

Glasfaser-Kaltlichtkabel *Fiberoptic cables*

Cables de lumière froide
Cables de fibra óptica
Cavi luce in fibra ottica

autoklavierbar / autoclavable
134°C / 273°F - 18 min.



Ø 3.5 mm	1800 mm	tk 39522-18	tk 39532-18
Ø 3.5 mm	2300 mm	tk 39522-23	tk 39532-23
Ø 3.5 mm	3000 mm	tk 39522-30	tk 39532-30
Ø 4.8 mm	1800 mm	tk 39523-18	tk 39533-18
Ø 4.8 mm	2300 mm	tk 39523-23	tk 39533-23
Ø 4.8 mm	3000 mm	tk 39523-30	tk 39533-30
Faserbündel <i>Fiber bundle</i>	Länge <i>Length</i>	Kabel ohne Adapter <i>Cable without adapters</i>	komplett mit 2 Adaptern: TEKNO / Storz <i>complete with 2 adapters: TEKNO / Storz</i>
Fibres	Longueur	Cable sans adaptateurs	complet avec 2 adaptateurs : TEKNO / Storz
Fibras	Longitud	Cable sin adaptadores	completo con 2 adaptadores : TEKNO / Storz
Cavo luce	Lunghezza	Cavo senza adattatori	completo di 2 adattatori: TEKNO / Storz

- Speziell für XENON-Lichtquellen

Unsere Hochleistungs-Kaltlichtkabel werden durch ein Spezialverfahren am Lichteintritt komprimiert und können so mehr Licht transportieren. Sie sind speziell für hochenergetische Xenon-Lichtquellen geeignet!

- adaptierbar an alle gängigen Systeme mittels Adapter

- Especially for XENON 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 light sources.

- suitable for all common systems with adapter

- Spécialement pour sources de lumière de XENON.

Les cables de haute performance sont préparés spécialement à l'entrée de la lumière pour pouvoir transporter plus de lumière. Ils sont appropriés pour les sources énergétiques de Xenon.

- compatibles avec tous systèmes commun avec adaptateurs

- Particularmente para fuentes de luz XENON.

Nuestros cables de fibra óptica de alto rendimiento disponen de un tratamiento especial en la punta proximal para una mayor transmisión de luz. Estos cables son especialmente recomendados para el uso con fuentes de luzes Xenon.

- compatibles con todos equipos corrientes con adaptador

- Speciale per fonti di luce allo XENON

I nostri cavi luce ad alta densità sono preparati in modo speciale nella connessione con la fonte per trasportare maggior quantità di luce. Essi sono costruiti per le fonti di luce XENON ad alta potenzialità.

- fornibili per tutti i sistemi più comuni con adattatori

Adapter
Adapters

Adaptateurs
Adaptadores
Adattatori

Projektor-Seite
Projector-side
Coté projecteur
Fuente de luz
Lato fonte luce



tk 39525-00	tk 39528-00	tk 39527-00	tk 39530-00
Tekno Storz Aesculap	Wolf HSW Dyonics Medicon Comeg Linvatec	Olympus	ACMI Stryker

Endoskop-Seite
Endoscope-side
Coté endoscope
Endoscopio
Lato endoscopio



tk 39525-10	tk 39528-20	tk 39530-10
Tekno Storz Aesculap Olympus	Wolf HSW Dyonics Medicon Comeg Stryker	ACMI Linvatec



Weitere Adapter auf Anfrage erhältlich
Further adapters available on request

Autres adaptateurs sont disponibles sur demande
Otros adaptadores son disponibles según demanda
Altri adattatori a richiesta

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



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	11-333
	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:

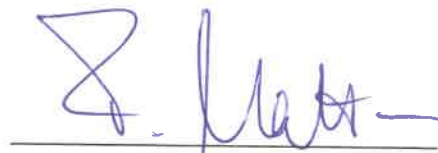
Die Entwicklung, Herstellung und der Vertrieb der Produkte wird durch ein QM-System gemäß den Forderungen der ISO 13485, des Medizinproduktegesetzes und der FDA unterstützt.
Development, manufacturing and distribution of the medical devices are supported by a QM-system in according with the requirements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



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	2018-07-05
Valid until	2021-07-04
Registration no.	D1043500073
Report no.	P18-00452-117473
Stuttgart	2018-06-27



Head of Certification Body



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

