

# 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

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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



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# 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

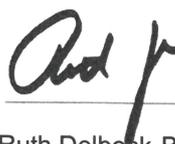
Devices/device categories included in the certificate:

## 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

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