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 Valid until
 2019-06-28

 Valid until
 2023-07-04

 Registration no.
 D1043500077

 Report no.
 P18-01364-150805

 Obstance
 2024-00-00-00

Stuttgart 2019-06-28

Head of Certification Body





Internet: http://www.mdc-ce.de

Attachment of the certificate

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Product category	Product	Class	Product code
Surgical instruments	Electrode holders	lla	11-497
endoscopic instruments with accessories	Arthroscopes/sinuscopes	lla	10-198
	Suction and irrigation cannulas	lla	10-566
	Sheaths for hysteroscopy	lla	10-580
	Sheaths for cystoscopes	lla	11-114
	Oesophagoscopes	lla	11-603
	Hysteroscopes	lla	12-081
	Laparoscopes	lla	12-291
	Needles, pneumoperitoneal	lla	12-750
	Otoscopes	lla	12-849
	Thoracoscopes	lla	14-047
	Bronchoscopes, rigid	lla	15-074
	Laryngoscopes, rigid	lla	15-076
	Suction and irrigation cannulas with handle	lla	15-206
	Sheaths for arthroscopy	lla	15-260
	Trocars (endoscopy)		
	Nephroscope, rigid	lla	15-290
	Sheaths for nephroscopy	lla	15-591
	Tocar sleeve	lla	16-146
	Cystoscopes, rigid	lla	17-145
	Spinalscope	lla	17-575
	Urethrotomes	lla	17-633
	Ureterorenoscopes	lla	17-690
	Instruments for laser guidance, endoscopic	lla	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	Ilb	16-101
	Clamps, bone	IIb	16-103
	Drill wires, bone	Ilb	16-104
	Cerclage wire		
Aneurysm clips	Aneurysm clip (sterile and non-sterile)	Ш	10-905



Head of Certification Body

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