

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	2014-12-16
Valid until	2018-07-04
Registration no.	D1043500061
Report no.	P14-01693-31947
Stuttgart	2014-12-16



Head of Certification Body



Attachment of the certificate

No. D1043500061

Date 2014-12-16

Page 1 of 2

Product category	Product	Class	Product code
Aneurysm clips	Aneurysm clip (sterile and non-sterile)	III	10-905
Surgical instruments	Medullary canal reamers	Ila	11-338
	Electrode holders, electrosurgical	Ila	11-497
	Metzenbaum scissors sterile	Iib	11-502
	Elevators, other	Ila	15-218
Endoscopic instruments with accessories	Arthroscopes/sinuscopes	Ila	10-198
	Spinal endoscope		
	Sheaths for spinal endoscope		
	Cannulae, uterine	Ila	10-580
	Sheaths for cystoscopes	Ila	11-114
	Dilation set for spinal endoscopy	Ila	11-254
	Oesophagoscopes	Ila	11-603
	Hysteroscopes	Ila	12-081
	Laparoscopes	Ila	12-291
	Needles, pneumoperitoneal	Ila	12-750
	Otoscopes	Ila	12-849
	Pistole handle	Ila	13-845
	Suction/irrigation tubes, suction/irrigation pistol handle		
	Valve handle, suction/irrigation handle with 2 trumpet valves		
	Thorascopes	Ila	14-047
	Tubing set, sterile, for arthroscopy pump	Ila	14-247
	Bronchoscopes, rigid	Ila	15-074
	Laryngoscopes, rigid	Ila	15-076
	Cannulae, other	Ila	15-206
	Sheaths for arthroscopy	Ila	15-260
	Trocars, other		
	Nephroscope, rigid	Ila	15-290
	Nephroscopy sheaths	Ila	15-591
	Elevators, uterine	Ila	15-677
	Sleeves	Ila	16-146
	Cystoscopes, rigid	Ila	17-145


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Page 2 of 2

Product category	Product	Class	Product code
Endoscopic instruments with accessories	Spinalscope	Ila	17-575
	Urethrotomes	Ila	17-633
	Ureterorenoscopes	Ila	17-690
	Instruments for laser guidance, endoscopic	Ila	18-097
Implants for osteosynthesis	Plates, bone steel and titanium, Mini-Micro-Medium plate systems	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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