

EU Certificate

for the assessment of the
quality management system



according to Medical Device Regulation (EU) 2017/745, Annex IX Chapter I

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the manufacturer

ERBE Elektromedizin GmbH

Single Registration Number (SRN): DE-MF-000005498

Waldhörnlestraße 17, 72072 Tübingen, Germany

applies a quality management system according to Annex IX Chapter I of the Medical Device Regulation (EU) 2017/745 for the medical devices listed in the annex. This certificate is based on the assessments listed in CNo50954-00.

EU Certificate no.: 50954-60-00

Certificate valid from: 2022-05-20

Certificate valid to: 2026-07-12

A handwritten signature in black ink, followed by the official DEKRA Certification GmbH logo. The logo is circular with 'DEKRA' in the center and 'DEKRA Certification GmbH' and 'D-70565 Stuttgart, Handwerkstraße 15' around the perimeter.

Natascha Jezyschek
DEKRA Certification GmbH Stuttgart; 2022-05-20
Notified Body ID number: 0124



Benannt durch/Designated by

Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten

www.zlg.de

BS-MDR-092

Annex to the EU Certificate no. 50954-60-00

valid from 2022-05-20 to 2026-07-12

Revision status of the annex: 0 dated 2022-05-20

Following devices/device categories are included in this certificate:

Class IIb

EMDN Code: Z12010902

Name of the device category: High frequency electro-surgical units

Intended purpose:

The electro-surgical unit with instruments and accessories is designed to deliver high frequency (HF) current for cutting, ablation, coagulation of tissue and sealing of vessels.

Name of the device category: Footswitch

Intended purpose:

The footswitch is intended for connection to the electro-surgical units used to activate the devices.

EMDN Code: Z12010903

Name of the device category: Argon electro-surgical units

Intended purpose:

The argon electro-surgical 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 electro-surgical unit.



Natascha Jezyschek

DEKRA Certification GmbH Stuttgart; 2022-05-20

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