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.: 50954-60-01-02

Certificate valid from: 2024-08-12
Certificate valid to: 2026-07-12

Previous certificate no. 50954-60-01-01, issued on 2024-07-19

Digitally signed by Stephanie Donner
Date: 2024-08-14 09:31:02+02:00

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

DEKRA Certification GmbH, Stuttgart
Notified Body ID number: 0124

Annex to the EU Certificate no. 50954-60-01-02

Following devices/device categories are included in this certificate:

Class IIb

EMDN Code: Z12010902

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

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

EMDN Code: Z120102

Name of the device category: Cryosurgical unit and accessories

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.

Name of the device category: Footswitch for cryosurgical units

Intended Purpose:
The footswitch is intended for connection to the cryosurgical units used to activate the devices.

Class IIa

MDA 0312

Name of the device category: Surgical-medical suction pumps and irrigation pumps

Intended purpose:
Surgical medical suction pumps and irrigation pumps are intended for suction and irrigation

Changes to previous certificate:

Extension of devices in the MDR device range based on technical documentations and based on submitted change notifications