# **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
 2021-04-19

 Valid until
 2023-07-29

 Registration no.
 D1228500014

 Report no.
 P20-01831-190588

 Stuttgart
 2021-04-19

Head of Certification Body





Internet: http://www.mdc-ce.de

#### Attachment of the certificate

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Product category	Product	Class	Product code
Instruments and accessories for electro surgery	HF-Handles (controllable)	IIb	11-499
	HF-Handles (non-controllable)	lla	11-499
	HF-Neutral Electrodes	IIb	11-500
	Bipolar Forceps	IIb	11-502
	HF-Electrodes, monopolar and bipolar, sterile	IIb	15-579
	HF-Electrodes, monopolar and bipolar, non-sterile	IIb	15-579
	Bipolar Scissors/ Clamp-Scissors	IIb	16-860
Instruments and accessories for surgery	Nebulizer, sterile and non-sterile for single use	lla	12-712
	Shaver sterile and non-sterile	lla	17-918
	Bur sterile and non-sterile	lla	17-995



**Head of Certification Body** 

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