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.

Digitally signed by Ermicev Alexandr
Date: 2019.11.29 16:03:39 EET
Reason: MoldSign Signature
Location: Moldova

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

medical device certification mdc

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

mdc medical device certification GmbH
Kriegerstraße 6
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Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

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

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Certificate

mdc medical device certification GmbH
certifies that

REGER
+medizintechnik gmbh

Gewerbestraße 10
78667 Villingendorf
Germany

for the scope

development, manufacturing and sales of instruments and accessories for surgery and electro surgery

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2018-07-30
Valid until	2021-07-29
Registration no.	D1228500010
Report no.	P18-00423-117154
Stuttgart	2018-07-16

Head of Certification Body

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

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