

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that

**REMA Medizintechnik GmbH  
In Breiten 10  
78589 Dürbheim  
Germany**

for the scope

**active surgery equipment for endoscopy,  
instruments for endoscopy and HF surgery and implants  
(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	2019-06-19
Valid until	2023-07-01
Registration no.	D1040900008
Report no.	P19-00477-150121
Stuttgart	2019-06-19



Head of Certification Body



**Attachment of the certificate**

**No. D1040900008**

Date 2019-06-19

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Product category	Product	Class	Product code
Implants	Interference screw	IIb	16-101
Instruments for endoscopy	Arthroscopy instruments Arthroscopy optic	IIa	10-198
	Cystoscope instruments Cystoscope optic	IIa	11-112
	Hysteroscope instruments Hysteroscope optic	IIa	12-081
	Laparoscope optic	IIa	12-291
	Veress needle	IIa	12-750
	Resectoscope instruments (sheaths)	IIa	13-335
	Sinuscope	IIa	13-396
	Thoracoscope	IIa	14-047
	Suction irrigation cannula	IIa	15-206
	Trocar / Trocar sleeves	IIa	15-260
	Shaver blades (sterile/non sterile)	IIa	17-117
	Ureterorenoscope	IIa	17-690
	Instruments for HF surgery	HF Handles, controlled	IIb
Turning and dismountable instruments with HF connection		IIb	11-779
Resectoscope instruments (working elements)		IIb	13-335
Electrodes HF surgery		IIb	15-579
Electrodes HF surgery, active electrodes		IIb	16-860



Head of Certification Body

