

ENDOSCOPY GERÄTE - UNITS

Glasfaser-Kaltlichtkabel *Fiberoptic cables* Cables de lumière froide *Cables de fibra óptica* Cavi luce in fibra ottica

autoclavable 134°C / 273°F



			Xenon	Xenon (TEKNO/Storz)	LED	LED (TEKNO/Storz)
< Ø 5mm	Ø 3.5 mm	1800 mm	tk 39522-18	tk 39532-18	tk 39562-18	tk 39564-18
	Ø 3.5 mm	2300 mm	tk 39522-23	tk 39532-23	tk 39562-23	tk 39564-23
	Ø 3.5 mm	3000 mm	tk 39522-30	tk 39532-30	tk 39562-30	tk 39564-30
	-					
	Ø 4.8 mm	1800 mm	tk 39523-18	tk 39533-18	tk 39563-18	tk 39565-18
≥Ø5mm	Ø 4.8 mm	2300 mm	tk 39523-23	tk 39533-23	tk 39563-23	tk 39565-23
	Ø 4.8 mm	3000 mm	tk 39523-30	tk 39533-30	tk 39563-30	tk 39565-30
für Optiken <i>for scopes</i>	Faserbündel <i>Fiber bundle</i>	Länge <i>Length</i>	ohne Adapter without adapters	Kabel mit 2 Adaptern cable with 2 adapters	ohne Adapter <i>without adapters</i>	komplett mit 2 Adaptern complete with 2 adapters

- Speziell für XENON & LED-Lichtquellen

Unsere Hochleistungs-Kaltlichtkabel werden durch ein Spezialverfahren am Lichteintritt komprimiert und

können so mehr Licht transportieren. Sie sind speziell für hochenergetische Xenon & LED-Lichtquellen geeignet!

- adaptierbar an alle gängigen Systeme mittels Adapter

- Especially for XENON & LED light sources

Our high density fiber optic cables are specially prepared at the light entrance for transporting more light. They are suited for high energy XENON & LED light sources.

- suitable for all common systems with adapter



Certificate

mdc medical device certification GmbH certifies that

Tekno-Medical Optik-Chirurgie GmbH Sattlerstraße 11 78532 Tuttlingen Germany

for the scope

development, manufacturing and distribution of surgical instruments and accessories, endoscopic instruments and devices with accessories, dental instruments, instruments and implants for osteosynthesis, OR-lamps, OR-tables and accessories and repair service for rigid endoscopes

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from Valid until Registration no. Report no. Stuttgart 2021-07-05 2024-07-04 D1043500084 P21-00826-205639 2021-06-23

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

mdc medical device certification GmbH

Notified Body 0483 herewith certifies that

Tekno-Medical Optik-Chirurgie GmbH Sattlerstraße 11 78532 Tuttlingen Germany

for the scope

sterile scalpel knives UMDNS 12-252; shaver blades, UMDNS 17-117; saw blades for orthopedics, UMDNS 13-447

has introduced and applies a

Quality System

for the manufacture of the products concerned and carries out a final inspection as specified in Annex V, Section 3.

The mdc audit has proven that this quality system meets all requirements according to

Annex V – Section 3 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex V, Section 4.

Valid from Valid until Registration no. Report no. Stuttgart 2018-07-05 2023-07-04 D1043500072 P18-00452-117481 2018-06-27

ahl.

Head of Certification Body





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mdc medical device certification GmbH

Notified Body 0483 herewith grants

Tekno-Medical Optik-Chirurgie GmbH Sattlerstraße 11 78532 Tuttlingen Germany

for the scope

aneurysm clip (sterile and non-sterile, temporary and permanent, made of titanium and steel), UMDNS 10-905

the

EC Design Examination Certificate

The examination of the design of the product by mdc has proven that the design meets the requirements according to

Annex II – Section 4 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

This certificate is only valid in connection with a valid mdc certificate according to Annex II – excluding section 4 for the above mentioned products.

> Valid from Valid until Registration no. Report no. Stuttgart

2018-11-22 2023-11-22 D1043500074 P18-00455-117538 2018-11-22

Head of Certification Body





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mdc medical device certification GmbH

Notified Body 0483 herewith certifies that

Tekno-Medical Optik-Chirurgie GmbH Sattlerstraße 11 78532 Tuttlingen Germany

for the scope

instruments for high frequency surgery, endoscopic instruments and devices with accessories, suction- and irrigation units, battery operated units (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 D1043500076 P18-00452-133952 2018-11-19

Head of Certification Body





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Attachment of the certificate

No. D1043500076

Date 2018-11-19

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Product category	Product		Product code
Battery operated units	Drill, battery operated and accessories Saw, battery operated and accessories	lla	16-868
	Electrosurgical units with accessories		11-490
	HF-handles		11-499
lastuursente for birth	Bipolar coagulation forceps, bipolar coagulation grippers Bipolar and monopolar forceps	llb	11-502
Instruments for high frequency surgery	Monoplar and bipolar electrodes Coagulation electrodes, coagulation grippers, scissors	llb	16-206
	Electrodes, electrosurgical, sterile and non sterile Bipolar coagulation forceps EVO II Bipolar clamps and scissors-clamps Monopolar laparoscopic electrodes	llb	16-860
	Morcellator handpiece complete	lla	11-333
	Morcellator	lla	11-333
Endoscopic instruments and devices with	Arthroscopic shaver systems with accessories	lla	17-918
accessories	Laparoscopic instruments for electrosurgery	llb	11-502
	Resectoscopes monoplar and bipolar	llb	13-335
	Insufflators, laparoscopy with accessories	llb	16-849
Suction- and irrigation units	Suction- /irrigation unit MULTI PUMP and accessories Pump for arthroscopy ART PUMP II and accessories Pump for arthroscopy ART PUMP II D and accessories Pump for hysteroscopy HYS PUMP II and accessories Pump for urology URO PUMP II and accessories	lla	17-424



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Head of Certification Body

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Notified Body 0483 herewith certifies that

Tekno-Medical Optik-Chirurgie GmbH Sattlerstraße 11 78532 Tuttlingen Germany

for the scope

instruments for high frequency surgery, endoscopic instruments and devices with accessories, suction- and irrigation units, battery operated units (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 2021-05-20 2023-07-04 D1043500083 P21-00826-205644 2021-05-20

Head of Certification Body





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Attachment of the certificate

No. D1043500083

Date 2021-05-20

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Product category	Product	Class	Product code
Instruments for high	Electrosurgical units with accessories		11-490
frequency surgery	HF-handles		11-499
	Bipolar coagulation forceps Bipolar forceps	llb	11-502
	Monoplar and bipolar electrodes Coagulation electrodes, coagulation grippers, scissors	llb	16-206
	Electrodes, electrosurgical, sterile and non sterile Bipolar coagulation forceps EVO II Bipolar clamps and scissors-clamps Monopolar laparoscopic electrodes	llb	16-860
	Pistol handle, with HF	lla	15-206
Endoscopic instruments and	Pistol handle, without HF	lla	15-206
devices with accessories	Laparoscopic instruments for electrosurgery	llb	11-502
	Resectoscopes monoplar and bipolar	llb	13-335
	Insufflators, laparoscopy with accessories	llb	16-849
	Arthroscopic shaver systems with accessories	lla	17-918
Suction- and irrigation units	Suction- /irrigation unit MULTI PUMP and accessories Pump for arthroscopy ART PUMP II and accessories Pump for arthroscopy ART PUMP II D and accessories Pump for hysteroscopy HYS PUMP II and accessories Pump for urology URO PUMP II and accessories	Ila	17-424
Battery operated units	Drill, battery operated and accessories Saw, battery operated and accessories	lla	16-868



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Head of Certification Body