

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

**surgical instruments, implants for osteosynthesis, retractors,
endoscopic instruments with accessories, aneurysm clips
(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	2020-07-20
Valid until	2023-07-04
Registration no.	D1043500080
Report no.	P20-00298-170161
Stuttgart	2020-07-20



Head of Certification Body



Attachment of the certificate

No. D1043500080

Date 2020-07-20

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Product category	Product	Class	Product code
Surgical instruments	Electrode holders	Ila	11-497
endoscopic instruments with accessories	Arthroscopes/sinusscopes	Ila	10-198
	Sheaths for hysteroscopy	Ila	10-580
	Sheaths for cystoscopes	Ila	11-114
	Oesophagosscopes	Ila	11-603
	Hysteroscopes	Ila	12-081
	Laparoscopes	Ila	12-291
	Needles, pneumoperitoneal	Ila	12-750
	Otoscopes	Ila	12-849
	Thoracoscopes	Ila	14-047
	Bronchoscopes, rigid	Ila	15-074
	Laryngoscopes, rigid	Ila	15-076
	Suction and irrigation cannulas with handle	Ila	15-206
	Suction and irrigation cannulas	Ila	10-566
	Sheaths for arthroscopy	Ila	15-260
	Trocars (endoscopy)		
	Nephroscope, rigid	Ila	15-290
	Sheaths for nephroscopy	Ila	15-591
	Tocar sleeve	Ila	16-146
	Cystoscopes, rigid	Ila	17-145
	Spinalscope	Ila	17-575
Ureterorenoscopes	Ila	17-690	
Instruments for laser guidance, endoscopic	Ila	18-097	
Implants for osteosynthesis	Plates, bone steel and titanium	IIb	13-050
	Nails, bone steel and titanium	IIb	16-078
	Screws, bone steel and titanium	IIb	16-101
	Clamps, bone	IIb	16-103
	Drill wires, bone Cerclage wire	IIb	16-104



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Product category	Product	Class	Product code
Retractors	Retractors, Self-Retaining	Ila	13-390
	Spreaders, Rib	Ila	13-709
	Tongs, Skull	Ila	14-064
Aneurysm clips	Aneurysm clip (sterile and non-sterile)	III	10-905



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