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 Registration no. Report no. Stuttgart 2018-11-19 2023-07-04 D1043500075 P18-00452-133946 2018-11-19

Head of Certification Body





mdc medical device certification GmbH Kriegerstraße 6 D-70191 Stuttgart, Germany Phone: +49-(0)711-253597-0 Fax: +49-(0)711-253597-10 Internet: http://www.mdc-ce.de

For electronic publication only

Attachment of the certificate

No. D1043500075

Date 2018-11-19

Page 1 of 1

Product category	Product	Class	Product code
Surgical instruments	Electrode holders	lla	11-497
endoscopic instruments with accessories	Arthroscopes/sinuscopes	lla	10-198
	Cannulae, uterine	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
	Cannulae, other	lla	15-206
	Sheaths for arthroscopy Trocars, other	lla	15-260
	Nephroscope, rigid	lla	15-290
	Nephroscopy sheaths	lla	15-591
	Sleeves	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,	llb	13-050
	Nails, bone steel and titanium	llb	16-078
	Screws, bone steel and titanium	Ilb	16-101
	Staples, bone	llb	16-103
	Wires, bone	llb	16-104
Aneurysm clips	Aneurysm clip (sterile and non-sterile)	III	10-905



mdc medical device certification GmbH Kriegerstraße 6 D-70191 Stuttgart, Germany Phone: +49-(0)711-253597-0 Fax: +49-(0)711-253597-10 Internet: http://www.mdc-ce.de

Head of Certification Body

For electronic publication only