

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



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-246.10.06

Attachment of the certificate

No. D1228500014

Date 2021-04-19

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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)	IIa	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	IIa	12-712
	Shaver sterile and non-sterile	IIa	17-918
	Bur sterile and non-sterile	IIa	17-995



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