

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	2017-06-07
Valid until	2018-07-04
Registration no.	D1043500067
Report no.	P15-00193-40214
Stuttgart	2017-06-07



Head of Certification Body



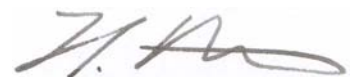
Attachment of the certificate

No. D1043500067

Date 2017-06-07

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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
	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			
Pump for urology URO 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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