

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that

**Tekno-Medical Optik-Chirurgie GmbH**  
**Sattlerstraße 11**  
**78532 Tuttlingen**  
**Germany**

for the scope

**instruments for high frequency surgery, endoscopic instruments and  
devices with accessories, suction- and irrigation units, battery operated units  
(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	2018-07-05
Valid until	2023-07-04
Registration no.	D1043500071
Report no.	P18-00452-124020
Stuttgart	2018-06-27



Head of Certification Body



**Attachment of the certificate**

**No. D1043500071**

Date 2018-06-27

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Product category	Product	Class	Product code
Battery operated units	Drill, battery operated and accessories	IIa	16-868
	Saw, battery operated and accessories		
Instruments for high frequency surgery	Electrosurgical units with accessories	IIb	11-490
	HF-handles	IIb	11-499
	Bipolar coagulation forceps, bipolar coagulation grippers	IIb	11-502
	Bipolar and monopolar forceps		
	Smoke evacuators	IIa	11-814
	Monopolar and bipolar electrodes	IIb	16-206
Coagulation electrodes, coagulation grippers, scissors			
Electrodes, electrosurgical, sterile and non sterile	IIb	16-860	
Bipolar coagulation forceps EVO II			
Bipolar clamps and scissors-clamps			
Monopolar laparoscopic electrodes			
Endoscopic instruments and devices with accessories	Laparoscopic instruments for electrosurgery	IIb	11-502
	Resectoscopes monopolar and bipolar	IIb	13-335
	Insufflators, laparoscopy with accessories	IIb	16-849
	Arthroscopic shaver systems with accessories	IIa	17-918
	Morcellator handpiece complete	IIa	11-333
	Morcellator	IIa	11-333
Suction- and irrigation units	Suction- /irrigation unit MULTI PUMP and accessories	IIa	17-424
	Pump for arthroscopy ART PUMP II and accessories		
	Pump for arthroscopy ART PUMP II D and accessories		
	Pump for hysteroscopy HYS PUMP II and accessories		
	Irrigation pump SPINE PUMP II and accessories		
	Pump for urology URO PUMP II and accessories		



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