

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	2020-12-04
Valid until	2023-07-04
Registration no.	D1043500081
Report no.	P20-00629-174693
Stuttgart	2020-12-04




Head of Certification Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-246.10.06

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>

Attachment of the certificate

No. D1043500081

Date 2020-12-04

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Product category	Product	Class	Product code
Surgical instruments	Electrode holders	Ila	11-497
Endoscopic instruments with accessories	Arthroscopes/sinuscopes	Ila	10-198
	Suction and irrigation cannulas	Ila	10-566
	Sheaths for cystoscopes	Ila	11-114
	Oesophagoscopes	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
	Sheaths for arthroscopy Trocars (endoscopy)	Ila	15-260
	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
	Screws, bone steel and titanium	IIb	16-101
	Drill wires, bone Cerclage wire	IIb	16-104
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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**Supplement to the Certificate
according to 93/42/EEC, Annex II, excluding 4
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Manufacturer	Tekno-Medical Optik-Chirurgie GmbH
Certificate	No. D1043500081 Date: 2020-12-04 surgical instruments, implants for osteosynthesis, retractors, endoscopic instruments with accessories, aneurysm clips (see attachment)
Products concerned	Implants for osteosynthesis
Intended change	Removal of the products: Bone plates and bone screws of steel and titanium in the product group: Implants for osteosynthesis
Review report no.	P21-00826-228897

The intended change is in compliance with the requirements of the Directive 93/42/EEC.

This supplement is valid only in conjunction with the aforementioned Certificate.

The aforementioned Certificate is valid only in conjunction with this supplement.

This supplement is valid until:	2023-07-04
Registration no.:	D1043500085
Stuttgart	2022-02-08




Head of Notified Body