

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

**REGER Medizintechnik GmbH
Gewerbestraße 10
78667 Villingendorf
Germany**

for the scope

**Instruments and accessories for surgery and electro surgery
(see attachment)**

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

**Annex II – excluding Section 4
of the Council Directive 93/42/EEC**

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2018-07-30
Valid until	2023-07-29
Registration no.	D1228500011
Report no.	P18-00423-117158
Stuttgart	2018-07-27



Head of Certification Body



Attachment of the certificate

No. D1228500011

Date 2018-07-27

Page 1 of 1

Product category	Product	Class	Product code
Instruments and accessories for surgery and electro surgery	HF-Handles (controllable)	IIb	11-499
	HF-Handles (non-controllable)	IIa	11-499
	Bipolar forceps	IIb	11-502
	HF-Electrodes, monopolar and bipolar	IIb	15-579
	Micropump (CapnoPen)	IIa	16-722
	Bipolar Scissors/ Clamp-Scissors	IIb	16-860
	HF-Neutral Electrodes	IIb	11-500



A handwritten signature in blue ink, appearing to read "n h c", is positioned above a horizontal line.

Head of Certification Body

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-Z5-00, the decision dated 2018-06-13 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2018-07-13 to 2023-07-12

Registration No.: 50954-16-04

Ruth Delbeck

Ruth Delbeck, Bayreuth

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-06-13
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten www.zlgf.de
ZLG-BS-295.10.02

Annex to the EC Certificate No. 50954-16-04

Valid from 2018-07-13 to 2023-07-12

Revision status of the annex: 0 dated 2018-07-13

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, 2018-06-13
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de