

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 5mm	Ø 4.8 mm	1800 mm	tk 39523-18	tk 39533-18	tk 39563-18	tk 39565-18
	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 <i>without adapters</i>	Kabel mit 2 Adaptern <i>cable with 2 adapters</i>	ohne Adapter <i>without adapters</i>	komplett mit 2 Adaptern <i>complete with 2 adapters</i>

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



Head of Certification Body



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

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



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

EC Certificate

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	2018-11-22
Valid until	2023-11-22
Registration no.	D1043500074
Report no.	P18-00455-117538
Stuttgart	2018-11-22



Head of Certification Body



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

**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	2018-11-19
Valid until	2023-07-04
Registration no.	D1043500076
Report no.	P18-00452-133952
Stuttgart	2018-11-19



Head of Certification Body



Attachment of the certificate

No. D1043500076

Date 2018-11-19

Page 1 of 1

Product category	Product	Class	Product code
Battery operated units	Drill, battery operated and accessories Saw, battery operated and accessories	Ila	16-868
Instruments for high frequency surgery	Electrosurgical units with accessories	Ilb	11-490
	HF-handles	Ilb	11-499
	Bipolar coagulation forceps, bipolar coagulation grippers Bipolar and monopolar forceps	Ilb	11-502
	Monopolar and bipolar electrodes Coagulation electrodes, coagulation grippers, scissors	Ilb	16-206
	Electrodes, electrosurgical, sterile and non sterile Bipolar coagulation forceps EVO II Bipolar clamps and scissors-clamps Monopolar laparoscopic electrodes	Ilb	16-860
	Endoscopic instruments and devices with accessories	Morcellator handpiece complete	Ila
Morcellator		Ila	11-333
Arthroscopic shaver systems with accessories		Ila	17-918
Laparoscopic instruments for electrosurgery		Ilb	11-502
Resectoscopes monopolar and bipolar		Ilb	13-335
Insufflators, laparoscopy with accessories		Ilb	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	Ila	17-424



Head of Certification Body



Konformitätserklärung Declaration of Conformity

im Sinne der Richtlinie 93/42 EWG: Anhang VII
according to the Medical Device Directive 93/42 /EEC: Annex VII

Wir, die Firma
We, the company

Tekno – Medical
Optik-Chirurgie GmbH
Sattlerstr. 11
78532 Tuttlingen

erklären in alleiniger Verantwortung, dass folgende Produktgruppe
declare on our sole responsibility that the product group

Medizinprodukte / medical devices

Produktnummer: siehe Anhang Produktliste zur Konformitätserklärung
Item numbers: see attached list Product list Declaration of Conformity

Klassifizierung nach 93/42/EWG nach Anhang IX: Klasse IIa
Classification according to 93/42/EEC Annex IX: class IIa

allen Anforderungen der Richtlinie 93/42/EWG, zuletzt geändert durch die EU-Richtlinie 2007/47EG entsprechen.
meet all the requirements of the Directive 93/42/EEC, last changed by the EU-Directive 2007/47/EC.

Zusätzliche Angaben/ Additional information:


Die Entwicklung, Herstellung und der Vertrieb der Produkte wird durch ein QM-System gemäß den Forderungen der ISO 13485, des Medizinproduktegesetzes und der FDA unterstützt.
Development, manufacturing and distribution of the medical devices are supported by a QM-system in according with the requirements of ISO 13485, the act on medical devices and the FDA.

Das QM-System wird überwacht durch die Benannte Stelle 0483 mdc medical device certification GmbH, Kriegerstr. 6, D-70191 Stuttgart, Germany.
The QM-system is controlled by the notified body 0483 mdc medical device certification GmbH, Kriegerstr. 6, D-70191 Stuttgart, Germany.

gültig bis 04.07.2023
valid untill 04.07.2023

Ort: Tuttlingen
Place:

Datum: 05.07.2018
Date:



Geschäftsführer
Managing Director
-Florian Mattes-

Produktliste zur Konformitätserklärung
 Product List Declaration of Conformity

UMDNS UMDNS	UMDNS Beschreibung	UMDNS-Description	Klasse Class	Regel Rule
10-198	Arthroskop	Arthroscopes	KL2A	7
10-580	Kanüle, Uterin	Cannulae, Uterine	KL2A	5
11-114	Zystourethroskop	Cystourethroscope	KL2A	7
11-333	Drillbohrer, zervikal	Drills, cervikal	KL2A	9
11-497	Elektrodenhalter, HF-Chirurgie	Electrode Holders, Electrosurgical	KL2A	5
11-603	Ösophagoskop	Esophagoscopes	KL2A	7
12-081	Hysteroskop	Hysteroscopes	KL2A	7
12-252	Messer, Skalpell	Knives, Scalpel	KL2A	6
12-291	Laparoskop	Laparoscopes	KL2A	7
12-750	Nadel, pneumoperitoneal	Needles, Pneumoperitoneal	KL2A	7
12-849	Otoskop	Otoscopes	KL2A	7
13-447	Klinge, Säge	Sawblade	KL2A	6
14-047	Thorakoskop	Thoracoscopes	KL2A	7
15-074	Bronchoskop, starr	Bronchoscopes, Rigid	KL2A	7
15-076	Laryngoskop, starr	Laryngoscopes, Rigid	KL2A	7
15-206	Kanüle, sonstige	Cannulae, Other	KL2A	7
15-260	Trokar, sonstige	Sleeves	KL2A	7

15-290	Nephroskop, starr	Nephroscopes, rigid	KL2A	7
15-591	Nephroskop	Nephroscopes	KL2A	7
16-146	Hülse	Sleeves	KL2A	7
16-146	Hülse	Sleeves	KL2A	5
16-849	Insufflationsgerät	Insufflators, Laparoscopic	KL2A	2
16-868	Antrieb	Drive	KL2A	9
17-117	Schneideinstrument, Meniskus	Cutters, Meniscus	KL2A	6
17-145	Zystoskop, starr	Cystoscopes, Rigid	KL2A	7
17-424	Absauggerät, endoskopische Spülung	Aspirators, Endoscopic Irrigation	KL2A	11
17-575	Diskektomiesystem, perkutan, automatisch	Percutameous Discectomy System, Automated	KL2A	7
17-633	Urethrotom	Urethrotomes	KL2A	7
17-690	Ureterorenoskop	Ureterorenoscopes	KL2A	6
17-690	Ureterorenoskop	Ureterorenoscopes	KL2A	7
17-918	Rasiersystem, Arthroskopie	Shaver-System	KL2A	2+11
18-097	Laserführung, endoskopisch	Laserguide, endoscopic	KL2A	7

Stand: 29.01.2019

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

**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	2021-05-20
Valid until	2023-07-04
Registration no.	D1043500083
Report no.	P21-00826-205644
Stuttgart	2021-05-20



Head of Certification Body



Attachment of the certificate

No. D1043500083

Date 2021-05-20

Page 1 of 1

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



Head of Certification Body

