

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

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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



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

