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Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-099



EU Quality Management System Certificate

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

Certificate No. G15 015373 0010 Rev. 02

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 (excluding custom-made implantable devices) 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 0010 Rev. 02

Report No.: 713282701

Preceding Certificate No.: G15 015373 0010 Rev. 01

Valid from: 2026-07-13

Valid until: 2031-07-12

Date of Initial Issuance: 2025-09-16

Christoph Dicks

Head of Certification/Notified Body

Issue date: 2026-07-13



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Classification:	Class IIb
Device Group:	Z120109 - ELECTROSURGICAL INSTRUMENTS
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. 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:	Single-use monopolar and bipolar electrodes and instruments are intended for cutting and/or coagulation 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 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 IIb
Device Group:	L180401 - OPEN ELECTROSURGERY FORCEPS, REUSABLE
Intended Purpose:	Reusable bipolar forceps and bipolar irrigation forceps are intended for coagulation or coagulation including irrigation of tissue.
Classification:	Class IIb
Device Group:	L180601 - OPEN ELECTROSURGERY ELECTRODES, REUSABLE



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Intended Purpose:

Reusable monopolar electrodes are intended for cutting and/or coagulation of tissue.

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.

The validity of this certificate depends on conditions and/or is limited to the following:

-none-

Revision History:

Rev.	Dated	Report	Description
00	2025-09-16	713375699	Administrative merge / transfer to new Certificate Type
01	2026-07-13	713381258	Renewal of certificate
02	2026-07-13	713282701	Supplemented: Device(s)/group of device(s) added