IIb
Device Group:	Z12010903 - ARGON ELECTROSURGICAL UNITS (ESU)
Intended Purpose:	The argon electrosurgical unit with instruments and accessories is designed to deliver argon gas for argon plasma coagulation, devitalization, ablation and for argon-assisted cutting of tissue when used in conjunction with a compatible high frequency electrosurgical unit.
Classification:	Class IIb
Device Group:	K020101 - MONO- AND BIPOLAR SURGICAL INSTRUMENTS, SINGLE-USE
Intended Purpose:	Monopolar and bipolar single-use instruments are intended for cutting and/or coagulating of tissue.
Classification:	Class IIb
Device Group:	Z120106 - HYDRODISSECTORS
Intended Purpose:	Waterjet surgical units, pump cartridge and applicators are intended for the application of a high-pressure waterjet for the layered preparation and separation, lifting, marking and rinsing of tissue using a sterile separation medium. The footswitch is intended for connection to the waterjet surgical units used to activate the devices
Classification:	Class IIb
Device Group:	K020401 - ARGON GAS SURGERY INSTRUMENTS, SINGLE-USE
Intended Purpose:	Argon plasma surgical instruments are intended for monopolar coagulation of tissue under argon plasma.
Classification:	Class IIb
Device Group:	Z120102 - CRYOSURGERY EQUIPMENT
Intended Purpose:	Cryosurgical unit and accessories are intended for cryoadhesion, devitalization (destruction) of tissue by the application of extreme cold, in addition cooling of tissue during electrosurgical interventions. The footswitch is intended for connection to the cryosurgical units used to activate the devices.
Classification:	Class IIa
Device Group:	MDA 0312 - Other active non-implantable surgical devices
Intended Purpose:	Surgical medical suction pumps and irrigation pumps are intended for suction and irrigation.

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Certificate No. G15 015373 0007 Rev. 00

The validity of this certificate depends on conditions and/or is limited to the following: -none-

Rev.	Dated	Report	Description
00	2025-05-31	713360866	Initial issuance

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