EU Certificate

for the assessment of the quality management system

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

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+III 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 and is only valid in conjunction with the successful completion of the annual surveillance audits.

EU Certificate no.: 50954-60-01-00

Certificate valid from: 2024-03-13
Certificate valid to: 2026-07-12

Previous certificate no. 50954-60-00, issued on 2022-05-20

Digitally signed by CORD JOHANNES WIORA
Date: 2024-03-13 17:30:15+01:00

DEKRA Certification GmbH, Stuttgart
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. 50954-60-01-00

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 for High frequency electrosurgical units

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.

EMDN Code: Z120106

Name of the device category: 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.

Name of the device category: Footswitch for Hydrodissectors

Intended purpose:

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

EMDN Code: K020401

Name of the device category: Argon gas surgery instruments, single use

Intended purpose:

Argon plasma surgical instruments are intended for monopolar coagulation of tissue under argon plasma.

Changes to previous certificate:
Extension of devices in the MDR device range based on technical documentations and based on submitted change notifications