

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	2021-05-20
Valid until	2023-07-04
Registration no.	D1043500083
Report no.	P21-00826-205644
Stuttgart	2021-05-20



Head of Certification Body



Attachment of the certificate

No. D1043500083

Date 2021-05-20

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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 forceps	IIb	11-502
	Monopolar and bipolar electrodes Coagulation electrodes, coagulation grippers, scissors	IIb	16-206
	Electrodes, electrosurgical, sterile and non sterile Bipolar coagulation forceps EVO II Bipolar clamps and scissors-clamps Monopolar laparoscopic electrodes	IIb	16-860
	Pistol handle, with HF	IIa	15-206
Endoscopic instruments and devices with accessories	Pistol handle, without HF	IIa	15-206
	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
Suction- and irrigation units	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 Pump for urology URO PUMP II and accessories	IIa	17-424
Battery operated units	Drill, battery operated and accessories Saw, battery operated and accessories	IIa	16-868



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