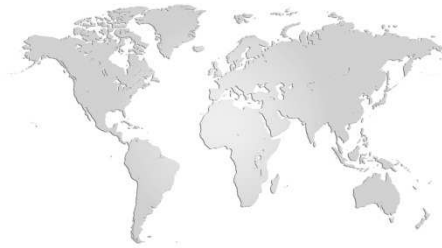


# EC CERTIFICATE

## for the Quality Assurance System



### according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company  
**ERBE Elektromedizin GmbH**

Waldhörnlestraße 17, 72072 Tübingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50954-Z6-00, the decision dated 2021-05-21 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2021-05-21 to 2024-05-26

Registration No.: 50954-16-05



Ruth Delbeck-Bayer  
DEKRA Certification GmbH Stuttgart; 2021-05-21  
Notified Body ID-number: 0124

DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* [www.dekra.de/audits](http://www.dekra.de/audits)



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
[www.zlg.de](http://www.zlg.de)

**ZLG-BS-295.10.02**

# Annex to the EC Certificate No. 50954-16-05

Valid from 2021-05-21 to 2024-05-26

Revision status of the annex: 0 dated 2021-05-21

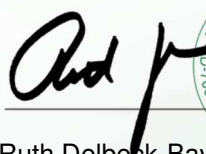
Devices/device categories included in the certificate:

## Class II a:

- Tubing set for irrigation pump
- Handle for smoke evacuator
- Irrigation pump
- Instruments for Cryosurgery (cryo probes)
- Suction module, surgical
- Membrane filter-Set
- Instruments for waterjet dissection, pump
- Adapter, electrosurgical unit (adapter for bipolar resection)
- Electrode holder, electrosurgical
- Electrode holder, electrosurgical, sterile
- Electrode, electrosurgical, active electrode, hand actuated
- Electrode, electrosurgical, active electrode, footswitch actuated

## Class II b:

- Electrosurgical unit
- Neutral electrodes for electrosurgical, reusable and single use
- Electrode holder, electrosurgical
- Electrode holder, electrosurgical, sterile
- Electrode, electrosurgical, active electrode
- Electrode, electrosurgical, active electrode, sterile
- Electrode, electrosurgical, active electrode, hand actuated
- Electrode, electrosurgical, active electrode, hand actuated, sterile
- Electrode, electrosurgical, active electrode, footswitch actuated
- Electrode, electrosurgical, active electrode, footswitch actuated, sterile
- Electrode, electrosurgical, active electrode, hand actuated, single use
- Adapter for Electrosurgery
- Coagulator unit, argon (argon plasma coagulator)
- Instruments for argon coagulation, single use
- Instruments for argon coagulation, reusable, hand actuated
- Instruments for argon coagulation, reusable, footswitch actuated
- Waterjet dissector
- Instruments for waterjet dissector, single use
- Instruments for waterjet dissector, applicator
- Cryosurgical unit



Ruth Delbeck-Bayer  
DEKRA Certification GmbH, Stuttgart, 2021-05-21  
Notified Body ID-number: 0124