

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, orthopedic burs,
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	2016-07-26
Valid until	2018-07-04
Registration no.	D1043500064
Report no.	P16-00596-71647
Stuttgart	2016-07-26



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. D1043500064

Date 2016-07-26

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Product category	Product	Class	Product code	
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			
Endoscopic instruments and devices with accessories	Electrodes, electrosurgical, sterile and non sterile	IIb	16-860	
	Bipolar coagulation forceps EVO II			
	Bipolar clamps and scissors-clamps			
	Monopolar laparoscopic electrodes			
	Conex Medicbus control unit	IIb	11-009	
	Laparoscopic instruments for electrosurgery	IIb	11-502	
	Resectoscopes monopolar and bipolar	IIb	13-335	
Suction- and irrigation units	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	
	Irrigation/distention systems with accessories (ARTpump)	IIa	17-233	
	Suction- and irrigation units	Suction and irrigation devices with accessories	IIa	17-424
		Suction- /irrigation unit MULTI PUMP and accessories		
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				
Orthopedic burs	Orthopedic burs	IIa	17-995	
Battery operated units	Drill, battery operated and accessories	IIa	16-868	
	Saw, battery operated and accessories			



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