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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-092

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

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

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

Revision status of the annex: 1 dated 2023-02-02

Following devices/device categories are included in this certificate:

Class IIb

EMDN Code: Z12010902

Name of the device category: High frequency electrosurgical units

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.

Name of the device category: Footswitch

Intended purpose:
The footswitch is intended for connection to the electrosurgical units used to activate the devices.

EMDN Code: Z12010903

Name of the device category: Argon electrosurgical units

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.

EMDN Code: K020101

Name of the device category: MONO- AND BIPOLAR SURGICAL INSTRUMENTS, SINGLE-USE

Intended purpose:
Monopolar and bipolar single-use instruments are intended for cutting and / or coagulating of tissue.

DEKRA Certification GmbH · DEKRA · D-70565 Stuttgart, Handwerkstraße 15

Karin Leicht
DEKRA Certification GmbH, Stuttgart, 2023-02-02
Notified Body ID-number: 0124