LAPAROSKOPIE - LAPAROSCOPY

ENDOSCOPY

Reinigungs- und Sterilisationszubehör Cleaning and sterilizing accessoires

Accessoires pour nettoyage et stérilisation Accesorios para limpieza y esterilización Accessori per pulizia e sterilizzazione



tk 707-600

Reinigungspistole komplett mit 9 Adaptern Cleaning gun complete with 9 adaptors

Pistolet de nettoyage avec 9 adaptateurs *Pistola de limpieza con 9 adaptatores* Pistola per pulire completa di 9 adattatori

	480 mm
Ø 3 mm	tk 707-604
Ø 5 mm	tk 707-605
Ø 10 mm	tk 707-610

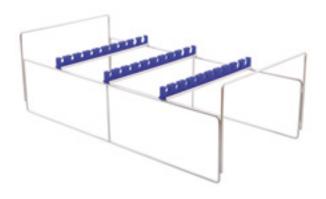
für Ø Rohr for Ø tube pour Ø tube para Ø tubos per Ø tubi Reinigungsbürste (10 Stück)

Cleaning brush (10 pieces)

Brosse de nettoyage (10 pièces)

Cepillo de limpieza (10 piezas)

Spazzolini (10 pezzi)



tk 87295-00

Halter für Laparoskopie-Instrumente (490 x 235 x 160 mm)

Sterilization tray for laparoscopy instruments (490 x 235 x 160 mm)

Support pour instruments de coelioscopie (490 x 235 x 160 mm) Soporte para instrumentos de laparoscopia (490 x 235 x 160 mm) Sostegno per strumenti di laparoscopia (490 x 235 x 160 mm)



tk 87015-20

Siebkorb (510 x 255 x 50 mm) für tk 87295-00 Wire basket (510 x 255 x 50 mm) for tk 87295-00

Panier (510 x 255 x 50 mm) pour tk 87295-00 Cesta (510 x 255 x 50 mm) para tk 87295-00 Cestello (510 x 255 x 50 mm) per tk 87295-00



tk 87200-1F-SI

Container für tk 87295-00 Container for tk 87295-00

Contenaire pour tk 87295-00 Contenedor para tk 87295-00 Container per tk 87295-00

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





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
 2018-11-22

 Valid until
 2023-11-22

 Registration no.
 D1043500074

 Report no.
 P18-00455-117538

 Stuttgart
 2018-11-22

Head of Certification Body





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	lla	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	IIb	11-502
	Monoplar 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
Endoscopic instruments and devices with accessories	Morcellator handpiece complete	lla	11-333
	Morcellator	lla	11-333
	Arthroscopic shaver systems with accessories	lla	17-918
	Laparoscopic instruments for electrosurgery	Ilb	11-502
	Resectoscopes monoplar and bipolar	IIb	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	lla	17-424



Head of Certification Body

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
 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	Ilb	11-502
	Monoplar 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	Ilb	16-860
	Pistol handle, with HF	lla	15-206
Endoscopic instruments and devices with accessories	Pistol handle, without HF	lla	15-206
	Laparoscopic instruments for electrosurgery	IIb	11-502
	Resectoscopes monoplar and bipolar	IIb	13-335
	Insufflators, laparoscopy with accessories	IIb	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



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

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 until2021-07-05
2024-07-04Registration no.
Report no.D1043500084
P21-00826-205639
2021-06-23

Head of Certification Body



