



HD - KOMPAKTEINHEIT

HD - COMPACT UNIT

TEKNO CAM 3700 HD - KOMPAKTEINHEIT

TEKNO CAM 3700 HD - COMPACT UNIT

Die TeknoCam 3700 HD vereint drei hochwertige Geräte für den professionellen Einsatz in einem kompakten Gehäuse. Die Kamera besticht durch ihr brillantes und scharfes HD Bild, ergänzt durch die exzellente Leuchtkraft der LED-Lichtquelle und die Archivierungsmöglichkeit von Bildern und Videos in HD-Qualität.

Dadurch wird die TeknoCam 3700 HD zum Multitalent mit vielfachen Einsatzmöglichkeiten und hoher Funktionalität. Das eingebaute Touchscreen-Display ermöglicht die schnelle, einfache und intuitive Bedienung der verschiedenen Funktionen. Zusätzlich können alle Funktionen auch über ein optional erhältliches Tablet gesteuert werden.

KAMERA / KAMERAKOPF

Die Kontrolleinheit bietet die Möglichkeit zwei verschiedene Kameraköpfe (3 CMOS HD / 1 CMOS HD), die jeweils ein Full-HD (1080p) Bild im Verhältnis 16:9 generieren, anzuschließen. Dadurch kann die TeknoCam 3700 HD in den verschiedensten Bereichen eingesetzt und auf die Bedürfnisse des Anwenders abgestimmt werden. Der ergonomische und robuste Kamerakopf ist autoklavierbar und ist zudem mit vier individuell programmierbaren Tasten ausgestattet.

LICHTQUELLE

Die hohe Leuchtkraft der langlebigen LED-Lichtquelle ist vergleichbar mit einer Xenon 300 Watt. Sie besitzt einen drehbaren Adapter für vier verschiedene Lichtleitkabel (Tekno [Wolf]/Storz/Olympus/ACMI). Dies hat den großen Vorteil, dass bereits vorhandene Lichtleitkabel nicht getauscht bzw. gewechselt werden müssen.

ARCHIVIERUNGSSYSTEM

Zur Komplettierung des Multifunktionaltalents TeknoCam 3700 HD ist auch ein Archivierungssystem vorhanden, das es dem Anwender erlaubt bis zu zwei HD-Videosignale gleichzeitig aufzunehmen. Ebenso besteht auch die Möglichkeit Bilder während des Eingriffes zu erstellen.

Optional kann das Gerät in verschiedene Netzwerke (beispielsweise DICOM / HL7) integriert werden, womit der Import, wie auch der Export von Daten durchgeführt werden kann.

Die TeknoCam 3700 HD verfügt neben verschiedenen Videoausgängen noch über weitere Anschlüsse wie z.B. einen Druckerausgang oder die Möglichkeit einen Fußschalter anzuschließen um Bilder oder Videos zu erstellen.

The TeknoCam 3700 HD combines three high-grade units for professional use in one compact housing. The camera convinces by its brilliant and sharp HD picture, completed by the excellent illuminating power of the LED light-source and the possibility of saving and storing pictures and videos in HD quality.

This makes the TeknoCam 3700 HD to a multi talent with high functionality to be used in various disciplines. The built-in touch-screen offers a quick, simple and intuitive command of the different functions. In addition, all functions may be controlled by an optional tablet-PC.

CAMERA / CAMERA-HEAD

The control unit offers the possibility to connect two different camera-heads (3 CMOS HD / 1 CMOS HD), both generating a full-HD (1080p) picture with a 16:9 ratio. This makes the TeknoCam 3700 HD suitable for several disciplines and adjustable according to the surgeon's specific needs. The ergonomic and robust camera-head is autoclavable and provides four individually programmable buttons.

LIGHTSOURCE

The high illumination power of the durable LED light-source is comparable to a Xenon 300 Watt. It provides a rotatable adapter for four different cold-light cables (Tekno [Wolf]/Storz/Olympus/ACMI), offering the advantage of using already existing light guides.

DATA STORAGE SYSTEM

The incorporated data storage system completes the multi-functional TeknoCam 3700 HD. It offers the possibility of saving two HD-video-signals at a time. Photos can also be taken during an intervention.

Optionally the device can be integrated into various networks (for example DICOM / HL7), making the import as well as the export of data possible.

Beside various video-outputs, the TeknoCam 3700 HD also provides several outputs, e.g. to connect a printer or a foot-switch for starting video-takes or photos

TEKNO CAM 3700 HD - KOMPAKTEINHEIT

TEKNO CAM 3700 HD - COMPACT UNIT



tk 754-2805-009

Netzwerkschnittstelle (DICOM / HL7)
Network interface (DICOM / HL7)

TEKNO CAM 3700 HD

tk 754-2805-000

mit Lichtquelle und Archivierung
with light source and capture system



3 CMOS	tk 754-2805-001
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1 CMOS	tk 754-2805-002
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HD Kamerakopf, autoklavierbar
HD camera head, autoclavable



Tablet	tk 754-2805-010
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f = 16-34 mm	tk 754-3910°
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Zoomobjektiv, autoklavierbar
Zoom objective, autoclavable



f = 15-35 mm	tk 754-3908
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ISO-Focal Zoom, einlegbar
ISO-Focal zoom, soakable

TECHNISCHE DATEN

TECHNICAL DATA

KAMERA

Sensor: 1/3" 3CMOS
Bildpunkte: 1920 x 1080p (FULL HD)
TV-Auflösung: > 1000 Linien
Bildformat: 16 : 9
Lichtempfindlichkeit: 1,5 lux
Signal-Rauschabstand: 58 dB
Digitale Videoausgänge: 1x DVI-D / 2x 3G HD-SDI
Sonstige Ausgänge: 2x Peripherie / 1x Netzwerk
Eingänge: 1x Fußschalter / 1x Tablet / 1x Mikrofon

Sterilisierbarer C-Mount Kamerakopf: Autoklav und Sterrad
4 belegbare Fernbedienknöpfe am Kamerakopf
Speicherung von Benutzereinstellungen
Digital Zoom (2x), in 20 Stufen regelbar
Simultane Aufnahme von zwei Videoquellen

Abmessungen Kontrolleinheit (B x H x T): ca. 40 x 12 x 34 cm
Gewicht Kontrolleinheit: ca. 8.2 kg
Abmessungen Kamerakopf (B x H x T): 8 x 4 x 5 cm
Gewicht Kamerakopf (B x H x T): ca. 0.53 kg

LICHTQUELLE:

Farbtemperatur: 5.700 °K
Lebensdauer: > 30.000h
Lichtleiteranschluss: TEKNO [Wolf] / Storz / Olympus / ACMI
Lichtintensitätsregelung: 0 - 100% einstellbar

ARCHIVIERUNGSSYSTEM:

Daten Ausgänge: 1x USB (Vorderseite) / 3x USB (Rückseite)
Bildauflösung: 1080p JPG
Videoformate: H.264 Encoding
Speicherkapazität (HDD): 256 GB (ca. 70 Stunden)
Fernsteuerung: Kamerakopf oder Fußschalter

DICOM / HL7 (Optional - tk 754-2805-009):
Import / Export von Daten

Netzspannung: 100 - 240 VAC; 50 - 60 Hz
Leistungsaufnahme: 400 VA
Klassifizierung / Typ: 1 / BF
Hergestellt und geprüft nach: IEC 60601-1 Ed. 3.1: 2012
CE-Kennzeichnung entsprechend: RL 93/42/EWG

CAMERA

Sensor: 1/3" 3CMOS
Pixel: 1920 x 1080p (FULL HD)
Resolution: > 1000 lines
Picture format: 16 : 9
Sensitivity: 1.5 lux
Signal noise ratio: 58 dB
Digital video outputs: 1x DVI-D / 2x 3G HD-SDI
Others outputs: 2x Peripherals / 1x Network
Inputs: 1x Footswitch / 1x Tablet / 1x Microphone

Sterilization C-Mount camera head: Autoclave and Sterrad
4 preselectable remote buttons on camera head
Memories to adjust and store applications
Digital zoom (2x), adjustable in 20 steps
Dual channel to record two video signals simultaneously

Dimensions CCU (W x H x D): approx. 40 x 12 x 34 cm
Weight CCU: approx. 8.2 kg
Dimensions camera head (L x W x H): 8 x 4 x 5 cm
Weight camera head with cable: Approx. 0.53 kg

LIGHT SOURCE:

Color temperature: 5.700 °K
Working life: > 30.000h
Light guide adapter: TEKNO [Wolf] / Storz / Olympus / ACMI
Intensity control: 0 - 100% adjustable

CAPTURE DEVICE:

Data outputs: 1x USB (Front) / 3x USB (Rear)
Image resolution: 1080p JPG
Video format: H.264 Encoding
Recording time (HDD): 256 GB (approx. 70 hours)
Remote control: by footswitch or camera head

DICOM / HL7 (Optional - tk 754-2805-009):
Import / Export of data

Line voltage: 100 - 240 VAC; 50 - 60 Hz
Power consumption: 400 VA
Classification / Type: 1 / BF
Produced and tested acc. to : IEC 60601-1 Ed. 3.1: 2012
CE Marking acc. to: MDD 93/42/EEC

Rotatable Continuous Flow

Resectoscope PLASMA, ESG-400

Recommended Set: 26 Fr.



Recommended Set



Alternatives



Options

Telescope

WA2T412A 1x Telescope, 4 mm,
autoclavable, 12°

WA2T430A 1x Telescope, 4 mm,
autoclavable, 30°

WA2T470A 1x Telescope, 4 mm,
autoclavable, 70°

Light-Guide Cable

WA03300A 1x Light-guide cable

Resection Sheaths

A22040A 1x Inner sheath,
standard obturator

A22040T 1x Inner sheath,
obturator with deflecting tip

A22041A 1x Inner sheath,
standard obturator

A22026A 1x Outer sheath, 26 Fr.

A22021A 1x Outer sheath, 27 Fr.

Working Elements

WA22366A 1x Working element, active

WA22367A 1x Working element, passive

WA00014A 1x HF cable

WA00014A 1x HF cable

Single Use Resection Electrodes

WA22302D 1x HF-resection electrode,
12 pcs., loop, 12°, medium

WA22306D 1x HF-resection electrode,
12 pcs., loop, 30°, medium

WA22301D 1x HF-resection electrode,
12 pcs., loop, 12°, small

WA22332D 1x HF-resection electrode,
12 pcs., angled loop, medium

WA22503D 1x HF-resection electrode,
12 pcs., loop, 12°, large

WA22305D 1x HF-resection electrode,
12 pcs., loop, 30°, small

WA22351C 1x HF-resection electrode,
12 pcs., roller

WA22507D 1x HF-resection electrode,
12 pcs., loop, 30°, large

WA22331D 1x HF-resection electrode,
12 pcs., angled loop, small

WA22355C 1x HF-resection electrode,
12 pcs., 45° needle

WA22521C 1x HF-resection electrode,
12 pcs., band, medium, 12°

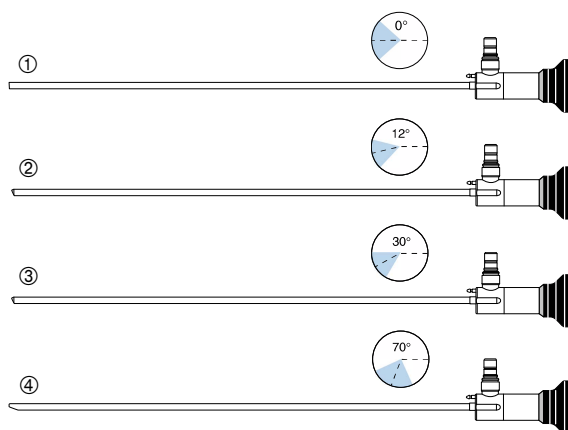
WA22523C 1x HF-resection electrode,
12 pcs., band, medium, 30°

WA22566S 1x HF-resection electrode
"Plasma-OvalButton",
oval button, 24 Fr., 12°-30°,
in saline



OES ELITE Telescopes

autoclave



- ① **WA2T400A** Telescope "OES ELITE",
4 mm, 0°,
HD,
autoclavable
- ② **WA2T412A** Telescope "OES ELITE",
4 mm, 12°,
HD,
autoclavable
- ③ **WA2T430A** Telescope "OES ELITE",
4 mm, 30°,
HD,
autoclavable
- ④ **WA2T470A** Telescope "OES ELITE",
4 mm, 70°,
HD,
autoclavable

We recommend to use our resectoscopes and optical obturators with 12° telescopes.

Delivery includes:

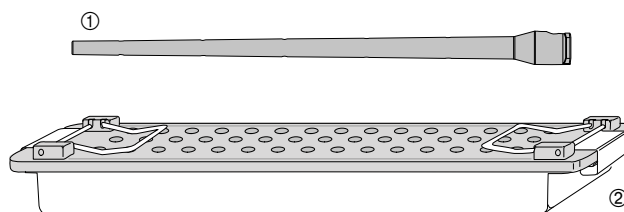
Protective tube WA2P400A.

Light-Guide Cable



- ① **WA03300A** Light-guide cable,
2.8 mm, 3 m,
CF type
- ② **A0460** Light-guide adapter,
for OES 4000 light-guide cables
- ③ **00332** Light-guide adapter,
for Wolf light-guide cables

Accessories

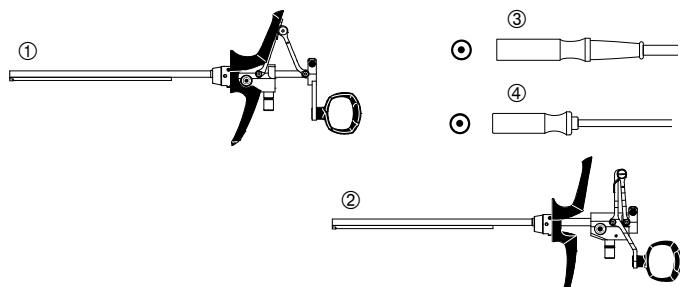


- ① **WA2P400A** Protective tube,
4 mm telescopes
- ② **WA05990A** Instrument tray,
for telescopes

 For plastic instrument trays, see page 637.

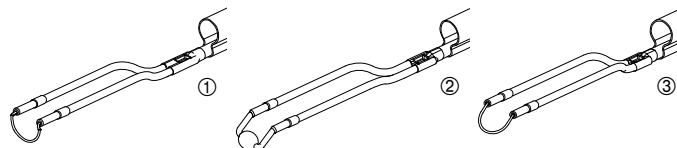


Monopolar Working Elements



- | | | |
|---|-----------------|---|
| ① | WA22066A | Working element, active |
| ② | WA22067A | Working element, passive |
| ③ | A0393 | HF cable, monopolar, 4 m,
for UES-30/-40, Erbe Int., Valleylab (new)
<i>Compatible HF-Unit: Olympus ESG-400</i> |
| | A0391 | HF cable, monopolar, 4 m,
for UES-10/-20, Valleylab (old) |
| | A0392 | HF cable, monopolar, 4 m,
for Erbe T series, Martin, Berchtold |
| ④ | WA00393S | HF cable, monopolar, 4m, single use
<i>Compatible HF-units: ESG-400, UES-40</i> |

Monopolar HF-Resection Electrodes

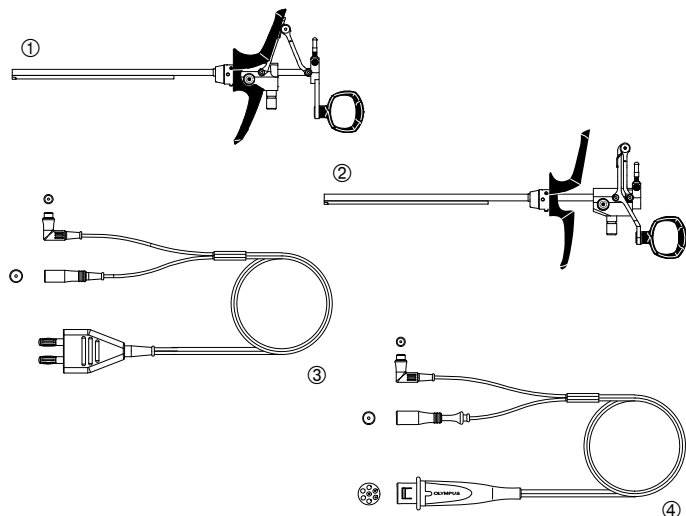


- | | | |
|---|-----------------|--|
| ① | WA22037A | HF-resection electrode,
loop, 12°, reusable, 1 pc. |
| | WA22037C | HF-resection electrode,
loop, 12°, sterile, single use, 12 pcs. |
| ② | WA22038A | HF-resection electrode,
roller, 12°, reusable, 1 pc.
■ For coagulation only |
| | WA22038C | HF-resection electrode,
roller, 12°, sterile, single use, 12 pcs.
■ For coagulation only |
| ③ | WA22039A | HF-resection electrode,
angled loop, 12°, reusable, 1 pc. |
| | WA22039C | HF-resection electrode,
angled loop, 12°, sterile, single use, 12 pcs. |

Long Resectoscope

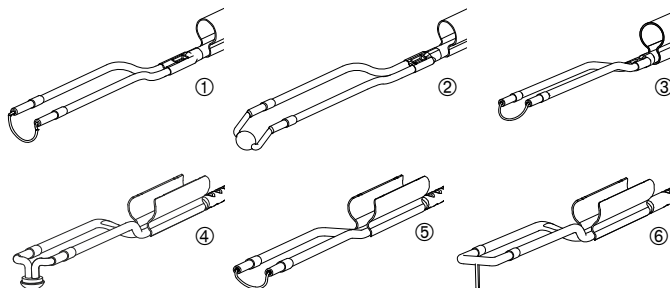
OES Pro
(cont.)

PLASMA Working Elements



- | | | |
|---|-----------------|--|
| ① | WA22366A | Working element,
for resection in saline, active |
| ② | WA22367A | Working element,
for resection in saline, passive |
| ③ | WA00013A | HF cable,
bipolar, 4 m, for UES-40 |
| ④ | WA00014A | HF cable,
bipolar, 4 m, for ESG-400 SALINE mode |

HF-Resection Electrodes for PLASMA



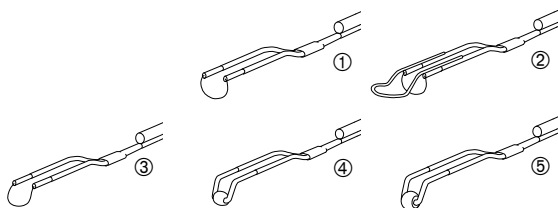
- | | | |
|---|-----------------|---|
| ① | WA22537D | HF-resection electrode, loop, 24 Fr., 0.2 wire, medium, 12°, long, sterile, single use, 12 pcs., for TURis |
| ② | WA22538A | HF-resection electrode, roller, 24-28 Fr., 12° and 30°, long, for TURis
■ For coagulation only |
| | WA22538C | HF-resection electrode, roller, 24-28 Fr., 12° and 30°, long, sterile, single use, 12 pcs., for TURis |
| ③ | WA22539D | HF-resection electrode, loop, 24-28 Fr., 0.2 wire, medium, 45° angled, 12° and 30°, long, sterile, single use, 12 pcs., for TURis |
| ④ | WA22541S | HF-resection electrode "Plasma-OvalButton", long oval button, 24 Fr., 12°-30°, in saline |
| ⑤ | WA22542S | HF-resection electrode "PlasmaLoop", long small loop, 24 Fr., 12°-30°, in saline |
| ⑥ | WA22544S | HF-resection electrode "PlasmaNeedle", long right-angled needle, 24 Fr., 12°-30°, in saline |

Monopolar HF-Resection Electrodes

Reusable HF-Resection Electrodes

24 Fr.	26 Fr.	28 Fr.
26 Fr.	28 Fr.	
27 Fr.		
A22041A/T	A22042A/T	A22043A/T
Compatible resection sheaths		
A22040A/T	-	-

Reusable HF-Resection Electrodes



24 Fr.	26 Fr.	28 Fr.
26 Fr.	28 Fr.	
27 Fr.		
① A22201A	A22202A	A22203A
HF-resection electrode, loop, 12°, 0.35 wire		
A22201B	-	-
HF-resection electrode, loop, 12°, 0.2 wire		
A22205A	A22206A	A22207A
HF-resection electrode, loop, 30°, 0.35 wire		
A22205B	-	-
HF-resection electrode, loop, 30°, 0.2 wire		
② A22211A	-	-
HF-resection electrode, loop, runner, 12°		
③ A22231A	A22231A	A22231A
HF-resection electrode, angled loop, 0.35 wire, 12° and 30°		
A22231B	A22231B	A22231B
HF-resection electrode, angled loop, 0.2 wire, 12° and 30°		
④ A22251A	A22251A	A22251A
HF-resection electrode, roller, 12° and 30°		
■ For coagulation only		
⑤ A22258A	A22258A	A22258A
HF-resection electrode, roller, large, 12° and 30°		
■ For coagulation only		

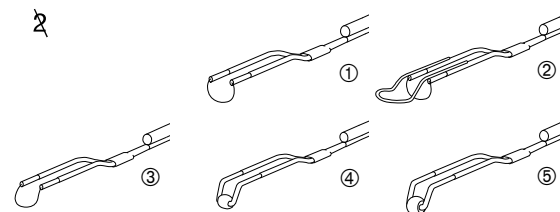
1 piece, reusable

Sterile, Single-Use HF-Resection Electrodes

24 Fr.	26 Fr.	28 Fr.
26 Fr.	28 Fr.	
27 Fr.		
A22041A/T	A22042A/T	A22043A/T
Compatible resection sheaths		

Sterile, Single-Use HF-Resection Electrodes

STERILE



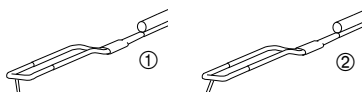
24 Fr.	26 Fr.	28 Fr.
26 Fr.	28 Fr.	
27 Fr.		
① A22201C	A22202C	A22203C
HF-resection electrode, loop, 12°, 0.35 wire		
A22201D	-	-
HF-resection electrode, loop, 12°, 0.2 wire		
A22205C	A22206C	A22207C
HF-resection electrode, loop, 30°, 0.35 wire		
A22205D	-	-
HF-resection electrode, loop, 30°, 0.2 wire		
② A22211C	-	-
HF-resection electrode, loop, runner, 12°		
③ A22231C	A22231C	A22231C
HF-resection electrode, angled loop, 0.35 wire, 12° and 30°		
A22231D	A22231D	A22231D
HF-resection electrode, angled loop, 0.2 wire, 12° and 30°		
④ A22251C	A22251C	A22251C
HF-resection electrode, roller, 12° and 30°		
■ For coagulation only		
⑤ A22258C	A22258C	A22258C
HF-resection electrode, roller, large, 12° and 30°		
■ For coagulation only		

12 pieces, sterile, single use

**Reusable HF-Resection Electrodes**

24 Fr. 26 Fr. 28 Fr.
 26 Fr. 28 Fr.
 27 Fr.

A22041A/T **A22042A/T** **A22043A/T** Compatible resection sheaths
A22040A/T - -

Reusable HF-Resection Electrodes

24 Fr. 26 Fr. 28 Fr.
 26 Fr. 28 Fr.
 27 Fr.

① **A22253A** **A22253A** **A22253A** HF-resection electrode, 90° needle, 12°
 ② **A22255A** **A22255A** **A22255A** HF-resection electrode, 45° needle, 12° and 30°

1 piece, reusable

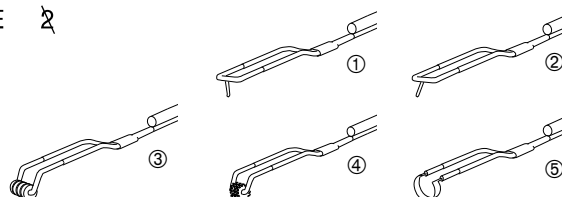
Sterile, Single-Use HF-Resection Electrodes

24 Fr. 26 Fr. 28 Fr.
 26 Fr. 28 Fr.
 27 Fr.

A22041A/T **A22042A/T** **A22043A/T** Compatible resection sheaths
A22040A/T - -

Sterile, Single-Use HF-Resection Electrodes

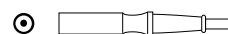
STERILE



24 Fr. 26 Fr. 28 Fr.
 26 Fr. 28 Fr.
 27 Fr.

① **A22253C** **A22253C** **A22253C** HF-resection electrode, 90° needle, 12°
 ② **A22255C** **A22255C** **A22255C** HF-resection electrode, 45° needle, 12° and 30°
 ③ **A22257C** **A22257C** **A22257C** HF-resection electrode, cylinder, with grooves, for vaporization, 12° and 30°, titanium
 ④ **A44728C** **A44728C** **A44728C** HF-resection electrode, cylinder, with spikes, 12° and 30°
 ⑤ **A22221C** **A22222C** - HF-resection electrode, band, for vaporization, 12°
 A22223C - - HF-resection electrode, band, for vaporization, 30°

12 pieces, sterile, single use

Monopolar HF Cables

A0393 HF cable, monopolar, 4 m,
 for UES-30/-40, Erbe Int., Valleylab (new)
 Compatible HF-Unit: Olympus ESG-400

A0391 HF cable, monopolar, 4 m,
 for UES-10/-20, Valleylab (old)

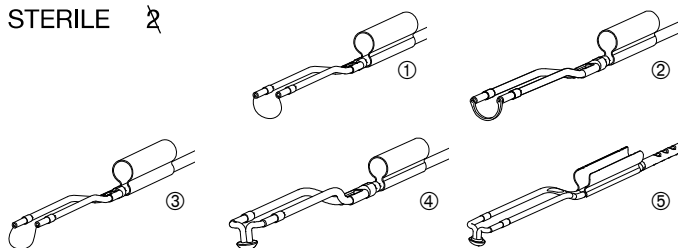
A0392 HF cable, monopolar, 4 m,
 for Erbe T series, Martin, Berchtold

WA0039S HF cable, monopolar, 4 m, single use
 Compatible HF-Units: Olympus ESG-400, UES 40

ESG PLASMA Electrodes

24 Fr. Sterile, Single-Use 26 Fr. HF-Resection Electrodes (1) 27 Fr.

STERILE

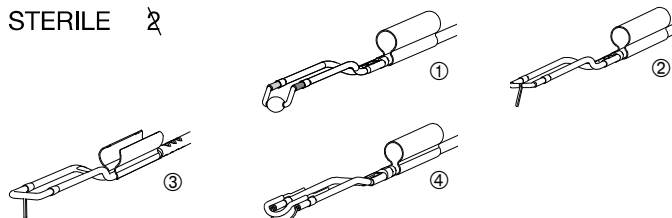


- ① **WA22301S** HF-resection electrode "PlasmaLoop", small loop, 24 Fr., 12°/16°, in saline
- WA22302D** HF-resection electrode, loop, 24 Fr., 0.2 wire, medium, 12°, sterile, single use, 12 pcs., for TURis
- WA22503D** HF-resection electrode, loop, 24 Fr., 0.2 wire, large, 12°, sterile, single use, 12 pcs., for TURis
- WA22305S** HF-resection electrode "PlasmaLoop", small loop, 24 Fr., 12°-30°, in saline
- WA22306D** HF-resection electrode, loop, 24 Fr., 0.2 wire, medium, 30°, sterile, single use, 12 pcs., for TURis
- WA22507D** HF-resection electrode, loop, 24 Fr., 0.2 wire, large, 30°, sterile, single use, 12 pcs., for TURis
- ② **WA22521C** HF-resection electrode, band, 24 Fr., medium, 12°, sterile, single use, 12 pcs., for TURis
- WA22523C** HF-resection electrode, band, 24 Fr., medium, 30°, sterile, single use, 12 pcs., for TURis
- ③ **WA22331D** HF-resection electrode, loop, 24-28 Fr., 0.2 wire, small, 45° angled, 12° and 30°, sterile, single use, 12 pcs., for TURis
- WA22332D** HF-resection electrode, loop, 24-28 Fr., 0.2 wire, medium, 45° angled, 12° and 30°, sterile, single use, 12 pcs., for TURis
- ④ **WA22557C** HF-resection electrode, button, 24-28 Fr., 12° and 30°, sterile, single use, 12 pcs., for TURis
- ⑤ **WA22566S** HF-resection electrode "Plasma-OvalButton", oval button, 24 Fr., 12°-30°, in saline

S = 5 pcs.
C/D = 12 pcs.

24 Fr. Sterile, Single-Use 26 Fr. HF-Resection Electrodes (2) 27 Fr.

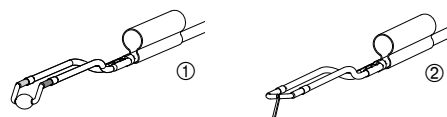
STERILE



- ① **WA22351C** HF-resection electrode, roller, 24-28 Fr., 12° and 30°, sterile, single use, 12 pcs., for TURis
■ For coagulation only
- ② **WA22355C** HF-resection electrode, 45° needle, 24-28 Fr., 12° and 30°, sterile, single use, 12 pcs., for TURis
- ③ **WA22540S** HF-resection electrode "PlasmaNeedle", right-angled needle, 24 Fr., 12°-30°, in saline
- ④ **WA22558C** HF-resection electrode, loop, 24-28 Fr., 45° angled, 12° and 30°, sterile, single use, 12 pcs., for TURis enucleation

S = 5 pcs.
C = 12 pcs.

24 Fr. Reusable 26 Fr. HF-Resection Electrodes 27 Fr.



- ① **WA22351A** HF-resection electrode, roller, 24-28 Fr., 12° and 30°, for TURis
- ② **WA22355A** HF-resection electrode, 45° needle, 24-28 Fr., 12° and 30°, for TURis

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bologna

EXCELL NHP/T

ELECTROSURGICAL UNITS FOR
MONOPOLAR AND BIPOLAR USE
WITH 7.0" TOUCH-SCREEN



*A NEW STEP AHEAD
TO THE FUTURE*

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CERTIFIED
IT-Net
MANAGEMENT SYSTEMS
IT - 1231

CSQ
MED
ISO 13485
9124. ALS2

CE 0051

The units EXCELL NHP/T series are provided with all the technical features, and the monopolar and bipolar currents needed to perform the most advanced electrosurgery

All models are provided with 10 currents for the monopolar cutting	
Pure Cut	Pure cut without coagulating effect. For open or laparoscopic surgery and for under liquid endoscopy (TURP, TURV).
Blend Cut 1	Cut blended with a medium coagulating effect. For open or laparoscopic surgery and for under liquid endoscopy (TURP, TURV).
Blend Cut 2	Cut blended with a very high coagulating effect. For open or laparoscopic surgery.
Pure Cut Pulsed	Pulsed pure cut without coagulating effect. For open or laparoscopic surgery.
Blend Cut Pulsed	Pulsed cut blended with a medium coagulating effect. For open or laparoscopic surgery.
Auto Pure Cut Micro	"Constant voltage" delicate pure cut without coagulating effect. For open or laparoscopic surgery and for under liquid endoscopy (TURP, TURV).
Auto Blend Cut Micro	"Constant voltage" delicate cut blended with a medium coagulating effect. For open or laparoscopic surgery and for under liquid endoscopy (TURP, TURV).
Auto Papillo Pure Cut	"Constant voltage" pure cut, without coagulating effect, for flexible endoscopy. With four modes of delivery: continuous and pulsed (slow, medium, fast).
Auto Polipo Blend Cut	"Constant voltage" cut, blended with a medium coagulating effect, for flexible endoscopy. With four modes of delivery: continuous and pulsed (slow, medium, fast).
Auto EndoCut	"Constant voltage" cut with alternating phases of cutting and blended cut, for flexible endoscopy. With four modes of delivery: 90% Coagulation and 10% Cut, 80% Coagulation and 20% Cut, 75% Coagulation and 25% Cut, 50% Coagulation and 50% Cut.
All models are provided with 5 currents for the monopolar coagulation	
Fulg Forced Coag	High voltage, contact free coagulation. For open or laparoscopic surgery, for under liquid endoscopy (TURP, TURV) and for flexible endoscopy.
Spray Coag	Very high voltage, contact free coagulation. For open or laparoscopic surgery, for under liquid endoscopy (TURP, TURV) and for flexible endoscopy.
Pulsed Spray Coag	Identical to the Spray coag current, but pulsed and more delicate.
Pin Point Contact Coag	Medium voltage, contact coagulation. For open or laparoscopic surgery, for under liquid endoscopy (TURP, TURV) and for flexible endoscopy.
Soft Micro Coag	Delicate, low voltage coagulation. For open or laparoscopic surgery.
The models NHP/TA-400 and NHP/TA-200 are provided with 2 currents for the Argon coagulation	
Standard	Very fast and efficacious coagulation (Spray Coag current enhanced by the Argon gas). For open or laparoscopic surgery and for flexible endoscopy.
Pulsed	Identical to the Standard current, but more delicate. (Pulsed Spray Coag current enhanced by the Argon gas).
All models are provided with 4 currents for the bipolar cutting	
Standard Bicut	Cut for open or laparoscopic surgery.
Blend Bicut	Cut blended with a very high coagulating effect (Coagulation = 95%) for open or laparoscopic surgery.
Saline Uro-Gyn Cut	Cut for endoscopy in saline (TURPis, TURVis) with two modes of delivery: continuous and pulsed. For urology and gynaecology. The continuous delivery is suitable to perform the vaporization.
Saline Arthro Cut	Cut for arthroscopy in saline with two modes of delivery: continuous and pulsed. For arthroscopy. The continuous delivery is suitable to perform the vaporization.
All models are provided with 3 currents for the bipolar coagulation and 2 currents for the bipolar vessel sealing	
Soft Micro Bicoag	Very precise and delicate coagulation. For open or laparoscopic surgery, for endoscopy in saline (TURPis, TURVis) and for flexible endoscopy.
Forced Macro Bicoag	Fast coagulation. For open or laparoscopic surgery.
Auto Soft Micro Bicoag	Identical to the Soft Micro Bicoag , but with <i>Impedance sensing</i> automatic activation/deactivation. It is not suitable for the endoscopy in saline. Activation with delay adjustable from 0 to 5 seconds and deactivation with bitonal, grave, acoustic signal.
Sealing	Current to coagulate/seal vessels up to 8 mm in open and laparoscopic surgery. Activation with pedal and automatic <i>Impedance sensing</i> deactivation with bitonal, acute, acoustic signal.
Auto Sealing	Identical to the Sealing , but with <i>Impedance sensing</i> automatic activation/deactivation. It is not suitable for the endoscopy in saline. Activation with delay adjustable from 0 to 5 seconds and deactivation with bitonal, grave, acoustic signal.

Technical features of all models

HF generator	Meets IEC 60601-1 and IEC 60601-2-2 (Latest editions). Supply section “switching” type.
EMC compatibility	Meets IEC 60601-1-2 (Latest edition).
EC Classification and approval	Class IIB according to 93/42/CEE (and its revised version) – Certificate nr. 187/MDD (IMQ 0051).
ALSA quality system	Meets ISO 9001 and ISO 13485 (Latest editions). Certificates 9120.ALSA and 9124.ALS2 (IMQ 0051).
Classification according to IEC 60601-1	Class I, CF type with the following typical low frequency leakage currents (all cables tied together): On the patient: 4µA = 0,004mA / Into the enclosure: 1µA = 0,001mA / To earth: 30µA = 0,03mA.
Output circuit according to IEC 60601-2-2	FLOATING (Isolated at high and low frequencies) and protected against the use of the defibrillator. Typical HF leakage currents measured at the unit: Monopolar currents = 90mA, Bipolar currents = 60mA.
Working frequency	Monopolar and bipolar currents: 440kHz ± 5%.
Functioning control	Computerized MASTER/SLAVE SYSTEM - It performs a Main Auto-check at the switching ON (repeated every 30 minutes of operation) and the continuous Standard Auto-check during use. - It stops the power activation in case of hardware/software failures, mistakes of use, an anomalous power delivery, and it signals them by acoustic and visual Error Codes. - It memorizes all Error Codes to help the check and the technical assistance.
Self-adjusting of output powers	Computerized self-adjustment with PER (Power Efficiency Rating > 98%) according to the impedances of tissues (Feed-back in real time - 7000 times/sec) by two different systems: ADC System – Dynamic self-adjustment with constant power The powers have a progressive setting (Micro and Macro setting with steps from 0,1 to 10W). Monopolar currents (from 1 to 10W), Bipolar currents (from 0,1W to 5W). APC System - Fully automatic control The powers have a setting with 10 effects (the unit shows, for each effect, the maximum delivered power).
Control of the HF leakage currents	By a specific computerized circuit with alarms.
Memorization of programs	100 programs identifiable by number and text (Surgical use or Name of the surgeon).
Usable pencils or instruments	All models allow the following use of the monopolar and bipolar accessories: - One/two either hand-switched or foot-switched monopolar pencils or instruments. Two monopolar pencils can be used simultaneously according to IEC 60601-2-2. - One/two bipolar instruments by foot-switch activation (When selecting the Auto Soft Micro Bicoag or the Auto Sealing currents, an instrument is usable by the Impedance sensing automatic activation/deactivation). The models TA-400 and TA-200 allow, when the Argon section is ON, the use also of the following: - One hand-switched or foot-switched pencil/instrument for the Argon enhanced electro-surgery.
Twin foot-switches	The unit can be used by either one or two waterproof (IPN8) twin foot-switches. - Only with one twin foot-switch (DS/Esw or DS/Eswl, large model for the use in endoscopy) with a Foot-selector to activate either the monopolar or the bipolar currents. - Only with one twin foot-switch (DS/B) to activate the bipolar currents only. - With both twin foot-switches, one to activate the monopolar currents and one to activate the bipolar ones.
Control circuit of the neutral electrode	NPCC System with double circuit: Contact quality monitor and Continuity monitor with four progressive alarm lights and stop of the power delivery. The circuit operates as follows: - It checks all kinds of neutral electrode, both “split” double area and “non split” single area. - It has two modes of use: Large electrodes for adults and Small electrodes for paediatrics and new-born. - It allows the use of cables with both European “Ø 6,35mm” and USA “2 pins” connectors.
Luminous and acoustic signals of activation and alarm	They meet IEC 60601-2-2 (Latest edition). Lights: Cutting = yellow, Coagulation = blue, Alarms and Error codes = red Activation sounds: Continuous (acute for the cut and grave for the coagulation, with level adjustable from 45 to 65dB), including a bitonal sound to indicate the power deactivation when using the currents: Auto Soft Micro Bicoag, Sealing and Auto Sealing. Alarm sound: Intermittent (High >65dB and not adjustable).
Mains supply and consumption, Mains switch, Fuses and Standby	100 / 230V ± 10% ~ 50/60Hz (Consumption: Max. 3,6A = 828VA, Standby 0,4A = 92VA). Bipolar switch (green), Two fuses 8A, Standby mode selectable on the touch-screen.
Equipotential connection	Standard DIN 42801 plug.
Enclosure, Cooling	Metal painted case, protected against the spilling of liquids according to IEC 60601-2-2. Cooling by convection (No fan).
Software updating and calibration	Updating by a serial port connected to a PC, calibration on-site.
Dimensions and weight (LxWxH)	NHP/T-400 and T-200: 38x35x19cm - 10Kg – NHP/TA-400 and TA-200: 38x38x19cm - 10,5Kg.
Technical features of the Argon gas section (Models TA-400 and TA-200 only)	
Gas (Supply)	By 1 or 2 cylinders (5lt) or by centralized supply with max pressure of 4,5 atm.
Gas (Antibacterial protection)	Antibacterial filter on the gas output.
Gas (Working pressure and Flow)	Pressure: 2 atm. Flow: Max 15lt/min, adjustable from 1 to 15 lt/min and self-adjusted.
Gas (Pressure, Consumption)	By the main Auto-check system of the unit and Pressure Safety System. It blocks the usability of the Argon section either if the gas is absent/not sufficient or its pressure is too high, by informing the users through alarms and Error Codes. The system includes a pressure reducer and a safety valve.

EXCELL NHP/T-400 and EXCELL NHP/TA-400 – THE CURRENTS

MONOPOLAR CUTTING

	Pure Cut	Blend Cut 1	Blend Cut 2	Pure Cut Pulsed	Blend Cut Pulsed	Auto Pure Cut Micro	Auto Blend Cut Micro	Auto Papillo Pure Cut	Auto Polipo Blend Cut	Auto Endocut
Max Output Power	400 W	300 W	250 W	400 W	250 W	300 W	300 W	300 W	300 W	300 W
Rated load	400 Ω	400 Ω	400 Ω	400 Ω	400 Ω	300 Ω	300 Ω	300 Ω	300 Ω	300 Ω
Vpp	2550	3390	3330	2640	3330	1137	1500	1140	1490	1670
Crest factor	1,46	1,94	2,29	2	3,2	1,5	1,98	1,5	1,98	
Modulation	0	17 kHz	17 kHz	3 Hz	50 Hz	0	17 kHz	0	17 kHz	-
Duty Cycle	100%	95%	65%	50%	50%	100%	90%	100%	95%	
Power setting	Progressive with steps from 1 to 10 W						10 Effects			
Power control	ADC System - Dynamic self-adjusting with constant power						APC System - Totally self-adjusting with constant voltage			

MONOPOLAR COAGULATION

	Fulg Forced Coag	Spray Coag	Pin Point Contact Coag	Pulsed Spray Coag	Soft Micro Coag
Max Output Power	150 W	200 W	300 W	200 W	280 W
Rated load	300 Ω	700 Ω	400 Ω	700 Ω	300 Ω
Vpp	4500	7750	3700	7850	3300
Crest factor	6,45	7,75	2,2	11,54	2,16
Modulation	60 kHz	30 kHz	17 kHz	3 Hz	17 kHz
Duty Cycle	18%	7%	85%	50%	75%
Power setting	Progressive with steps from 1 to 10 W				10 Effects
Power control	ADC System - Dynamic self-adjusting with constant power				APC System - Totally self-adjusting with constant voltage

ARGON PLASMA COAGULATION (Model NHP/TA-400 only)

	Spray Coag + Gas Argon	Pulsed Spray Coag + Gas Argon
Max Output Power	200 W	200 W
Rated load	700 Ω	700 Ω
Vpp	7750	7850
Crest factor	7,75	11,54
Modulation	30 kHz	3 Hz
Duty Cycle	7%	50%
Power setting	Progressive with steps from 1 to 10 W	
Gas setting	From 1 to 15 Lt/min	
Power control	ADC System - Dynamic self-adjusting with constant power	

BIPOLAR CUTTING

	Saline Uro-Gyn Cut	Saline Arthro Cut	Standard Bicut	Blend Bicut
Max Output Power	350 W	230 W	200 W	160 W
Rated load	350 Ω	350 Ω	300 Ω	200 Ω
Vpp	1070	1070	1070	740
Crest factor	1,5	1,5	1,5	1,57
Modulation	0	0	0	17 kHz
Duty Cycle	100%	100%	100%	95%
Power setting	10 Effects		Progressive with steps from 0,1 to 5 W	
Power control	ADC System - Dynamic self-adjusting with constant power			

BIPOLAR COAGULATION AND VESSEL SEALING

	Soft Micro Bicoag	Auto Soft Micro Bicoag	Sealing	Auto Sealing	Forced Macro Bicoag
Max Output Power	140 W	140 W	320 W	320 W	200 W
Rated load	100 Ω	100 Ω	50 Ω	50 Ω	100 Ω
Vpp	460	460	780	780	550
Crest factor	1,56	1,56	2,47	2,47	1,6
Modulation	0	0	0	0	0
Duty Cycle	100%	100%	100%	100%	100%
Power setting	Progressive with steps from 0,1 to 5 W		10 Effects		Progressive with steps from 0,1 to 5 W
Power control	APC System - Totally self-adjusting with constant voltage				ADC System - Dynamic self-adjusting with constant power

EXCELL NHP/T-200 and EXCELL NHP/TA-200 – THE CURRENTS

MONOPOLAR CUTTING

	Pure Cut	Blend Cut 1	Blend Cut 2	Pure Cut Pulsed	Blend Cut Pulsed	Auto Pure Cut Micro	Auto Blend Cut Micro	Auto Papillo Pure Cut	Auto Polipo Blend Cut	Auto Endocut
Max Output Power	200 W	200 W	200 W	200 W	200 W	200 W	200 W	200 W	200 W	200 W
Rated load	400 Ω	400 Ω	400 Ω	400 Ω	400 Ω	300 Ω	300 Ω	300 Ω	300 Ω	300 Ω
Vpp	2550	3390	3330	2640	3330	1137	1500	1140	1490	1670
Crest factor	1,46	1,94	2,29	2	3,2	1,5	1,98	1,5	1,98	
Modulation	0	17 kHz	17 kHz	3 Hz	50 Hz	0	17 kHz	0	17 kHz	-
Duty Cycle	100%	95%	65%	50%	50%	100%	90%	100%	95%	
Power setting	Progressive with steps from 1 to 10 W						10 Effects			
Power control	ADC System – Dynamic self-adjusting with constant power						APC System - Totally self-adjusting with constant voltage			

MONOPOLAR COAGULATION

	Fulg Forced Coag	Spray Coag	Pin Point Contact Coag	Pulsed Spray Coag	Soft Micro Coag
Max Output Power	150 W	200 W	200 W	200 W	200 W
Rated load	300 Ω	700 Ω	400 Ω	700 Ω	300 Ω
Vpp	4500	7750	3700	7850	2875
Crest factor	6,4	7,75	2,2	11,54	2,1
Modulation	60 kHz	30 kHz	17 kHz	3 Hz	17 kHz
Duty Cycle	18%	7%	85%	50%	75%
Power setting	Progressive with steps from 1 to 10 W				10 Effects
Power control	ADC System - Dynamic self-adjusting with constant power				APC System - Totally self-adjusting with constant voltage

ARGON PLASMA COAGULATION (Model NHP/TA-200 only)

	Spray Coag + Gas Argon	Pulsed Spray Coag + Gas Argon
Max Output Power	200 W	200 W
Rated load	700 Ω	700 Ω
Vpp	7750	7850
Crest factor	7,75	11,54
Modulation	30 kHz	3 Hz
Duty Cycle	7%	50%
Power setting	Progressive with steps from 1 to 10 W	
Gas setting	From 1 to 15 Lt/min	
Power control	ADC System - Dynamic self-adjusting with constant power	

BIPOLAR CUTTING

	Saline Uro-Gyn Cut	Saline Arthro Cut	Standard Bicut	Blend Bicut
Max Output Power	350 W	230 W	200 W	160 W
Rated load	350 Ω	350 Ω	300 Ω	200 Ω
Vpp	1070	1070	1070	740
Crest factor	1,5	1,5	1,5	1,57
Modulation	0	0	0	17 kHz
Duty Cycle	100%	100%	100%	95%
Power setting	10 Effects		Progressive with steps from 0,1 to 5 W	
Power control	ADC System – Dynamic self-adjusting with constant power			

BIPOLAR COAGULATION AND VESSEL SEALING

	Soft Micro Bicoag	Auto Soft Micro Bicoag	Sealing	Auto Sealing	Forced Macro Bicoag
Max Output Power	140 W	140 W	320 W	320 W	200 W
Rated load	100 Ω	100 Ω	50 Ω	50 Ω	100 Ω
Vpp	460	460	780	780	550
Crest factor	1,56	1,56	2,47	2,47	1,6
Modulation	0	0	0	0	0
Duty Cycle	100%	100%	100%	100%	100%
Power setting	Progressive with steps from 0,1 to 5 W		10 Effects		Progressive with steps from 0,1 to 5 W
Power control	APC System - Totally self-adjusting with constant voltage			ADC System - Dynamic self-adjusting with constant power	



*EXCELL NHP/T-400
with footswitch DS/Esw*



*EXCELL NHP/T-400
with footswitch DS/Eswl*

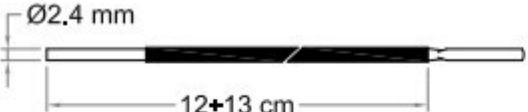
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ACCESSORI ARTROSCOPICI
ARTHROSCOPIC ACCESSORIES
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ACCESORIOS DE ARTROSCOPI



	MPE/E MPE/F
	MPE/CMS
ANGLED NEEDLE	E/ND12
DAGGER	E/DR12
HOOK	E/HK12
HOCKEY	E/HY14

	A lama • Knife À lame • De cuchillo	E40
	A lama (spatola) isolata • Insulated knife (spatula) À lame (spatule) isolé • De cuchillo (espátula) aislado	E40/I
	Ad ago grosso • Thick needle À aiguille grosse • De aguja grueso	E41
	Ad ago sottile • Thin needle À aiguille fine • De aguja fino	E42
	Ad ago sottile isolato • Insulated thin needle À aiguille fine isolé • De aguja fino aislado	E42/I

MD-2702 CLINICAL REVIEW MONITOR



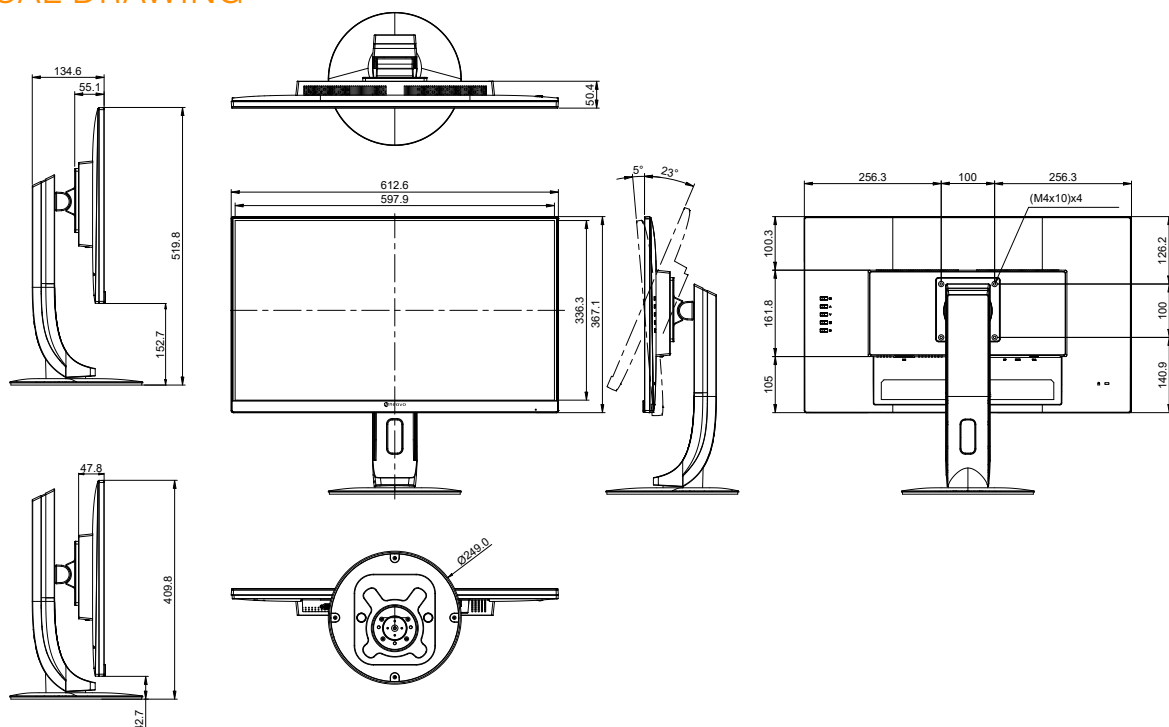
FEATURES

- Full HD 1920 x 1080 resolution
- 178° / 178° wide viewing angle
- Support DICOM Part 14 with calibrated greyscale and brightness
- Crisp 20,000,000:1 dynamic contrast ratio
- 3-sided narrow bezel design for seamless multi-display setups
- Medical adapter certified to the IEC/EN 60601-1 medical standard
- White exterior design for easy contaminant detection
- Versatile Connectivity: DisplayPort, HDMI and VGA
- HDMI inputs for Full HD connectivity with a variety of devices
- Selectable aspect ratio
- VESA mounting for flexible installation in healthcare settings
- Height adjustable stand allows users to tilt, pivot and swivel



Featuring DICOM preset and medical-grade power supply, the MD-2702 clinical review monitor ensures correct and consistent brightness and greyscale levels of medical images in detail at any viewing angle. Its image stability, medical-grade power supply, and VESA-compatible mounts give clinical professionals confidence in clinical review and easy to set up a mobile workstation while meeting the standards of premium quality assurance and financial benefits.

TECHNICAL DRAWING



SPECIFICATIONS

Panel

Panel Type	LED-Backlit TFT LCD (VA Technology)
Panel Size	27.0"
Max. Resolution	FHD 1920 x 1080
Pixel Pitch	0.311 mm
Brightness	300 cd/m ² 180 cd/m ² (DICOM Preset)
Contrast Ratio	20,000,000:1 (DCR)
Viewing Angle (H/V)	178°/178°
Display Colour	16.7M
Response Time	5 ms

Frequency

Frequency (H)	30 kHz-83 KHz
Frequency (V)	50 Hz-76 Hz

Signal Input

DisplayPort	x 1
HDMI	1.4 x 1
VGA	15-Pin D-Sub x 1

Power

Power Supply	External
Power Requirements	DC 12V, 2.5A
On Mode	16W (On)
Stand-by Mode	< 0.3W
Off Mode	< 0.2W

Operating Conditions

Temperature	0°C-40°C (32°F-104°F)
Humidity	10%-85% (non-condensing)

Storage Conditions

Temperature	-25°C-55°C (-13°F-131°F)
Humidity	5%-93%(non-condensing)

Mounting

VESA FPMPI	Yes (100 x 100 mm)
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Stand

Tilt	-5° to 23°
Pivot	-2.5° to 92.5°
Swivel	± 65°
Height Adjustment	0-110 mm

Security

Kensington Security Slot	Yes
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Dimensions

Product with Base (W x H x D)	612.6 x 519.8 x 249.0 mm (24.1" x 20.5" x 9.8")
Product w/o Base (W x H x D)	612.6 x 367.1 x 50.4 mm (24.1" x 14.6" x 2.0")
Packaging (W x H x D)	700.0 x 456.0 x 282.0 mm (27.6" x 18.0" x 11.1")

Weight

Product w/o Base	3.7 kg (8.2 lb)
Product with Base	6.1 kg (14.5 lb)
Packaging	8.8 kg (19.4 lb)

Regulation Approval

Certifications & Compliance	CE, LVD, WEEE, RoHS, REACH, EAC, UKCA, BSMI
Power Adaptor Certifications	ADAPTER/ATM065T-P120: CE, FCC, PSE, WEEE, BSMI, Medical Grade

Accessories

Supplied	Power Adaptor, Power Cord, HDMI Cable, Quick Start Guide, Warranty Card
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Optional Accessories

Ceiling Mount (Landscape only)	CMP-01+WMK-03
Wall Mount (Landscape only)	WMA-01, WMK-01, WMK-03, PMK-01
Desk Mount (Landscape only)	DMC-01, ES-02



EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60123878 0001

Report No.: 12018179 022

Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo 192-8507
Japan

Products: Design and Development, Manufacture of Medical Endoscopy
Systems, Diagnostic, Operation and Treatment Products

(see attachments for products and additional sites included)

Replaces Approval, Registration No.: HD 60078827 0001

Expiry Date: 2022-11-02

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2017-11-03

Date: 2017-10-12



Notified Body

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number D197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev.0

**Attachment to
Certificate**

Registration No.: HD 60123878 0001

Report No.: 12018179 022

Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo 192-8507
Japan

Products included:

Medical Endoscopy Systems:

- Endoscopes
- Endotherapy Devices
- Imaging Processors
- Pumps for Endoscopy
- Light Sources
- Position Detecting Units
- Electrothermal Cautery Units
- Integrated Endosurgery Systems
- Endoscopic Regulation/Control Units

Electrosurgical Equipment
Probes and Transducers for Ultrasonic Lithotriptors
Laparoscopic Insufflators
Ultrasound Surgical Equipment
Disinfecting Units
Capsule Endoscopes and Systems
Ultrasound Diagnostic Imaging Systems



Notified Body

M. Aihara

M.Sc. M. Aihara

Date: 2017-10-12

Traducere din limba engleza



APROBARE
Directiva CE 93/42/CEE Anexa II, excluzând Secțiunea 4
Sistem complet de asigurare a calității
Echipamente medicale

Nr. Înregistrare: HD 60123878 0001
Nr. Raport: 12018179 022

Producător: Olympus Medical Systems Corp.
2951 Ishikawa-cho
HACHIOJI-SHI, TOKIO 192-8507
JAPONIA

Produse: Proiectare și dezvoltare, producție de sisteme de endoscopie medicală, produse de diagnostic, operație și tratament.
(a se vedea atasamentele pentru produse și locații suplimentare incluse)
Înlocuiește Aprobarea cu nr. de înregistrare: HD 60078827 0001

Data expirării: 02.11.2022

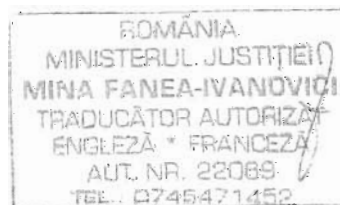
Organismul Notificat declară prin prezenta că au fost îndeplinite cerințele Anexei II, excluzând secțiunea 4 a directivei 93/42/CEE pentru produsele specificate. Producătorul mai sus menționat a stabilit și aplică un sistem de asigurare a calității, care este supus unei supravegheri periodice, definită în Anexa II, secțiunea 5 a directivei menționate anterior. Pentru comercializarea echipamentelor din clasa III acoperite de acest certificat, este necesar un certificat CE de examinare proiectare în conformitate cu Anexa II, secțiunea 4.

Data intrării în vigoare: 03-11-2017

Data: 12.10.2017

Organism notificat
Ștampilă:
TUV Rheinland LGA Products GmbH
Zertifizierungsstelle
M.Sc. M. Aihara
(semnătură indescifrabilă)

TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431 Nürnberg
TÜV Rheinland LGA Products GmbH este un Organism Notificat în conformitate cu Directiva 93/42/CEE cu privire la echipamentele medicale, cu numărul de identificare 0197



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Atasament la
Certificat

Nr. de înregistrare: HD 60123878 0001
Nr. raport: 12018179 022

Producător: Olympus Medical Systems Corp.
2951 Ishikawa-cho
HACHIOJI-SHI, TOKIO 192-8507
JAPONIA

Produse incluse:

- Sisteme medicale de endoscopie:
 - Endoscoape
 - Echipamente endoterapie
 - Procesoare de imagine
 - Pompe pentru endoscopie
 - Surse de lumină
 - Unități de detectare poziție
 - Unități de cauterizare electrotermică
 - Sisteme endochirurgicale integrate
 - Unitati de control/reglare endoscopice
- Echipamente electrochirurgicale
- Sonde și traductoare pentru litotriptoare cu ultrasunete
- Insuflatoare laparoscopice
- Echipamente chirurgicale cu ultrasunete
- Unitati de sterilizare
- Sisteme și endoscoape capsulă
- Sisteme de imagistica pentru diagnostic cu ultrasunete

Data: 12.10.2012

Organism notificat
Șampilă:
TUV Rheinland LGA Products GmbH
Zertifizierungsstelle
M.Sc. M. Aihara
(semnătură indescifrabilă)



EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60123877 0001

Report No.: 12018179 022

Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo 192-8507
Japan

Products: Sterile Endotherapy Devices used in conjunction with
Endoscopes, Sterile Non Active Instruments used in
conjunction with Endoscopes and Sterile Non Active
Instruments used in conjunction with Medical Ultrasound
Diagnostic Imaging Systems
Replaces Approval, Registration No.: DD 60116725 0001

Expiry Date: 2022-11-02

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2017-11-03

Date: 2017-10-12



Notified Body

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Traducere din limba engleza



CERTIFICAT CE
Directiva CE 93/42/CEE Anexa V
Asigurarea calității producției
Echipamente medicale

Nr. Înregistrare: DD 60123877 0001

Nr. Raport: 12018179 022

Producător: Olympus Medical Systems Corp.
2951 Ishikawa-cho
HACHIOJI-SHI, TOKIO 192-8507
JAPONIA

Produse: Echipamentelor sterile pentru endoterapie, utilizate împreună cu endoscoape, instrumente sterile non-active utilizate împreună cu endoscoape și instrumente sterile non-active utilizate împreună cu sisteme medicale de imagistică diagnostic cu ultrasunete.
Înlocuiește Aprobarea. nr. înregistrare: DD 60116725 0001

Data expirării: 02.11.2022

Organismul Notificat declară prin prezenta că au fost îndeplinite cerințele Anexei V a directivei 93/42/CEE pentru produsele specificate. Producătorul mai sus menționat a stabilit și aplică un sistem de asigurare a calității, care este supus unei supravegheri periodice, definită în Anexa V, secțiunea 4 a directivei menționate anterior. Pentru comercializarea echipamentelor din clasa IIb și clasa III acoperite de acest certificat, este necesar un certificat CE de examinare tip în conformitate cu Anexa III.

Data intrării în vigoare: 03-11-2017

Data: 12.10.2017

Organism notificat

Ștampilă:

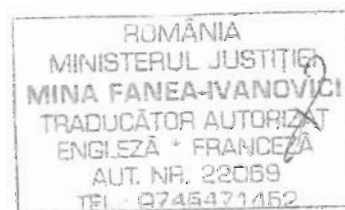
TÜV Rheinland LGA Products GmbH

Zertifizierungsstelle

M.Sc. M. Aihara

(semnătură indescifrabilă)

TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431 Nürnberg
TÜV Rheinland LGA Products GmbH este un Organism Notificat în conformitate cu Directiva 93/42/CEE cu privire la echipamentele medicale, cu numărul de identificare 0197



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

has established and applies a quality management system for medical devices
for the following scope:

**Marketing, sales and servicing of optical, opto-digital,
electronic and mechanical systems as well as associated
accessories and consumables in the field of
endoscopy and microscopy**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-06-21
Certificate Registration No.: SX 60148788 0001
An audit was performed. Report No.: 60319405 001
This Certificate is valid until: 2023-06-20

Certification Body



Date 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope: Subsidiary:

Olympus Europa SE & Co. KG
Albert-Schweitzer-Ring 24-26
22045 Hamburg
Germany

Scope:
Servicing of optical, opto-digital, electronic and
mechanical systems as well as associated accessories
in the field of endoscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope: Subsidiary:

Olympus Deutschland GmbH
Albert-Schweitzer-Ring 35
22045 Hamburg
Germany

Scope:

Servicing of optical, opto-digital, electronic and
mechanical systems as well as associated accessories
in the field of endoscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope: Subsidiary:

Olympus Deutschland GmbH
Amsinckstr. 63
20097 Hamburg
Germany

Scope:
Marketing, sales and servicing of optical, opto-digital,
electronic and mechanical systems as well as associated
accessories and consumables in the field of endoscopy
and microscopy

Certification Body



Date: 2020-04-29



TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope: Subsidiary:

Olympus France S.A.S.
65 Rue de Monthléry
94533 Rungis
France

Scope:
Servicing of optical, opto-digital, electronic and
mechanical systems as well as associated accessories in
the field of endoscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 5/13, Rev.0

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

OLYMPUS IBERIA S.A.U.
PL. Europa 29-31
08908 L'Hospitalet de Llobregat
Barcelona
Spain

Scope:

Marketing, sales and servicing of optical, opto-digital,
electronic and mechanical systems as well as associated
accessories and consumables in the field of endoscopy
microscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus France S.A.S.
19 rue d'Arcueil
94150 Rungis
France

Scope:

Marketing, sales and servicing of optical, opto-digital, electronic and mechanical systems as well as associated accessories and consumables in the field of endoscopy and microscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus Czech Group, s.r.o.
Evropská ul. 176/16
160 41 Praha 6
Czech Republic

Scope:

Marketing, sales and servicing of optical, opto-digital,
electronic and mechanical systems as well as associated
accessories and consumables in the field of endoscopy
and microscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus Czech Group, s. r.o.
clen koncernu
Telickova 457/29
751 24 Prerov-Predmosti
Czech Republic

Scope:

Servicing of optical, opto-digital, electronic and
mechanical systems as well as associated accessories
in the field of endoscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus Service Facility Portugal
Tecnologias Opticas e Digitais, Lda.
Rua de Alcorredores 43 A
3020-923 Torre de Vilela (Coimbra)
Portugal

Scope:

In-house servicing of optical, opto-digital, electronic and
mechanical systems as well as associated accessories in the
field of endoscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 10/13, Rev.0

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus Austria GmbH
Shuttleworthstr. 25
1210 Vienna
Austria

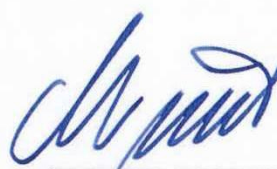
Scope:

Marketing, sales and servicing of optical, opto-digital,
electronic and mechanical systems as well as associated
accessories and consumables in the field of endoscopy
and microscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus Nederland B.V.
Simon Smitweg 18
2353 GA Leiderdorp
Netherlands

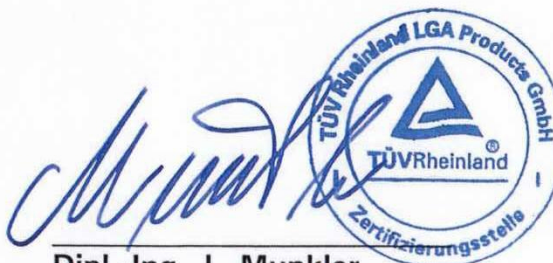
Scope:

Marketing, sales and servicing of optical, opto-digital,
electronic and mechanical systems as well as associated
accessories and consumables in the field of endoscopy
and microscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus Schweiz AG
Chriesbaumstr. 6
8604 Volketswil
Switzerland

Scope:

Servicing of optical, opto-digital, electronic and
mechanical systems as well as associated accessories
in the field of endoscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 13/13, Rev.0

**Attachment to
Certificate**

Registration No.: SX 60148788 0001
Report No.: 60319405 001

Organization: Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Deutschland

Scope:

Subsidiary:

Olympus Schweiz AG
Richtiring 30
8304 Wallisellen
Switzerland

Scope:

Marketing, sales and servicing of optical, opto-digital, electronic and mechanical systems as well as associated accessories and consumables in the field of endoscopy and microscopy

Certification Body



Date: 2020-04-29



Dipl.-Ing. I. Munkler



Certificat

Organismul de certificare al TÜV Rheinland LGA Products GmbH

certifică prin prezenta faptul că organizația

OLYMPUS EUROPA SE & Co. KG

**Amsinckstr. 63
20097 Hamburg
Germania**

a implementat și aplică un sistem de management al calității pentru dispozitive
medicale pentru următoarele domenii:

**Marketing, distribuție și service pentru sisteme optice, opto-digitale, electronice și mecanice,
precum și pentru accesoriile corespunzătoare și consumabilele din domeniul endoscopiei și
microscopiei**

S-a furnizat dovada faptului că au fost îndeplinite cerințele specificate în

EN ISO 13485:2016

Sistemul de management al calității este supus unei supravegheri anuale.

Data intrării în vigoare: 21.06.2020

Nr. înregistrare certificat: SX 60148788 0001

A fost efectuat auditul, raport nr. 60319405 001

Acest certificat este valabil până la 20.06.2023.



Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
Rheinland LGA Products GmbH)
Dipl. Ing. I. Munkler

TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431 Nürnberg

Tel: +49 221 806-1371 Fax: +49 221 806-3935 email: cert-validity@de.tuv.com <http://www.tuv.com/safety>



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

Nr. raport: 60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate: Filială

Olympus Europa SE & Co. KG
Albert-Schweitzer-Ring 24-26
22045 Hamburg
Germania

Domeniul de aplicabilitate:

**Service pentru sisteme optice, opto-digitale, electronice și mecanice,
precum și pentru accesoriile corespunzătoare și consumabilele din
domeniul endoscopiei**



Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate: Filială

Olympus Deutschland GmbH
Albert-Schweitzer-Ring 35
22045 Hamburg
Germania

Domeniul de aplicabilitate:

**Service pentru sisteme optice, opto-digitale, electronice și mecanice,
precum și pentru accesoriile corespunzătoare și consumabilele din
domeniul endoscopiei**



Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germany**

Domeniu de aplicabilitate: Filială

Olympus Deutschland GmbH
Amsinckstr. 63
20097 Hamburg
Germany

Domeniul de aplicabilitate:

**Marketing, distribuție și service pentru sisteme optice, opto-digitale,
electronice și mecanice, precum și pentru accesoriile corespunzătoare și
consumabilele din domeniul endoscopiei și microscopiei**



Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler





TÜVRheinland®

Doc. 4/13 Rev. 0

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate:

Filială

Olympus France S.A.S.
65 Rue de Monthléry
94533 Rungis
Franța

Domeniul de aplicabilitate:

**Service pentru sisteme optice, opto-digitale, electronice și mecanice,
precum și pentru accesoriile corespunzătoare și consumabilele din
domeniul endoscopiei**



DAKkS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate: Filială

Olympus Iberia S.A.U.
PL. Europa, 29-31
08908 L'Hospitalet de Llobregat
Barcelona
Spania

Domeniul de aplicabilitate:

**Marketing, distribuție și service pentru sisteme optice, opto-digitale,
electronice și mecanice, precum și pentru accesoriile corespunzătoare și
consumabilele din domeniul endoscopiei și microscopiei**



Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

Nr. raport: 60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate: Filială

Olympus France S.A.S.
19 rue d'Arcueil
94150 Rungis
Franța

Domeniul de aplicabilitate:

**Marketing, distribuție și service pentru sisteme optice, opto-digitale,
electronice și mecanice, precum și pentru accesoriile corespunzătoare și
consumabilele din domeniul endoscopiei și microscopiei**



Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler





TÜVRheinland®

Doc. 7/13 Rev. 0

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate:

Filială

Olympus Czech Group, s.r.o.
Evropská ul. 176/16
160 41, Praga 6
Republica Cehă

Domeniul de aplicabilitate:

**Marketing, distribuție și service pentru sisteme optice, opto-digitale,
electronice și mecanice, precum și pentru accesoriile corespunzătoare și
consumabilele din domeniul endoscopiei și microscopiei**



DAKkS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler





TÜVRheinland®

Doc. 8/13 Rev. 0

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate:

Filială

Olympus Czech Group, s.r.o.
clen koncernu
Telickova 457/29
751 24 Prerov-Predmosti
Republica Cehă

Domeniul de aplicabilitate:

**Service pentru sisteme optice, opto-digitale, electronice și mecanice,
precum și pentru accesoriile corespunzătoare și consumabilele din
domeniul endoscopiei**



DAKKS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

Nr. raport: 60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate: Filială

Olympus Service Facility Portugal
Tecnologias Optica e Digitais, Lda.
Rua de Alcorredores, 43 A
3020-923 Torre de Vilela (Coimbra)
Portugalia

Domeniul de aplicabilitate:

**Service intern pentru sisteme optice, opto-digitale, electronice și mecanice
precum și accesorii corespunzătoare din domeniul endoscopiei.**



Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

Nr. raport: 60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate: Filială

Olympus Austria GmbH
Shuttleworthstr. 25
1210 Viena
Austria

Domeniul de aplicabilitate:

Marketing, distribuție și service pentru sisteme optice, opto-digitale, electronice și mecanice, precum și pentru accesoriile corespunzătoare și consumabilele din domeniul endoscopiei și microscopiei



Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare: SX 60148788 0001

Nr. raport: 60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate: Filială

Olympus Nederland B.V.
Simon Smitweg 18
2353 GA Leiderdorp
Țările de Jos

Domeniul de aplicabilitate:

**Marketing, distribuție și service pentru sisteme optice, opto-digitale,
electronice și mecanice, precum și pentru accesoriile corespunzătoare și
consumabilele din domeniul endoscopiei și microscopiei**



Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate: Filială

Olympus Schweiz AG
Chriesbaumstr. 6
8604 Volketswil
Elveția

Domeniul de aplicabilitate:

**Service pentru sisteme optice, opto-digitale, electronice și mecanice,
precum și pentru accesoriile corespunzătoare și consumabilele din
domeniul endoscopiei**



Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și ștampilă TÜV
Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler



**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

Atașament la Certificat

Nr. de înregistrare:

SX 60148788 0001

Nr. raport:

60319405 001

Organizație:

**Olympus Europa SE & Co. KG
Amsinckstr. 63
20097 Hamburg
Germania**

Domeniu de aplicabilitate: Filială

Olympus Schweiz AG
Richtiring 30
8304 Wallisellen
Elveția

Domeniul de aplicabilitate:

Marketing, distribuție și service pentru sisteme optice, opto-digitale, electronice și mecanice, precum și pentru accesoriile corespunzătoare și consumabilele din domeniul endoscopiei și microscopiei



Data, 29.04.2020

Organism de certificare
(Semnătură indescifrabilă și șampilă TÜV
Rheinland LGA Products GmbH)
Dipl.-Ing. I. Munkler





CERTIFICATO CE

Certificato n. 187/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

ALSA APPARECCHI MEDICALI SRL

40013 CASTEL MAGGIORE (BO) - VIA C. BONAZZI 16 (ITA) - Italy

mantiene nello stabilimento di:

40013 CASTEL MAGGIORE (BO) - VIA C. BONAZZI 16 (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Aspiratori chirurgici

Accessori per elettrobisturi

Aspiratori di fumi elettrochirurgici

Elettrobisturi

Modd. come da documento 'Allegato al Certificato CE no. 187/MDD - Elenco dei Dispositivi' rev. 0 del 2021/03/05; tale allegato costituisce parte integrante e sostanziale del presente certificato.

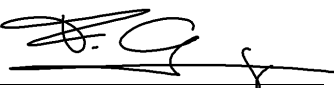
ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Riferimento pratiche IMQ:

10A9800405; 10A9900240; 10AA00040; 10AA00016; 10AA00060; 10AA00156; 10AA00262; 10AB00169; 10AB000170; 10AC00210; 10AE00050; 10AF00011; 10AF00032; 10AF00192; 10AG00183; 10AH00132; 10AH00244; 10AI00034; 10AI00127; 10AI00122; 10AJ00093; 10EL00005; COMEDCONMHDM110021912-01; 10SN00082; DM16-0007485-01; 10AN00148; 10EO00012; DM16-0007485-01; DM17-0017739-01; DM18-0029069-01; DM18-0029585-01; DM18-0031303; DM19-0046045-01; DM21-0060400-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il: 1999-05-10
Data aggiornamento: 2021-03-05
Sostituisce: 2019-11-25
Data scadenza: 2024-05-26


IMQ DocuSign



EC CERTIFICATE

Certificate No 187/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

ALSA APPARECCHI MEDICALI SRL

40013 CASTEL MAGGIORE (BO) - VIA C. BONAZZI 16 (ITA) - Italy

manages in the factory of:

40013 CASTEL MAGGIORE (BO) - VIA C. BONAZZI 16 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Surgical aspirators

Accessories for electrosurgical units

Electrosurgical smoke evacuators

Electrosurgical unit

Type ref. as to document 'Annex of EC Certificate no. 187/MDD - Device List' rev. 0 dated 2021/03/05; this annex is integral and substantial part of this certificate.

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

10A9800405; 10A9900240; 10AA00040; 10AA00016; 10AA00060; 10AA00156; 10AA00262; 10AB00169; 10AB000170; 10AC00210; 10AE00050; 10AF00011; 10AF00032; 10AF00192; 10AG00183; 10AH00132; 10AH00244; 10AI00034; 10AI00127; 10AI00122; 10AJ00093; 10EL00005; COMEDCONMHDM110021912-01; 10SN00082; DM16-0007485-01; 10AN00148; 10EO00012; DM16-0007485-01; DM17-0017739-01; DM18-0029069-01; DM18-0029585-01; DM18-0031303; DM19-0046045-01; DM21-0060400-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date: 1999-05-10
Updated: 2021-03-05
Substitution Date: 2019-11-25
Expiry Date: 2024-05-26


IMQ DocuSign

Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 187/MDD - Device List

rev. 0 del/of 2021/03/05

Categoria di dispositivo: Device category:	Aspiratori chirurgici Surgical aspirators
Serie: Series:	VACUMSOL
Modello/i: Model(s):	VACUMSOL AS-60; VACUMSOL AS-65; VACUMSOL AS-65/H
Serie: Series:	VORTEX-S
Modello/i: Model(s):	VORTEX-S AS-200/20LT; VORTEX-S AS-200/30LT; VORTEX-S AS-200/20LT VE; VORTEX-S AS-200/30LT VE
Serie: Series:	VORTECO
Modello/i: Model(s):	VORTECO AS-100/15LT; VORTECO AS-100/20LT; VORTECO AS-100/30LT; VORTECO AS-100/30LT VE
Serie: Series:	POLIVAC
Modello/i: Model(s):	POLIVAC B4/SLT 30 1; POLIVAC B4/SLT 30 2; POLIVAC B4/SLT 30 1-EXP; POLIVAC B4/SLT 30 2-EXP; POLIVAC B4/SLT 30 P-EXP; POLIVAC B4/SLT 50 E; POLIVAC B4/SLT 30 1VE-EXP; POLIVAC B4/SLT 30 PVE-EXP

Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 187/MDD - Device List

rev. 0 del/of 2021/03/05

Categoria di dispositivo: Device category:	Accessori per elettrobisturi Accessories for electrosurgical units
Serie: Series:	MPE e MLD
Modello/i: Model(s):	Manipoli porta elettrodi monopolari riusabili per utilizzo con comando a pedale
	Codici / Codes: • MPE/S; MPE/E; MPE/E5; MPE/F • MLD; MLD/F
Serie: Series:	MPE/CMS
Modello/i: Model(s):	Manipoli porta elettrodi monopolari riusabili per utilizzo con comando manuale a doppio pulsante
	Codici / Codes: • MPE/CMS; MPE/CMS5; MPE/CMS300; MPE/CMS300-4
Serie: Series:	E
Modello/i: Model(s):	Serie di elettrodi attivi monopolari riusabili per elettrochirurgia
	Codici / Codes: • SEL/VI; SEL/D; SEL/E
Serie: Series:	E
Modello/i: Model(s):	Elettrodi attivi monopolari riusabili per elettrochirurgia
	Codici / Codes: • E1; E11; E3; E1L; E3L; E5; E6; E7; E7L; E8; E10; E12; E13; E14; E15; E16; E17; E18; E19; E21; E23; E23N; E25; E25N; E26: EXT/15 • E27; E29; E30; E31; E32; E33; E34; E35; E37; E39; • E40I; E40; E41; E41I; E42; E43; E46; E47; E47/6; • E48; E49; E50; E51; E52; E53; E54; E55; E56; E57; E58 • E101; E102; E103; E105; E106; E109; E110; E111; E112; E120; E121; • E/ND12; E/DR12; E/HK12; E/HY12; • E/ND18; E/DR18; E/HK18; E/HY18
Serie: Series:	SAD
Modello/i: Model(s):	Elettrodi attivi monopolari (aghi sottili) per elettrochirurgia
	Codici / Codes: • SAD; SAD/AN; SAD/1; SAD/1AN; SAD/2; SAD/2AN; SAD/3; SAD/3AN
Serie: Series:	AID
Modello/i: Model(s):	Elettrodi attivi monopolari (aghi sottili) per elettrochirurgia
	Codici / Codes: • AID

Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 187/MDD - Device List

rev. 0 del/of 2021/03/05

Categoria di dispositivo: Device category:	Accessori per elettrobisturi Accessories for electrosurgical units
Serie: Series:	SAD e AID
Modello/i: Model(s):	Mandrino riduttore per aghi Codici / Codes: MID
Serie: Series:	EL/MLH
Modello/i: Model(s):	Elettrodi attivi monopolari riusabili per laparoscopia Codici / Codes: EL/MLH-J; EL/MLH-L
Serie: Series:	PMC e PBC
Modello/i: Model(s):	Pinze bipolari isolate standard Codici / Codes: PMC/JR; PMC/JC; PMC/RS; PMC/CS; PMC/R; PMC/C; PMC/R25; PMC/C25; PMC/RSB; PMC/B; PMC/B25; PMC/BCD; PMC/BCU PBC/R; PBC/C; PBC/R25; PBC/C25; PBC/B; PBC/B25; PBC/BCD; PBC/BCU
Serie: Series:	PMC/L e PBC/L
Modello/i: Model(s):	Pinze bipolari isolate con irrigazione Codici / Codes: PMC/JRL; PMC/JCL; PMC/RSI; PMC/CSI; PMC/RI; PMC/CL; PMC/R25L; PMC/C25L; PMC/RSBL; PMC/BL; PMC/B25L; PMC/BCDL; PMC/BCUL PBC/RI; PBC/CL; PBC/R25L; PBC/C25L; PBC/BL; PBC/B25L; PBC/BCDL; PBC/BCUL
Serie: Series:	PBC/ns, PMC/ns
Modello/i: Model(s):	Pinze bipolari isolate con punte no-stick Codici / Codes: PMC/JRns; PMC/JCns; PMC/RSns; PMC/CSns; PMC/R15ns; PMC/C15ns; PMC/Rns; PMC/Cns; PMC/R25ns; PMC/C25ns; PMC/RSBns; PMC/B16ns; PMC/Bns; PMC/B25ns; PMC/BCDns; PMC/BCUns; PBC/Rns; PBC/Cns; PBC/R25ns; PBC/C25ns; PBC/Bns; PBC/B25ns; PBC/BCDns; PBC/BCUns

Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 187/MDD - Device List

rev. 0 del/of 2021/03/05

Categoria di dispositivo: Device category:	Accessori per elettrobisturi Accessories for electrosurgical units
Serie: Series:	EB
Modello/i: Model(s):	Elettrodi bipolari isolati rigidi Codici / Codes: EBT; EBT20; EBT22; EBL; EBL16,5; EBA45; EBA90; EBD18; EBD20; EBD22
Serie: Series:	EL/BL
Modello/i: Model(s):	Elettrodi bipolari isolati rigidi per laparoscopia Codici / Codes: EL/BL-J; EL/BL-J45; EL/BL-L; EL/BL-L45; EL/BL-DL; EL/BL-DV; EL/BL-DN
Serie: Series:	BITecD
Modello/i: Model(s):	Forbici bipolari isolate con lame delicate Codici / Codes: BITecD-18; BITecD-21; BITecD-23; BITecD-28
Serie: Series:	BCS e BC
Modello/i: Model(s):	Pinze "clamps" bipolari isolate Codici / Codes: - BCS-15; BCS-19; BCS-S19; BCS-S23 - BC-16; BC-20; BC-23; BC-26
Serie: Series:	POWER GRIP
Modello/i: Model(s):	Strumenti bipolari isolati per laparoscopia Codici / Codes: POWER GRIP – LGF; 82400010; POWER GRIP – MFG; 82400014; POWER GRIP – FGC; 82400015; POWER GRIP – DCG; 82400011; POWER GRIP – MD; 82400019; POWER GRIP – CMS; 82400018
Serie: Series:	CPB e CPB/E
Modello/i: Model(s):	Cavi di collegamento per pinze, elettrodi, strumenti bipolari Codici / Codes: - CPB; CPB/5; CPB/U; CPB/U5; CPB/MU; CPB/MU5; CPB/RU; CPB/RU5; - CPB/E; CPB/E5; CPB/EM; CPB/EM5; CPB/ER; CPB/ER5; CPB/EU; CPB/EU5; - CPB/EE; CPB/EE5; CPB/EE-4; CPB/EE5-4; CPB/EEM; CPB/EEM5; CPB/EES; - CPB/EES5; CPB/EST; CPB/E-WMS; CPB/WMS

Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 187/MDD - Device List

rev. 0 del/of 2021/03/05

Categoria di dispositivo: Device category:	Accessori per elettrobisturi Accessories for electrosurgical units
Serie: Series:	CPB/tec e CPB/E-tec
Modello/i: Model(s):	Cavi di collegamento per forbici bipolari isolate Codici / Codes: - CPB/E-tec; CPB/E-tec5; - CPB/tec; CPB/tec5; CPBS/tec; CPBS/tec5; CPBM/tec; CPBM/tec5; CPBV/tec; CPBV/tec5
Serie: Series:	PMI, PIC, PMI/P, FI e CFI
Modello/i: Model(s):	Pinze (con collegamento all'elettrobisturi e utilizzo mediante comando a pedale) Codici / Codes: PMI/1; PMI/1-20; PMI/1-25; PMI/1C25; PMI/2; PMI/2-25; PMI/B1-18; PMI/B2-18; PMI/B1; PMI/B; PMI/DB1-20; PMI/DB1-25; PMI/DB2-20; PMI/DB2-25
Modello/i: Model(s):	Pinze (senza collegamento all'elettrobisturi e utilizzo mediante contatto) Codici / Codes: PIC/1; PIC/1-25; PIC/2; PIC/2-25; PIC/B1-18; PIC/B2-18; PIC/B1; PIC/B; PIC/DB1-20; PIC/DB1-25; PIC/DB2-20; PIC/DB2-25
Modello/i: Model(s):	Pinze (con collegamento all'elettrobisturi e utilizzo mediante comando manuale) Codici / Codes: PMI/PB; PMI/PB14; PMI/PB19; PMI/PJ18; PMI/PJ21; PMI/PJ24
Modello/i: Model(s):	Forbici (con collegamento all'elettrobisturi e utilizzo mediante comando a pedale) Codici / Codes: FI/18; FI/18C; FI/24; FI/24C; FI/W18; FI/W18C; FI/W24; FI/W24C
Modello/i: Model(s):	Cannule di aspirazione (con collegamento all'elettrobisturi e utilizzo mediante comando a pedale) Codici / Codes: CFI/1; CFI/2; CFI/3
Serie: Series:	EL/ML
Modello/i: Model(s):	Strumenti attivi monopolari riutilizzabili per laparoscopia Codici / Codes: EL/ML-J; EL/ML-JS; EL/ML-L; EL/ML-LS

Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 187/MDD - Device List

rev. 0 del/of 2021/03/05

Categoria di dispositivo: Device category:	Accessori per elettrobisturi Accessories for electrosurgical units
Serie: Series:	CPI, CPE, CEP3, CEP4M e CEP4
Modello/i: Model(s):	Cavi di collegamento per strumenti/elettrodi monopolari Codici / Codes: • CPI; CPI/5; CPI-M4; CPI/5-M4; CPI-M6; CPI-M8; CPI/SM; CPI/L • CPE/5; CPE-M4; CPE/5-M4; CPE-M6; CPE-M8; • CEP3; CEP3/5; CEP3-M4; CEP3/5-M4; CEP3-M6; CEP3-M8; • CEP4M; CEP4M/5; CEP4M-M4; CEP4M/5-M4; CEP4M-M6; CEP4M-M8; • CEP4; CEP4/5; CEP4-M4; CEP4/5-M4; CEP4-M6; CEP4-M8
Serie: Series:	NP/A e EIP
Modello/i: Model(s):	Elettrodi neutri con cavi di collegamento Codici / Codes: • EIP/9; EIP/9-5; EIP/S; • NP/A; NP/A5
Serie: Series:	CMS/E
Modello/i: Model(s):	Cavi di collegamento per elettrodi neutri Codici / Codes: • CMS/E; CMS/E5; CMS/EA; CMS/EA5; CMS/EEN; CMS/E5EN
Serie: Series:	NP/GA e NP/GP
Modello/i: Model(s):	Elettrodi neutri in gomma conduttiva Codici / Codes: • NP/GA • NP/GP
Serie: Series:	AC/E
Modello/i: Model(s):	Manico AC/HANDLE ed elettrodi attivi rigidi per chirurgia con gas argon Codici / Codes: • AC/HANDLE; AC/E25-C; AC/E100-C; AC/E320-C; AC/E320-H; AC/E40-A; AC/E100-A; AC/E40-L; AC/E100-L

Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 187/MDD - Device List

rev. 0 del/of 2021/03/05

Categoria di dispositivo: Device category:	Accessori per elettrobisturi Accessories for electrosurgical units
Serie: Series:	AC/FP
Modello/i: Model(s):	Cavo di collegamento AC/CABLE ed elettrodi attivi flessibili per chirurgia con gas argon
	Codici / Codes: AC/CABLE; AC/FP1; AC/FP1-5; AC/FP2; AC/FP3; AC/FP3s; AC/FP3-5; AC/FP4; AC/FP4-5

Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 187/MDD - Device List

rev. 0 del/of 2021/03/05

Categoria di dispositivo: Device category:	Aspiratori di fumi elettrochirurgici Electrosurgical smoke evacuators
Serie: Series:	CS
Modello/i: Model(s):	CS200; CS200LC; CS900LC

Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 187/MDD - Device List

rev. 0 del/of 2021/03/05

Categoria di dispositivo: Device category:	Elettrobisturi Electrosurgical unit
Serie: Series:	ALSATOM
Modello/i: Model(s):	ALSATOM SU 50-MPC; ALSATOM SU 100-MPC; ALSATOM SU 140-MPC; ALSATOM SU 140/D-MPC; ALSATOM SU 140/BD-MPC; ALSATOM SU 140/D-MPC (100V-60Hz).
Serie: Series:	MCDSe
Modello/i: Model(s):	EXCELL 200 MCDSe; EXCELL 250 MCDSe; EXCELL 350 MCDSe; EXCELL 400 MCDSe; EXCELL 400/A MCDSe
Serie: Series:	NHP
Modello/i: Model(s):	EXCELL NHP 250/D; EXCELL NHP 350/D; EXCELL NHP 400/D; EXCELL NHP 250/DA; EXCELL NHP 400/DA; EXCELL NHP ENDOMED
Serie: Series:	NHP/T
Modello/i: Model(s):	EXCELL NHP/T-400; EXCELL NHP/T-200; EXCELL NHP/TA-400; EXCELL NHP/TA-200
Serie: Series:	TopTom
Modello/i: Model(s):	TopTom SU 50; TopTom SU 100; TopTom SU 140; TopTom SU 140/D



Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 187/MDD - Device List

rev. 0 del/of 2021/03/05

Marca Trade mark:	BUTTERFLY ITALIA
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Categoria di dispositivo: Device category:	Elettrobisturi Electrosurgical unit
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Modello/i: Model(s):	BIPOLAR HF 100; BIPOLAR HF 140.
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Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 187/MDD - Device List

rev. 0 del/of 2021/03/05

Marca Trade mark:	TONTARRA
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Categoria di dispositivo: Device category:	Elettrobisturi Electrosurgical unit
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Modello/i: Model(s):	PWT-400
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Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 187/MDD - Device List

rev. 0 del/of 2021/03/05

Marca Trade mark:	AMNOTECH
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Categoria di dispositivo: Device category:	Elettrobisturi Electrosurgical unit
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Serie: Series:	AMNOTOM
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Modello/i: Model(s):	AMNOTOM 160 BASE; AMNOTOM 400 COMPACT; AMNOTOM 400 PREMIUM; AMNOTOM 400 PREMIUM A
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Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 187/MDD - Device List

rev. 0 del/of 2021/03/05

Marca Trade mark:	ZACCANTI S.p.A.
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Categoria di dispositivo: Device category:	Elettrobisturi Electrosurgical unit
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Modello/i: Model(s):	BIPOGYN
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Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 187/MDD - Device List

rev. 0 del/of 2021/03/05

Marca Trade mark:	EFER ENDOSCOPY
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Categoria di dispositivo: Device category:	Elettrobisturi Electrosurgical unit
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Modello/i: Model(s):	SIRIUS 900
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Allegato al Certificato CE n. 187/MDD - Elenco dei Dispositivi

Annex of EC Certificate no. 187/MDD - Device List

rev. 0 del/of 2021/03/05

Marca Trade mark:	MEDICAL SWAN
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Categoria di dispositivo: Device category:	Elettrobisturi Electrosurgical unit
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Modello/i: Model(s):	PULSAR MB350
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www.imq.it



**CERTIFICATO N.
CERTIFICATE N. 9120.ALSA**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

ALSA APPARECCHI MEDICALI SRL

VIA C. BONAZZI 16 - 40013 CASTEL MAGGIORE (BO)

UNITA' OPERATIVE / OPERATIVE UNITS

VIA C. BONAZZI 16 - 40013 CASTEL MAGGIORE (BO)

E' CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD
ISO 9001:2015

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Progettazione, produzione, immissione in commercio, assistenza tecnica e produzione conto terzi di elettrobisturi con o senza gas ARGON e relativi accessori, aspiratori chirurgici e relativi accessori, aspiratori di fumi elettrochirurgici e relativi accessori
Design, manufacture, placing on the market, technical service and contract manufacturing of electrosurgical units with or without ARGON gas and related accessories, electrosurgical aspirators and related accessories, electrosurgical smoke evacuators and related accessories

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 9001:2015 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
*THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE
REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS*

DATE:	PRIMA CERTIFICAZIONE FIRST CERTIFICATION	EMISSIONE CORRENTE CURRENT ISSUE	SCADENZA EXPIRY
	1998-05-05	2022-03-18	2025-12-19

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago



SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

IAF: 19

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years



Organismo di Certificazione Federato CISQ
www.imq.it



www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ has issued an IQNet recognized certificate that the organization:

ALSA APPARECCHI MEDICALI SRL

VIA C. BONAZZI 16 - 40013 CASTEL MAGGIORE (BO)

*has implemented and maintains a
Quality Management System
for the following scope:*

***Design, manufacture, placing on the market, technical service and contract manufacturing
of electrosurgical units with or without ARGON gas and related accessories,
electrosurgical aspirators and related accessories, electrosurgical smoke evacuators
and related accessories***

Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

which fulfills the requirements of the following standard:

ISO 9001:2015

Issued on: 2022 - 03 - 18

Expires on: 2025 - 12 - 19

*This attestation is directly linked to the IQNet Partner's original certificate
and shall not be used as a stand-alone document*

Registration Number: IT - 1231



*Alex Stoichituiu
President of IQNET*



*Ing. Mario Romersi
President of CISQ*

IQNet Partners*:

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA
FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia



www.imq.it



**CERTIFICATO N.
CERTIFICATE N. 9124.ALS2**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

ALSA APPARECCHI MEDICALI SRL

VIA C. BONAZZI 16 - 40013 CASTEL MAGGIORE (BO)

UNITA' OPERATIVE / OPERATIVE UNITS

VIA C. BONAZZI 16 - 40013 CASTEL MAGGIORE (BO)

E' CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD
ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Progettazione, produzione, immissione in commercio, assistenza tecnica e produzione conto terzi di elettrobisturi con o senza gas ARGON e relativi accessori, aspiratori chirurgici e relativi accessori, aspiratori di fumi elettrochirurgici e relativi accessori
Design, manufacture, placing on the market, technical service and contract manufacturing of electrosurgical units with or without ARGON gas and related accessories, electrosurgical aspirators and related accessories, electrosurgical smoke evacuators and related accessories

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE
REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:

PRIMA CERTIFICAZIONE
FIRST CERTIFICATION
1998-11-30

EMISSIONE CORRENTE
CURRENT ISSUE
2022-03-18

SCADENZA
EXPIRY
2025-12-19

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago



SGQ N° 005 A

Membro degli Accordi di Mutuo
Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC
Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo
del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment
of the entire management System within three years



Organismo di Certificazione Federato CISQ
www.imq.it



www.cisq.com

CISQ è la Federazione Italiana di Organismi di
Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management
system Certification Bodies.



CE – Declaration of Conformity

We hereby certify that AG Neovo complies - with the following specific products – with the requirements of the guideline in the Council Directive on the Approximation of the Laws of the Member States relating to Electromagnetic Compatibility (2014/30/EU), Low-voltage Directive (2014/35/EU), and the ErP Directive (2009/125/EC).

Brand Name : AG Neovo
Product : MD-2702
Type of Equipment : LCD Monitor

Name of the Manufacturer: ASSOCIATED INDUSTRIES CHINA, INC.
Address of the Manufacturer: 5F-1, NO.3-1, PARK ST., NANGANG DISTRICT, TAIPEI,
11503, TAIWAN
TEL: +886-2-2655-8080 FAX: +886-2-2655-7878

In accordance with the following standards:

- ◆ EN 55032:2015 / AS/NZS CISPR 32:2015 / CISPR 32:2015, Class B
- ◆ EN 55032:2015+AC:2016 / EN 55032:2015+A11:2020 / CISPR 32:2015+COR1:2016, Class B
- ◆ EN 55032:2015+A1:2020 / AS/NZS CISPR 32:2015+AMD1:2020, Class B
- ◆ EN 55035:2017 / CISPR 35:2016
- ◆ EN 55035:2017+A11:2020
- ◆ IEC 61000-3-2:2014 / EN 61000-3-2:2014, Class D
- ◆ IEC 61000-3-2:2018 / EN IEC 61000-3-2:2019, Class D
- ◆ EN IEC 61000-3-2:2019+A1:2021, Class D
- ◆ IEC 61000-3-3:2013 / EN 61000-3-3:2013
- ◆ IEC 61000-3-3:2013+A1:2017 / EN 61000-3-3:2013+A1:2019
- ◆ EN IEC 62368-1:2020+A11:2020
- ◆ IEC 62368-1:2018
- ◆ IEC 62368-1:2014 / EN 62368-1:2014; A11:2017

In case of product changes that are not previously agreed by AG Neovo, this declaration of Conformity will lose its validity.

Date of CE Mark: September 23, 2021
Date of Issue: September 24, 2021
Place of the signature: Taiwan



Tony Chu (Senior Manager)

This declaration of conformity is issued under the sole responsibility of the manufacturer.

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	IIb	11-490
	HF-handles	IIb	11-499
	Bipolar coagulation forceps, bipolar coagulation grippers Bipolar and monopolar 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
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	IIb	11-502
	Resectoscopes monopolar and bipolar	IIb	13-335
	Insufflators, laparoscopy with accessories	IIb	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



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
	Arthroscopic shaver systems with accessories	IIa	17-918
Suction- and irrigation units	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	2021-07-05
Valid until	2024-07-04
Registration no.	D1043500084
Report no.	P21-00826-205639
Stuttgart	2021-06-23



Head of Certification Body

