

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,
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	2017-06-07
Valid until	2018-07-04
Registration no.	D1043500066
Report no.	P15-00193-40212
Stuttgart	2017-06-07



Head of Certification Body



Attachment of the certificate

No. D1043500066

Date 2017-06-07

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Product category	Product	Class	Product code
Aneurysm clips	Aneurysm clip (sterile and non-sterile)	III	10-905
Surgical instruments	Medullary canal reamers	IIa	11-338
	Electrode holders, electrosurgical	IIa	11-497
	Elevators, other	IIa	15-218
Endoscopic instruments with accessories	Arthroscopes/sinuscopes	IIa	10-198
	Cannulae, uterine	IIa	10-580
	Sheaths for cystoscopes	IIa	11-114
	Oesophagoscopes	IIa	11-603
	Hysteroscopes	IIa	12-081
	Laparoscopes	IIa	12-291
	Needles, pneumoperitoneal	IIa	12-750
	Otoscopes	IIa	12-849
	Thoracoscopes	IIa	14-047
	Bronchoscopes, rigid	IIa	15-074
	Laryngoscopes, rigid	IIa	15-076
	Cannulae, other	IIa	15-206
	Sheaths for arthroscopy	IIa	15-260
	Trocars, other		
	Nephroscope, rigid	IIa	15-290
	Nephroscopy sheaths	IIa	15-591
	Elevators, uterine	IIa	15-677
	Sleeves	IIa	16-146
	Cystoscopes, rigid	IIa	17-145
	Spinalscope	IIa	17-575
	Urethrotomes	IIa	17-633
	Ureterorenoscopes	IIa	17-690
	Instruments for laser guidance, endoscopic	IIa	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
	Staples, bone	IIb	16-103
	Wires, bone	IIb	16-104



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