

EC CERTIFICATE

for the Quality Assurance System



**according the Directive 93/42/EEC,
Annex II excluding section (4)**

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company
Richard Wolf GmbH

Pforzheimer Straße 32, 75438 Knittlingen, Germany

Certified location:

Pforzheimer Straße 32, 75438 Knittlingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50593-Z7-00, the decision dated 2020-04-01 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2020-04-01 to 2024-05-26

Registration No.: 50593-16-05

Ruth Delbeck-Bayer



Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2020-04-01
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Annex to the EC Certificate No. 50593-16-05

Valid from 2020-04-01 to 2024-05-26

Revision status of the annex: 0 dated 2020-04-01

Devices/device categories included in the certificate:

Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

- Endoscopic suction valve, single-use, sterile
- Suction system filter, plume particulate
- Suction/irrigation tubing, single use

Class II a:

- Basic endotracheal tube, reusable
- Basic roller pump
- Bone cutting forceps
- Bone graft funnel
- Bronchoscopy tube
- Cannulated surgical drill bit, reusable
- Endoscope assembly adaptor
- Endoscope sheath, reusable
- Endoscopic electrosurgical handpiece/electrode, bipolar, reusable
- Endoscopic electrosurgical handpiece/electrode, monopolar, reusable
- Endoscopic insufflation tubing set, single-use
- Endoscopic insufflation tubing set, sterile, reusable
- Flexible fibreoptic cystourethroscope
- Flexible fibreoptic hysteroscope
- Flexible fibreoptic nasopharyngoscope
- Flexible fibreoptic ureterorenoscope
- Flexible video bronchoscope, reusable
- Flexible video cystoscope, reusable
- Flexible video ureterorenoscope, reusable
- Fluted surgical drill bit, reusable
- General-purpose endoscopic needle, reusable
- General-purpose endoscopic needle, single-use
- Haemorrhoid ligator
- High-pressure medical gas tubing
- Laparoscopic access cannula, reusable
- Laparoscopic multi-instrument access port, reusable
- Laparoscopic multi-instrument access port, single-use
- Laser fibre
- Line-powered surgical power tool system motor
- Medical air low pressure tubing
- Microbial medical gas filter, sterile, single-use
- Operating room audiovisual data/device management system application software
- Orthopaedic bur, reusable
- Orthopaedic bur, single-use
- Resectoscope
- Rigid bronchoscope
- Rigid cystourethroscope
- Rigid endoscope telescope
- Rigid endoscopic grasping forceps, reusable
- Rigid optical hysteroscope
- Rigid intubation laryngoscope, reusable

Annex to the EC Certificate No. 50593-16-05

Valid from 2020-04-01 to 2024-05-26

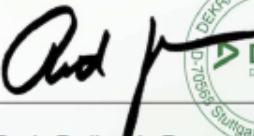
Revision status of the annex: 0 dated 2020-04-01

Devices/device categories included in the certificate:

- Rigid mediastinoscope
- Rigid nephroscope
- Rigid optical laparoscope
- Rigid ureterorenoscope
- Spinal needle, single-use
- Spring-loaded pneumoperitoneum needle, reusable
- Surgical drill guide, reusable
- Surgical fluid/smoke waste management system suction unit
- Surgical guillotine
- Surgical irrigation tubing set, reusable
- Surgical irrigation tubing set, single-use
- Surgical irrigation/aspiration handpiece, reusable
- Surgical irrigation/aspiration tubing set
- Surgical power tool system control unit, line-powered
- Tissue extraction bag
- Tissue morcellation system
- Tissue morcellation system handpiece, line-powered
- Uterine manipulator cervical cup/transilluminator
- Uterine manipulator, reusable
- Uterine probe

Class II b:

- Electrosurgical system generator
- Endoscopic electrosurgical electrode, bipolar, reusable
- Endoscopic electrosurgical electrode, bipolar, single-use, sterile
- Endoscopic electrosurgical handpiece/electrode, monopolar, reusable
- Endoscopic electrosurgical electrode, monopolar, single-use
- Endoscopic electrosurgical handpiece/electrode, bipolar, reusable
- Endoscopic electrosurgical handpiece/electrode, monopolar, reusable
- Endoscopic electrosurgical handpiece/electrode, monopolar, single-use
- General/multiple surgical diode Laser system
- Hysteroscopic irrigation/insufflation system
- Laparoscopic insufflator
- Laser lithotripsy system
- Operating room audiovisual data/device management system application software
- Piezoelectric lithotripsy system
- Soft-tissue/mesh anchor, non-bioabsorbable
- Ultrasonic lithotripsy system
- Electromechanical orthopaedic extracorporeal shock wave therapy system


Ruth Delbeck-Bayer



DEKRA Certification GmbH, Stuttgart, 2020-04-01
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

CERTIFICATE



EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

Richard Wolf GmbH

Scope of certification:

Design and development, production, distribution, installation and service of systems, active medical devices (sterile, non-sterile), non-active medical devices (sterile, non-sterile) for human medicine, in particular for endoscopy and extracorporeal shockwave application.

Design and development, production, and distribution of non-active implants in urology and surgery as well as accessories for processing (cleaning, disinfection, sterilization).

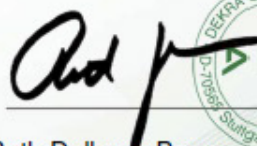
Certified location:

Pforzheimer Straße 32, 75438 Knittlingen, Germany

(further locations see annex)

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50593-Z7-00.

Certificate registration no.:	50593-14-01	Certificate valid from:	2020-04-01
Validity of previous certificate:	2020-03-31	Certificate valid to:	2023-03-31


Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-04-01



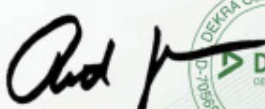
Annex to the Certificate No. 50593-14-01

Revision status: 0

valid from 2020-04-01 to 2023-03-31

The following locations / companies belong to the certificate above:

	Headquarter	Certified location	Scope of certification
	Richard Wolf GmbH	Pforzheimer Straße 32 75438 Knittlingen Deutschland	See page 1
	at the following locations / at the companies at the following locations		Scope of certification
1.	Richard Wolf GmbH	Reuchlinstraße 10-11 10553 Berlin Deutschland	Manufacture of flexible and rigid endoscopes



Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-04-01



CERTYFIKAT WE / EC CERTIFICATE

zgodny z 93/42/EWG Załącznik II(b.p. 4) / acc. 93/42/EEC Annex II(w.o. 4)

Niniejszym zaświadcza się, że firma / This certifies, that the company

EMED Sp. z o.o. Sp.k.
ul. Ryżowa 69a, PL / 05-816 Opacz-Kolonia

dla kategorii wyrobów klasy IIa, IIb / for the product category class IIa, IIb
(Lista wyrobów patrz załącznik 1 / List of products see annex 1)

Aparaty elektrochirurgiczne / Electrosurgical units.

Endoskopowa pompa irygacyjna / Endoscopic irrigation pump.

Akcesoria elektrochirurgiczne / Electrosurgical accesories.

stosuje system zapewnienia jakości w projektowaniu, produkcji i kontroli końcowej wymienionych wyrobów zgodny z wymaganiami Załącznika II (z wyłączeniem sekcji 4) dyrektywy 93/42/EWG. Dodatkowo, przy znaku CE musi zostać naniesiony numer identyfikacyjny jednostki notyfikowanej. Ważność tego certyfikatu zależna jest od utrzymania systemu zapewnienia jakości zgodnego z wymaganiami dyrektywy i jego nadzorowania przez jednostkę notyfikowaną zgodnie z Załącznikiem II, rozdział 5. Certyfikat nie może być przenoszony pod żadnym warunkiem.

has established a quality system for design, production and final testing acc. to the requirements of Annex II (excluding section 4) of the directive 93/42/EEC. Additional to the CE-marking the notification number of the Notified Body has to be affixed. The validity of this certificate is based on the maintenance of the quality system in accordance with the requirements of the directive and its surveillance by the Notified Body according Annex II section 5. The certificate may not be transferred under any circumstances.

Nr rej. / Reg.-No. TNP/MDD/0320/4919/2020

Ważny od / Valid from **21-04-2020**

Raport nr / Report No.: PL4919/2021-03

Ważny do / Valid until **20-04-2023**



Jowita Juźwiak
Jednostka Certyfikująca Wyroby Medyczne /
Certification body for medical devices

Katowice, 24-05-2021

Jednostka notyfikowana Numer identyfikacyjny 2274
Notified Body ID. No. 2274

TÜV NORD Polska Sp. z o.o.
ul. Mickiewicza 29 40-085 Katowice

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www.tuv-nord.pl, biuro@tuv-nord.pl

ZAŁĄCZNIK nr 1, strona 1 z 12 / ANNEX No. 1, page 1 of 12

do certyfikatu numer rejestracyjny / to Certificate Registration No.:

Raport nr / Report No.: PL4919/2021-03

TNP/MDD/0320/4919/2020

Ważny od / Valid from 21-04-2020

Ważny do / Valid until 20-04-2023

Typ / Type	Nr Ref	Wyroby / Products	Klasa Class	UMDNS
Aparat elektrochirurgiczny/ Electrosurgical unit	100-001	Aparat elektrochirurgiczny ES 300 / Electrosurgical unit ES 300	I Ib	11-490
	100-007	Aparat elektrochirurgiczny ES 350 / Electrosurgical unit ES 350	I Ib	11-490
	100-008	Aparat elektrochirurgiczny ES 350 z modulem argonowym / Electrosurgical unit ES 350 with argon module	I Ib	11-490
	100-008-T	Aparat elektrochirurgiczny ES 350 z modulem argonowym i ThermoStapler® / Electrosurgical unit ES 350 with argon and ThermoStapler®	I Ib	11-490
	100-013	Aparat elektrochirurgiczny SPECTRUM / Electrosurgical unit SPECTRUM	I Ib	11-490
	100-014	Aparat elektrochirurgiczny Argo Plasma / Electrosurgical unit Argo Plasma	I Ib	11-490
	66-402-00	ESU - IM GALAXY	I Ib	11-490
	100-015	Aparat elektrochirurgiczny ES 120 / Electrosurgical unit ES 120	I Ib	11-490
	100-600	Aparat elektrochirurgiczny ENDO / Electrosurgical unit ENDO	I Ib	11-490
	100-610	Aparat elektrochirurgiczny ARTRO / Electrosurgical unit ARTRO	I Ib	11-490
	100-620	Aparat elektrochirurgiczny ATOM / Electrosurgical unit ATOM	I Ib	11-490
	66-403-00	ESU - IM GALAXY Smart	I Ib	11-490
	100-630	Aparat elektrochirurgiczny ATOM Smart / Electrosurgical unit ATOM smart	I Ib	11-490
	66-404-00	ESU - IM GALAXY S JUNIOR	I Ib	11-490
	11010042	RF electrosurgical unit for arthroscopy	I Ib	11-490
Endoskopowa pompa irygacyjna / Endoscopic irrigation pump	020-100	WATERFALL endoskopowa pompa irygacyjna / WATERFALL endoscopic irrigation pump	I Ia	17-424
Aksesoria elektrochirurgiczne: Elektroda neutralna Electrosurgical accessories: Neutral electrode	812-80H	Elektroda neutralna jednorazowa EMED SAFE, hydrożel, dzielona, dla dorosłych i dzieci, 176x122mm, 110cm2 Disposable neutral electrode EMED SAFE, hydrogel, split, for adults and children, 176x122mm, 110cm2	I Ib	11-500
	812-83H	Elektroda neutralna jednorazowa EMED SAFE, hydrożel, dzielona, dla noworodków, 181x76mm, 37cm2 / Disposable neutral electrode EMED SAFE, hydrogel, split, for infants, 181x76mm, 37cm2	I Ib	11-500
	812-85H	Elektroda neutralna jednorazowa EMED SAFE, hydrożel, dzielona, dla dorosłych i dzieci, 176x122mm, 110cm2, z kablem USA 3m / Disposable neutral electrode EMED SAFE, hydrogel, split, for adults and children, 176x122mm, 110cm2, with 3m US cable	I Ib	11-500
	812-88H	Elektroda neutralna jednorazowa EMED SAFE, hydrożel, dzielona, dla noworodków, 181x76mm, 37cm2, z kablem USA 3m / Disposable neutral electrode EMED SAFE, hydrogel, split, for infants, 181x76mm, 37cm2, with 3m US cable	I Ib	11-500
	193-008	Elektroda neutralna silikonowa, wielorazowa, dla dorosłych, 30x17cm, kabel dl. 0.5m, standard ERBE / Neutral silicone electrode, reusable, for adults, 30x17cm, cable 0.5m, ERBE plug	I Ib	11-500
	242-003	Elektroda neutralna silikonowa, wielorazowa, dla dorosłych, 30x17cm, kabel dl. 0.5m / Neutral silicone electrode, reusable, for adults, 30x17cm, cable 0.5m	I Ib	11-500
	242-004	Elektroda neutralna silikonowa, wielorazowa, dla dorosłych, 30x17cm, kabel dl. 4m/ wtyk EU/6,3mm / Neutral silicone electrode, reusable, for adults, 30x17cm, cable 4m, EU/6,3mm plug	I Ib	11-500
	242-007	Elektroda neutralna silikonowa, wielorazowa, dla dorosłych, 30x17cm, kabel dl. 4m, wtyk Valleylab / Neutral silicone electrode, reusable, for adults, 30x17cm, cable 4m, Valleylab plug	I Ib	11-500
	242-008	Elektroda neutralna silikonowa, wielorazowa, dla dorosłych, 30x17cm, kabel dl. 4m, wtyk EMED / Neutral silicone electrode, reusable, for adults, 30x17cm, cable 4m, EMED plug	I Ib	11-500



Jowita Juźwiak
Jednostka Certyfikująca Wyroby Medyczne /
Certification body for medical devices

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Katowice, 24-05-2021

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ZAŁĄCZNIK nr 1, strona 2 z 12 / ANNEX No. 1, page 2 of 12

do certyfikatu numer rejestracyjny / to Certificate Registration No.:

Raport nr / Report No.: PL4919/2021-03

TNP/MDD/0320/4919/2020

Ważny od / Valid from 21-04-2020

Ważny do / Valid until 20-04-2023

Typ / Type	Nr Ref	Wyroby / Products	Klasa Class	UMDNS
Akcesoria elektrochirurgiczne Narzędzia laparoskopowe/ Electrosurgical accessories: Laparoscopic instruments	700-003	Elektroda laparoskopowa, szpatuła, śr. 5mm, dł. 360mm / Laparoscopic electrode, spatula, dia. 5mm, L: 360mm	IIb	16-860
	700-004	Elektroda laparoskopowa, hak szeroki, śr. 5mm, dł. 360mm / Laparoscopic electrode, wide hook, dia. 5mm, L: 360mm	IIb	16-860
	700-005	Elektroda laparoskopowa, hak wąski, śr. 5mm, dł. 360mm / Laparoscopic electrode, thin hook, dia. 5mm, L: 360mm	IIb	16-860
	710-003	Elektroda laparoskopowa, szpatuła, śr. 5mm, dł. 360mm, z kanałem ssącym / Laparoscopic electrode, spatula, dia. 5mm, L: 360mm, with suction tube	IIb	16-860
	710-004	Elektroda laparoskopowa, hak szeroki, śr. 5mm, dł. 360mm, z kanałem ssącym / Laparoscopic electrode, wide hook, dia. 5mm, L: 360mm, with suction tube	IIb	16-860
	710-005	Elektroda laparoskopowa, hak wąski, śr. 5mm, dł. 360mm, z kanałem ssącym / Laparoscopic electrode, thin hook, dia. 5mm, L: 360mm, with suction tube	IIb	16-860
	824-010	Wkład grasper, okienkowy, dł. 340mm, wielorazowy do bipolarnego instrumentu laparoskopowego / Insert: grasping forceps, fenestrated, L: 340mm, reusable, for bipolar laparoscopic instrument	IIb	16-206
	824-011	Wkład szczypce lekko zakrzywione, dł. 340mm, wielorazowy do bipolarnego instrumentu laparoskopowego / Insert: forceps, delicate curved, L: 340mm, reusable, for bipolar laparoscopic instrument	IIb	16-206
	824-014	Wkład mikro-grasper, okienkowy, dł. 340mm, wielorazowy do bipolarnego instrumentu laparoskopowego / Insert: micro-grasper, fenestrated, L: 340mm, reusable, for bipolar laparoscopic instrument	IIb	16-206
	824-015	Wkład grasper bipolarny, okienkowy, zakrzywiony, dł. 340mm, wielorazowy do bipolarnego instrumentu laparoskopowego / Insert: grasping forceps, fenestrated, curved, L: 340mm, reusable, for bipolar laparoscopic instrument	IIb	16-206
	824-018	Wkład nożyczki bipolarnie, zakrzywione, dł. 340mm, wielorazowy do bipolarnego instrumentu laparoskopowego / Insert: scissors, curved, L: 340mm, reusable, for bipolar laparoscopic instrument	IIb	16-206
	824-019	Wkład dissektor Maryland, dł. 340mm, wielorazowy do bipolarnego instrumentu laparoskopowego / Insert: dissector Maryland, L: 340mm, reusable, for bipolar laparoscopic instrument	IIb	16-206
	824-030	Wkład grasper ząbkowany, pełny, dł. 340mm, wielorazowy do bipolarnego instrumentu laparoskopowego / Insert: grasping forceps, toothed, large, L: 340mm, reusable, for bipolar laparoscopic instrument	IIb	16-206
	824-031	Wkład dissektor Maryland, szeroki, dł. 340mm, wielorazowy do bipolarnego instrumentu laparoskopowego / Insert: dissector Maryland, wide, L: 340mm, reusable, for bipolar laparoscopic instrument	IIb	16-206
	824-101	Uchwyt, wielorazowy do bipolarnego instrumentu laparoskopowego / Handle, reusable, for bipolar laparoscopic instrument	IIb	16-206
	824-110	Rurka zewnętrzna, śr. 5mm, dł. 100mm, wielorazowa do bipolarnego instrumentu laparoskopowego / Outer shaft, dia. 5mm, L: 100mm, reusable, for bipolar laparoscopic instrument	IIb	16-206
	824-134	Rurka zewnętrzna, śr. 5mm, dł. 340mm, wielorazowa do bipolarnego instrumentu laparoskopowego / Outer shaft, dia. 5mm, L: 340mm, reusable, for bipolar laparoscopic instrument	IIb	16-206
	824-13S	Uchwyt z kablem 3m, wtyk SDS, wielorazowy, do bipolarnego instrumentu laparoskopowego / Handle, cable 3m, SDS plug, reusable, for bipolar laparoscopic instrument	IIb	16-206
	824-501	Wkład grasper okienkowy, dł. 100mm, wielorazowy do bipolarnego instrumentu laparoskopowego / Insert: grasping forceps, fenestrated, L: 100mm, for bipolar laparoscopic instrument	IIb	16-206
	824-519	Wkład dissektor Maryland, dł. 100mm, wielorazowy do bipolarnego instrumentu laparoskopowego / Insert: dissector Maryland, L: 100mm, for bipolar laparoscopic instrument	IIb	16-206


Jowita Juzwiak
Jednostka Certyfikująca Wyroby Medyczne /
Certification body for medical devices

Katowice, 24-05-2021

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ZAŁĄCZNIK nr 1, strona 3 z 12 / ANNEX No. 1, page 3 of 12

do certyfikatu numer rejestracyjny / to Certificate Registration No.:

Raport nr / Report No.: PL4919/2021-03

TNP/MDD/0320/4919/2020

Ważny od / Valid from 21-04-2020

Ważny do / Valid until 20-04-2023

Typ / Type	Nr Ref	Wyroby / Products	Klasa Class	UMDNS
Akcesoria elektrochirurgiczne: Kleszczyki do bipolarnego zamykania naczyń ThermoStapler® /	801-023	ThermoStapler® - kleszczyki do bipolarnego zamykania naczyń, zakrzywione, dł. 23cm, ząbkowane / ThermoStapler® - bipolar vessel sealing clamps, angled, L:23 cm with teeth	IIb	16-206
Electrosurgical accessories: ThermoStapler® - bipolar vessel sealing clamps	801-024	ThermoStapler® - kleszczyki do bipolarnego zamykania naczyń, mocno zakrzywione, dł. 22cm / ThermoStapler® - bipolar vessel sealing clamps, strongly angled, L:22cm	IIb	16-206
	801-116	ThermoStapler® - kleszczyki do bipolarnego zamykania naczyń, zakrzywione, dł. 16cm, gładkie / ThermoStapler® - bipolar vessel sealing clamps, angled, L:16 cm smooth	IIb	16-206
	801-118	ThermoStapler® - kleszczyki do bipolarnego zamykania naczyń, zakrzywione, dł. 18cm, gładkie / ThermoStapler® - bipolar vessel sealing clamps, angled, L:18 cm smooth	IIb	16-206
	801-123	ThermoStapler® - kleszczyki do bipolarnego zamykania naczyń, zakrzywione, dł. 23cm, gładkie / ThermoStapler® - bipolar vessel sealing clamps, angled, L:23 cm smooth	IIb	16-206
	801-128	ThermoStapler® - kleszczyki do bipolarnego zamykania naczyń, zakrzywione, dł. 28cm, gładkie / ThermoStapler® - bipolar vessel sealing clamps, angled, L:28 cm smooth	IIb	16-206
	801-16S	ThermoStapler®, kleszczyki do bipolarnego zamykania naczyń, zagięte, gładkie, dł. 16 cm, z kablem 3m, wtyk SDS / ThermoStapler® - vessel sealing clamps, angled, smooth, L:16 cm cable 3m, SDS plug	IIb	16-206
	801-18S	ThermoStapler®, kleszczyki do bipolarnego zamykania naczyń, zagięte, gładkie, dł. 18 cm, z kablem 3m, wtyk SDS / ThermoStapler® - vessel sealing clamps, angled, smooth, L:18 cm cable 3m, SDS plug	IIb	16-206
	801-216	ThermoStapler® - kleszczyki do bipolarnego zamykania naczyń, proste, dł. 16cm, gładkie / ThermoStapler® - bipolar vessel sealing clamps, straight, L:16 cm smooth	IIb	16-206
	801-218	ThermoStapler® - kleszczyki do bipolarnego zamykania naczyń, proste, dł. 18cm, gładkie / ThermoStapler® - bipolar vessel sealing clamps, straight, L:18 cm smooth	IIb	16-206
	801-223	ThermoStapler® - kleszczyki do bipolarnego zamykania naczyń, proste, dł. 23cm, gładkie / ThermoStapler® - bipolar vessel sealing clamps, straight, L:23 cm smooth	IIb	16-206
	801-228	ThermoStapler® - kleszczyki do bipolarnego zamykania naczyń, proste, dł. 28cm, gładkie / ThermoStapler® - bipolar vessel sealing clamps, straight, L:28 cm smooth	IIb	16-206
	801-23S	ThermoStapler®, kleszczyki do bipolarnego zamykania naczyń, zagięte, gładkie, dł. 23 cm, z kablem 3m, wtyk SDS / ThermoStapler® - vessel sealing clamps, angled, smooth, L:23 cm cable 3m, SDS plug	IIb	16-206
	801-28S	ThermoStapler®, kleszczyki do bipolarnego zamykania naczyń, zagięte, gładkie, dł. 28 cm, z kablem 3m, wtyk SDS / ThermoStapler® - vessel sealing clamps, angled, smooth, L:28 cm cable 3m, SDS plug	IIb	16-206
	801-66S	ThermoStapler®, kleszczyki do bipolarnego zamykania naczyń, proste, gładkie, dł. 16 cm, z kablem 3m, wtyk SDS / ThermoStapler® - vessel sealing clamps, straight, smooth, L:16 cm cable 3m, SDS plug	IIb	16-206
	801-68S	ThermoStapler®, kleszczyki do bipolarnego zamykania naczyń, proste, gładkie, dł. 18 cm, z kablem 3m, wtyk SDS / ThermoStapler® - vessel sealing clamps, straight, smooth, L:18 cm cable 3m, SDS plug	IIb	16-206
	801-73S	ThermoStapler®, kleszczyki do bipolarnego zamykania naczyń, proste, gładkie, dł. 23 cm, z kablem 3m, wtyk SDS / ThermoStapler® - vessel sealing clamps, straight, smooth, L:23 cm cable 3m, SDS plug	IIb	16-206
	801-78S	ThermoStapler®, kleszczyki do bipolarnego zamykania naczyń, proste, gładkie, dł. 28 cm, z kablem 3m, wtyk SDS / ThermoStapler® - vessel sealing clamps, straight, smooth, L:28 cm cable 3m, SDS plug	IIb	16-206



Jowita Juźwiak
Jednostka Certyfikująca Wyroby Medyczne /
Certification body for medical devices

Katowice, 24-05-2021

Jednostka notyfikowana Numer identyfikacyjny 2274
Notified Body ID. No. 2274

TÜV NORD Polska Sp. z o.o.
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ZAŁĄCZNIK nr 1, strona 4 z 12 / ANNEX No. 1, page 4 of 12

do certyfikatu numer rejestracyjny / to Certificate Registration No.:

Raport nr / Report No.: PL4919/2021-03

TNP/MDD/0320/4919/2020

Ważny od / Valid from 21-04-2020

Ważny do / Valid until 20-04-2023

Typ / Type	Nr Ref	Wyroby / Products	Klasa Class	UMDNS
Akcesoria elektrochirurgiczne: Instrumenty bipolarnie/	804-020	Nóż do instrumentu ThermoStapler Alpha®, dl. 20cm, jednorazowy, niesterylny / Blade for ThermoStapler Alpha® instrument, L: 20cm, disposable, non-sterile	IIb	16-206
Electrosurgical accessories: Bipolar instruments	804-037	Nóż do instrumentu ThermoStapler Alpha®, dl. 37cm, jednorazowy, niesterylny / Blade for ThermoStapler Alpha® instrument, L: 37cm, disposable, non-sterile	IIb	16-206
	804-100	Rękojeść do instrumentu ThermoStapler Alpha®, z kablem SDS 4m, wielorazowa, niesterylna / Handpiece for ThermoStapler Alpha® instrument, SDS cable 4m, reusable, non-sterile	IIb	16-206
	804-120	Element roboczy do instrumentu ThermoStapler Alpha®, śr. 10mm, dl. 20cm, wielorazowy, niesterylny / Working element for ThermoStapler Alpha® instrument, dia. 10mm, L: 20cm, reusable, non-sterile	IIb	16-206
	804-137	Element roboczy do instrumentu ThermoStapler Alpha®, śr. 10mm, dl. 37cm, wielorazowy, niesterylny / Working element for ThermoStapler Alpha® instrument, dia. 10mm, L: 37cm, reusable, non-sterile	IIb	16-206
	804-220	Kompletny instrument ThermoStapler Alpha®, zamykająco-tnący, śr. 10mm, dl. 20cm, z kablem SDS 4m, wielorazowy, niesterylny / ThermoStapler Alpha® complete sealing and cutting instrument, dia. 10mm, L: 20cm, SDS cable 4m, reusable, non-sterile	IIb	16-206
	804-237	Kompletny instrument ThermoStapler Alpha®, zamykająco-tnący, śr. 10mm, dl. 37cm, z kablem SDS 4m, wielorazowy, niesterylny / ThermoStapler Alpha® complete sealing and cutting instrument, dia. 10mm, L: 37cm, SDS cable 4m, reusable, non-sterile	IIb	16-206
Akcesoria elektrochirurgiczne: Uchwyt elektrody/	104-230	Uchwyt elektrody 4mm, wąski, 2 przyciski, kabel 3m, wtyk ERBE / Electrode handle 4mm, small, 2 switches, cable 3m, ERBE plug	IIb	11-499
Electrosurgical accessories: Electrode handles	104-250	Uchwyt elektrody 4mm, wąski, 2 przyciski, kabel 5m, wtyk ERBE / Electrode handle 4mm, small, 2 switches, cable 5m, ERBE plug	IIb	11-499
	105-230	Uchwyt elektrody 2,4mm, wąski, 2 przyciski, kabel 3m, wtyk ERBE / Electrode handle 2.4mm, small, 2 switches, cable 3m, ERBE plug	IIb	11-499
	105-250	Uchwyt elektrody 2,4mm, wąski, 2 przyciski, kabel 5m, wtyk ERBE / Electrode handle 2.4mm, small, 2 switches, cable 5m, ERBE plug	IIb	11-499
	110-145	Uchwyt elektrody 4mm, szeroki, 2 przyciski, kabel 4m, wtyk ERBE / Electrode handle 4mm, large, 2 switches, cable 4m, ERBE plug	IIb	11-499
	111-145	Uchwyt elektrody 2,4mm, szeroki, 2 przyciski, kabel 4m, wtyk ERBE / Electrode handle 2.4mm, large, 2 switches, cable 4m, ERBE plug	IIb	11-499
	215-230	Uchwyt elektrody 4mm, wąski, 2 przyciski, kabel 3m, wtyk 3-pin / Electrode handle 4mm, small, 2 switches, cable 3m, 3-pin plug	IIb	11-499
	215-23S	Uchwyt elektrody 4mm, wąski, 2 przyciski, kabel 3m, wtyk SDS / Electrode handle 4mm, small, 2 switches, cable 3m, SDS plug	IIb	11-499
	215-250	Uchwyt elektrody 4mm, wąski, 2 przyciski, kabel 5m, wtyk 3-pin / Electrode handle 4mm, small, 2 switches, cable 5m, 3-pin plug	IIb	11-499
	215-25S	Uchwyt elektrody 4mm, wąski, 2 przyciski, kabel 5m, wtyk SDS / Electrode handle 4mm, small, 2 switches, cable 5m, SDS plug	IIb	11-499
	218-230	Uchwyt elektrody 2,4mm, wąski, 2 przyciski, kabel 3m, wtyk 3-pin / Electrode handle 2.4mm, small, 2 switches, cable 3m, 3-pin plug	IIb	11-499
	218-23S	Uchwyt elektrody 2,4mm, wąski, 2 przyciski, kabel 3m, wtyk SDS / Electrode handle 2.4mm, small, 2 switches, cable 3m, SDS plug	IIb	11-499
	218-250	Uchwyt elektrody 2,4mm, wąski, 2 przyciski, kabel 5m, wtyk 3-pin / Electrode handle 2.4mm, small, 2 switches, cable 5m, 3-pin plug	IIb	11-499
	218-25S	Uchwyt elektrody 2,4mm, wąski, 2 przyciski, kabel 5m, wtyk SDS / Electrode handle 2.4mm, small, 2 switches, cable 5m, SDS plug	IIb	11-499
	227-145	Uchwyt elektrody 4mm, szeroki, 2 przyciski, kabel 4m, wtyk MARTIN / Electrode handle 4mm, large, 2 switches, cable 4m, MARTIN plug	IIb	11-499
	228-145	Uchwyt elektrody 2,4mm, szeroki, 2 przyciski, kabel 4m, wtyk MARTIN / Electrode handle 2.4mm, large, 2 switches, cable 4m, MARTIN plug	IIb	11-499
	322-145	Uchwyt elektrody 4mm, szeroki, 2 przyciski, kabel 4m, wtyk 3-pin / Electrode handle 4mm, large, 2 switches, cable 4m, 3-pin plug	IIb	11-499
	322-14S	Uchwyt elektrody 4mm, szeroki, 2 przyciski, kabel 4m, wtyk SDS / Electrode handle 4mm, large, 2 switches, cable 4m, SDS plug	IIb	11-499
	325-14S	HandyPen, uchwyt elektrody 4mm, szeroki, 2 przyciski, kabel 4m, wtyk SDS / HandyPen, electrode handle 4mm, large, 2 switches, cable 4m, SDS plug	IIb	11-499
	325-145	HandyPen, uchwyt elektrody 4mm, szeroki, 2 przyciski, kabel 4m, wtyk 3-pin / HandyPen, electrode handle 4mm, large, 2 switches, cable 4m, 3-pin plug	IIb	11-499
	326-145	HandyPen, uchwyt elektrody 2,4mm, szeroki, 2 przyciski, kabel 4m, wtyk 3-pin / HandyPen, electrode handle 2.4mm, large, 2 switches, cable 4m, 3-pin plug	IIb	11-499


Jowita Juźwiak

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Certification body for medical devices

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ZAŁĄCZNIK nr 1, strona 5 z 12 / ANNEX No. 1, page 5 of 12

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Raport nr / Report No.: PL4919/2021-03

TNP/MDD/0320/4919/2020

Ważny od / Valid from 21-04-2020

Ważny do / Valid until 20-04-2023

Typ / Type	Nr Ref	Wyroby / Products	Klasa Class	UMDNS
Aksesoria elektrochirurgiczne: Uchwyt elektrody/	326-14S	HandyPen, uchwyt elektrody 2,4mm, szeroki, 2 przyciski, kabel 4m, wtyk SDS / HandyPen, electrode handle 2.4mm, large, 2 switches, cable 4m, SDS plug	IIb	11-499
Electrosurgical accessories: Electrode handles	327-14S	Uchwyt elektrody 2,4mm, szeroki, 2 przyciski, kabel 4m, wtyk 3-pin / Electrode handle 2.4mm, large, 2 switches, cable 4m, 3-pin plug	IIb	11-499
	327-14S	Uchwyt elektrody 2,4mm, szeroki, 2 przyciski, kabel 4m, wtyk SDS / Electrode handle 2.4mm, large, 2 switches, cable 4m, SDS plug	IIb	11-499
	847-030	Uchwyt jednorazowy z elektrodą, nóż, 2 przyciski, kabel dl. 3m, wtyk 3-pin, steryliz. / Disposable handle with knife electrode, 2 switches, cable 3m, 3-pin plug, sterile.	IIb	11-499
	847-031	Uchwyt jednorazowy z elektrodą, igła, 2 przyciski, kabel dl. 3m, wtyk 3-pin, steryliz. / Disposable handle with needle electrode, 2 switches, cable 3m, 3-pin plug, sterile.	IIb	11-499
	847-032	Uchwyt jednorazowy z nożem w zestawie z pojemnikiem i czyszcikiem, kabel dl. 3m, wtyk 3-pin, steryliz. / Disposable handle with knife electrode, holster and tip cleaner, cable 3m, 3-pin plug, sterile.	IIb	11-499
	847-033	Uchwyt jednorazowy z elektrodą, nóż, 2 przyciski, kabel dl. 3m, wtyk Erbe, steryliz. / Disposable handle with knife electrode, 2 switches, cable 3m, Erbe plug, sterile.	IIb	11-499
	847-S30	Uchwyt jednorazowy z elektrodą, nóż, 2 przyciski, kabel dl. 3m, wtyk SDS, steryliz. / Disposable handle with knife electrode, 2 switches, cable 3m, SDS plug, sterile.	IIb	11-499
	847-S31	Uchwyt jednorazowy z elektrodą, igła, 2 przyciski, kabel dl. 3m, wtyk SDS, steryliz. / Disposable handle with needle electrode, 2 switches, cable 3m, SDS plug, sterile.	IIb	11-499
	847-S32	Uchwyt jednorazowy z nożem w zestawie z pojemnikiem i czyszcikiem, kabel dl. 3m, wtyk SDS, steryliz. / Disposable handle with knife electrode, holster and tip cleaner, cable 3m, SDS plug, sterile.	IIb	11-499
	848-030	Uchwyt jednorazowy do odsysania dymu z elektrodą nieklejącą, nóż, 2 przyciski, kabel dl. 3m, wtyk 3-pin, steryliz. / Smoke evacuation handle with non-stick knife electrode, 2 switches, cable 3m, 3-pin plug, disposable, sterile.	IIb	11-499
	848-S30	Uchwyt jednorazowy do odsysania dymu z elektrodą nieklejącą, nóż, 2 przyciski, kabel dl. 3m, wtyk SDS, steryliz. / Smoke evacuation handle with non-stick knife electrode, 2 switches, cable 3m, SDS plug, disposable, sterile.	IIb	11-499
	932-141	Uchwyt elektrody argonowej, szeroki, 2 przyciski, kabel 3,5m, wtyk 3-pin/ LuerLock / Argon electrode handle, large, 2 switches, cable 3.5m, 3-pin/LuerLock plug	IIb	11-499
	932-14A	Uchwyt elektrody argonowej, szeroki, 2 przyciski, kabel 3,5m, wtyk SDSA / Argon electrode handle, large, 2 switches, cable 3.5m, SDSA plug	IIb	11-499
	932-14S	Uchwyt elektrody argonowej, szeroki, 2 przyciski, kabel 3,5m, wtyk SDS/ LuerLock / Argon electrode handle, large, 2 switches, cable 3.5m, SDS/LuerLock plug	IIb	11-499
Aksesoria elektrochirurgiczne: Szczypce /	605-001	Szczypce bipolarne, kątowe, 1mm, dl. 195 mm / Bipolar forceps, angled, 1mm, L: 195mm	IIb	11-502
Electrosurgical accessories: Forceps	605-002	Szczypce bipolarne, bagietkowe, 1mm, dl. 195mm / Bipolar forceps, bayonet, 1mm, L: 195mm	IIb	11-502
	605-007	Szczypce bipolarne, kątowe, 2mm, dl. 195mm / Bipolar forceps, angled, 2mm, L: 195mm	IIb	11-502
	605-008	Szczypce bipolarne, bagietkowe, igła, dl. 195mm / Bipolar forceps, bayonet, needle, L: 195mm	IIb	11-502
	605-011	Szczypce bipolarne, proste, igła, dl. 160mm / Bipolar forceps, straight, needle, L: 160mm	IIb	11-502
	605-013	Szczypce bipolarne, kątowe, 0,5mm, dl. 160mm / Bipolar forceps, angled, 0.5mm, L: 160mm	IIb	11-502
	605-014	Szczypce bipolarne, kątowe, 1mm, dl. 160mm / Bipolar forceps, angled, 1mm, L: 160mm	IIb	11-502
	605-016	Szczypce bipolarne, proste, 1mm, dl. 110mm / Bipolar forceps, straight, 1mm, L: 110mm	IIb	11-502
	605-017	Szczypce bipolarne, bagietkowe, 0,5mm, dl. 160mm / Bipolar forceps, bayonet, 0.5mm, L: 160mm	IIb	11-502
	605-018	Szczypce bipolarne, bagietkowe, 1mm, dl. 160mm / Bipolar forceps, bayonet, 1mm, L: 160mm	IIb	11-502
	605-019	Szczypce bipolarne, proste, igła, dl. 110mm / Bipolar forceps, straight, needle, L: 110mm	IIb	11-502


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Ważny od / Valid from 21-04-2020

Ważny do / Valid until 20-04-2023

Typ / Type	Nr Ref	Wyroby / Products	Klasa Class	UMDNS
Akcesoria elektrochirurgiczne: Szczypce / Electrosurgical accessories: Forceps	605-020	Szczypce bipolarne, proste, 0,5mm, dl. 110mm / Bipolar forceps, straight, 0.5mm, L: 110mm	IIb	11-502
	605-021	Szczypce bipolarne, kątowe, 0,5mm, dl. 110mm / Bipolar forceps, angled, 0.5mm, L: 110mm	IIb	11-502
	605-023	Szczypce bipolarne, kątowe, igła, dl. 110mm / Bipolar forceps, angled, needle, L: 110mm	IIb	11-502
	605-024	Szczypce bipolarne, kątowe, 1mm, dl. 220mm / Bipolar forceps, angled, 1mm, L: 220mm	IIb	11-502
	605-026	Szczypce bipolarne, bagietkowe, kątowe, góra, 1mm, dl. 195mm / Bipolar forceps, bayonet, angled, up, 1mm, L: 195mm	IIb	11-502
	605-027	Szczypce bipolarne, proste, 2mm, dl. 160mm / Bipolar forceps, straight, 2mm, L: 160mm	IIb	11-502
	605-029	Szczypce bipolarne, proste, 2mm, dl. 195mm / Bipolar forceps, straight, 2mm, L: 195mm	IIb	11-502
	605-030	Szczypce bipolarne, proste, 2mm, dl. 220mm / Bipolar forceps, straight, 2mm, L: 220mm	IIb	11-502
	605-031	Szczypce bipolarne, bagietkowe, 0,5mm, dl. 220mm / Bipolar forceps, bayonet, 0.5mm, L: 220mm	IIb	11-502
	605-033	Szczypce bipolarne, bagietkowe, igła, dl. 160mm / Bipolar forceps, bayonet, needle, L: 160mm	IIb	11-502
	605-034	Szczypce bipolarne, bagietkowe, 2mm, dl. 195mm / Bipolar forceps, bayonet, 2mm, L: 195mm	IIb	11-502
	605-036	Szczypce bipolarne, kątowe, igła, dl. 160mm / Bipolar forceps, angled, needle, L: 160mm	IIb	11-502
	605-039	Szczypce bipolarne, proste, 1mm, dl. 160mm / Bipolar forceps, straight, 1mm, L: 160mm	IIb	11-502
	605-040	Szczypce bipolarne, proste, 1mm, dl. 195mm / Bipolar forceps, straight, 1mm, L: 195mm	IIb	11-502
	605-041	Szczypce bipolarne, proste, 1mm, dl. 220mm / Bipolar forceps, straight, 1mm, L: 220mm	IIb	11-502
	605-045	Szczypce bipolarne, bagietkowe, igła, dl. 220mm / Bipolar forceps, bayonet, needle, L: 220mm	IIb	11-502
	605-057	Szczypce bipolarne, proste, profil 2mm, dl. 195mm / Bipolar forceps, straight, 2mm profile, L: 195mm	IIb	11-502
	605-058	Szczypce bipolarne, kątowe, profil 2mm, dl. 195mm / Bipolar forceps, angled, 2mm profile, L: 195mm	IIb	11-502
	605-059	Szczypce bipolarne, bagietkowe, profil 2mm, dl. 195mm / Bipolar forceps, bayonet, 2mm profile, L: 195mm	IIb	11-502
	605-063	Szczypce bipolarne, bagietkowe, kątowe, 1mm, dl. 220mm / Bipolar forceps, bayonet, angled, 1mm, L: 220mm	IIb	11-502
	605-064	Szczypce bipolarne, bagietkowe, kątowe, 2mm, dl. 220mm / Bipolar forceps, bayonet, angled, 2mm, L: 220mm	IIb	11-502
	605-065	Szczypce bipolarne, bagietkowe, kątowe, 1mm, dl. 195mm / Bipolar forceps, bayonet, angled, 1mm, L: 195mm	IIb	11-502
	605-066	Szczypce bipolarne, kątowe, 2mm, dl. 300mm / Bipolar forceps, angled, 2mm, L: 300mm	IIb	11-502
	605-070	Szczypce bipolarne, proste, 2mm, dl. 300mm / Bipolar forceps, straight, 2mm, L: 300mm	IIb	11-502
Akcesoria elektrochirurgiczne: Elektrody aktywne / Electrosurgical accessories: Active electrodes	520-100	Elektroda lancet prosty, owalny, 25 x 3,5mm, uchwyt 4mm / Lancet electrode straight, oval shape, 25 x 3.5mm, handle 4mm	IIb	16-860
	520-200	Elektroda lancet kątowny, romboidalny, 19 x 1,8mm, uchwyt 4mm / Lancet electrode angled, rhombic, 19 x 1.8mm, handle 4mm	IIb	16-860
	520-300	Elektroda lancet prosty, romboidalny, 25 x 1,8mm, uchwyt 4mm / Lancet electrode straight, rhombic, 25 x 1.8mm, handle 4mm	IIb	16-860
	520-400	Elektroda lancet prosty, wąski, 25 x 1,8mm, uchwyt 4mm / Lancet electrode, thin, 25 x 1.8mm, handle 4mm	IIb	16-860
	520-500	Elektroda nóż prosty, 25 x 3,5mm, uchwyt 4mm / Knife electrode straight, 25 x 3.5mm, handle 4mm	IIb	16-860
	520-600	Elektroda szpatuła owalna, prosta, 2 x 24mm, uchwyt 4mm / Spatula electrode, oval shape, straight, 2 x 24mm, handle 4mm	IIb	16-860
	520-650	Elektroda szpatuła owalna, kątowna, 3 x 24mm, uchwyt 4mm / Spatula electrode, oval shape, angled, 3 x 24mm, handle 4mm	IIb	16-860
	520-700	Elektroda nóż prosty, 25mm, uchwyt 4mm / Knife electrode straight, 25mm, handle 4mm	IIb	16-860
	520-800	Elektroda lancet kątowny, uchwyt 4mm / Lancet electrode, angular, handle 4mm	IIb	16-860
	520-900	Elektroda lancet prosty, uchwyt 4mm / Lancet electrode straight, handle 4mm	IIb	16-860

Juzwiak
Jowita Juzwiak

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Ważny do / Valid until 20-04-2023

Typ / Type	Nr Ref	Wyroby / Products	Klasa Class	UMDNS
Akcesoria elektrochirurgiczne: Elektrody aktywne/ Electrosurgical accessories: Active electrodes	521-010	Elektroda igła prosta, 0,5mm, uchwyt 4mm / Needle electrode, straight, 0.5 mm, handle 4mm	IIb	16-860
	521-020	Elektroda igła prosta, 0,7mm, uchwyt 4mm / Needle electrode, straight, 0.7mm, handle 4mm	IIb	16-860
	521-050	Elektroda igła prosta, krótka, 0,5mm, uchwyt 4mm / Needle electrode, short, 0.5mm, handle 4mm	IIb	16-860
	521-110	Elektroda igła prosta, krótka, 0,5 mm, uchwyt 4mm / Needle electrode, short, 0.5mm, handle 4mm	IIb	16-860
	521-120	Elektroda igła prosta, krótka, 0,7mm, uchwyt 4mm / Needle electrode, short, 0.7mm, handle 4mm	IIb	16-860
	521-180	Elektroda igła wolframowa z izolacją ceramiczną, 0,5 x 5mm, uchwyt 4mm / Tungsten needle electrode with ceramic insulation, 0.5 x 5mm, handle 4mm	IIb	16-860
	521-210	Elektroda pętla druciana, 5mm, uchwyt 4mm / Wire loop electrode, 5mm, handle 4mm	IIb	16-860
	521-220	Elektroda pętla druciana, 10mm, uchwyt 4mm / Wire loop electrode, 10mm, handle 4mm	IIb	16-860
	521-230	Elektroda pętla druciana, 14mm, uchwyt 4mm / Wire loop electrode, 14mm, handle 4mm	IIb	16-860
	521-310	Elektroda pętla taśmowa, 10mm, uchwyt 4mm / Ribbon loop electrode, 10mm, handle 4mm	IIb	16-860
	521-320	Elektroda pętla taśmowa, 15mm, uchwyt 4mm / Ribbon loop electrode, 15mm, handle 4mm	IIb	16-860
	521-350	Elektroda pętla taśmowa, 12mm, uchwyt 4mm / Ribbon loop electrode, 12mm, handle 4mm	IIb	16-860
	521-380	Elektroda pętla taśmowa, 16mm, uchwyt 4mm / Ribbon loop electrode, 16mm, handle 4mm	IIb	16-860
	521-410	Elektroda kulka prosta, 2mm, uchwyt 4mm / Ball electrode straight, 2mm, handle 4mm	IIb	16-860
	521-420	Elektroda kulka prosta, 4mm, uchwyt 4mm / Ball electrode straight, 4mm, handle 4mm	IIb	16-860
	521-430	Elektroda kulka prosta, 6mm, uchwyt 4mm / Ball electrode straight, 6mm, handle 4mm	IIb	16-860
	521-480	Elektroda kulka kątowa, 2mm, uchwyt 4mm / Ball electrode, angled, 2mm, handle 4mm II b	IIb	16-860
	521-490	Elektroda kulka kątowa, 4mm, uchwyt 4mm / Ball electrode, angled, 4mm, handle 4mm	IIb	16-860
	521-600	Elektroda igła prosta, 0,8 x 29mm, uchwyt 4mm / Needle electrode, straight, 0.8 x 29mm, handle 4mm	IIb	16-860
	522-300	Elektroda igła wolframowa prosta, izolowana, 0,5 x 20mm, uchwyt 4mm / Tungsten needle electrode, straight, insulated, 0.5 x 20mm, handle 4mm	IIb	16-860
	522-400	Elektroda igła wolframowa kątowa, izolowana, 0,5x20mm, uchwyt 4mm / Tungsten needle electrode, angled, insulated, 0.5 x 20mm, handle 4mm	IIb	16-860
	522-500	Elektroda igła wolframowa prosta, izolowana, 0,5 x 40mm, uchwyt 4mm / Tungsten needle electrode, straight, insulated, 0.5 x 40mm, handle 4mm	IIb	16-860
	522-600	Elektroda igła wolframowa kątowa, izolowana, 0,5 x 40mm, uchwyt 4mm / Tungsten needle electrode, angled, insulated, 0.5 x 40mm, handle 4mm	IIb	16-860
	522-700	Elektroda szpatuła prosta, 3 x 24mm, uchwyt 4mm / Spatula electrode, straight, 3 x 24mm, handle 4mm	IIb	16-860
	523-200	Elektroda szpatuła prosta, 2 x 16mm, dł. 80mm, uchwyt 4mm / Spatula electrode, straight, 2 x 16mm, L: 80mm, handle 4mm	IIb	16-860
	523-210	Elektroda szpatuła prosta, 2 x 16mm, dł. 40mm, uchwyt 4mm / Spatula electrode, straight, 2 x 16mm, L: 40mm, handle 4mm	IIb	16-860
	523-910	Elektroda pętla, 5mm, dł. 100mm, uchwyt 4mm / Wire loop electrode, 5mm, L: 100mm, handle 4mm	IIb	16-860
	523-920	Elektroda pętla, 10mm, dł. 100mm, uchwyt 4mm / Wire loop electrode, 10mm, L: 100mm, handle 4mm	IIb	16-860
	523-930	Elektroda pętla, 14mm, dł. 100mm, uchwyt 4mm / Wire loop electrode, 14mm, L: 100mm, handle 4mm	IIb	16-860
	524-010	Elektroda kulka prosta, 2mm, dł. 100mm, uchwyt 4mm / Ball electrode straight, 2mm, L: 100mm, handle 4mm	IIb	16-860

Juzwiak

Jowita Juzwiak

Jednostka Certyfikująca Wyroby Medyczne /
Certification body for medical devices

Jednostka notyfikowana Numer identyfikacyjny 2274
Notified Body ID. No. 2274

Katowice, 24-05-2021

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ZAŁĄCZNIK nr 1, strona 8 z 12 / ANNEX No. 1, page 8 of 12

do certyfikatu numer rejestracyjny / to Certificate Registration No.:

Raport nr / Report No.: PL4919/2021-03

TNP/MDD/0320/4919/2020

Ważny od / Valid from 21-04-2020

Ważny do / Valid until 20-04-2023

Typ / Type	Nr Ref	Wyroby / Products	Klasa Class	UMDNS
Akcesoria elektrochirurgiczne: Elektrody aktywne/ Electrosurgical accessories: Active electrodes	524-020	Elektroda kulka prosta, 4mm, dł. 100mm, uchwyt 4mm / Ball electrode straight, 4mm, L: 100mm, handle 4mm	Ib	16-860
	524-030	Elektroda kulka prosta, 6mm, dł. 100mm, uchwyt 4mm / Ball electrode straight, 6mm, L: 100mm, handle 4mm	Ib	16-860
	524-050	Elektroda kulka kątowa, 4mm, dł. 100mm, uchwyt 4mm / Ball electrode, angled, 4mm, L: 100mm, handle 4mm	Ib	16-860
	524-070	Elektroda kulka kątowa, 6mm, dł. 100mm, uchwyt 4mm / Ball electrode, angled, 6mm, L: 100mm, handle 4mm	Ib	16-860
	524-110	Elektroda igła prosta, 0,5mm, dł. 100mm, uchwyt 4mm / Needle electrode straight, 0.5mm, L: 100mm, handle 4mm	Ib	16-860
	524-120	Elektroda igła prosta, 0,7mm, dł. 100mm, uchwyt 4mm / Needle electrode straight, 0.7mm, L: 100mm, handle 4mm	Ib	16-860
	524-130	Elektroda igła prosta, 0,8 x 12mm, dł. 100mm, uchwyt 4mm / Needle electrode straight, 0.8 x 12mm, L: 100mm, handle 4mm	Ib	16-860
	524-160	Elektroda igła kątowa, 0,8 x 12mm, dł. 100mm, uchwyt 4mm / Needle electrode, angled, 0.8 x 12mm, L: 100mm, handle 4mm	Ib	16-860
	524-200	Elektroda nóż prosty, 2,4 x 10mm, dł. 100mm, uchwyt 4mm / Knife electrode, straight, 2.4 x 10mm, L: 100 mm, handle 4mm	Ib	16-860
	524-260	Elektroda nóż prosty, 25mm, dł. 100mm, uchwyt 4mm / Knife electrode, straight, 25mm, L: 100mm, handle 4mm	Ib	16-860
	524-261	Elektroda nóż prosty, 25mm, dł. 150mm, uchwyt 4mm / Knife electrode, straight, 25mm, L: 150mm, handle 4mm	Ib	16-860
	524-270	Elektroda nóż prosty, 3,3 x 20mm, dł. 100mm, uchwyt 2,4mm / Knife electrode, straight, 3.3 x 20mm, L: 100 mm, handle 2.4mm	Ib	16-860
	524-280	Elektroda nóż prosty, 2,54 x 8mm, dł. 100mm, uchwyt 4mm / Knife electrode, straight, 2.54 x 8mm, L: 100mm, handle 4mm	Ib	16-860
	524-300	Elektroda nóż kątowy 2,4 x 10mm, dł. 100mm, uchwyt 4mm / Knife electrode, angled, 2.4 x 10mm, L: 100 mm, handle 4mm	Ib	16-860
	524-400	Elektroda lancet prosty, romboidalny, dł. 100mm, uchwyt 4mm / Lancet electrode, straight, rhombic, L: 100mm, handle 4mm	Ib	16-860
	524-460	Elektroda nóż prosty, 2,2 x 20mm, dł. 100mm, uchwyt 4mm / Knife electrode, straight, 2.2 x 20mm, L: 100mm, handle 4mm	Ib	16-860
	524-600	Elektroda pętla, 10 x 10mm, dł. 120mm, uchwyt 4mm / Loop electrode, 10 x 10mm, L: 120mm, handle 4mm	Ib	16-860
	524-700	Elektroda pętla, 15 x 8mm, dł. 120mm, uchwyt 4mm / Loop electrode, 15 x 8mm, L: 120mm, handle 4mm	Ib	16-860
	524-800	Elektroda pętla, 15 x 10mm, dł. 120mm, uchwyt 4mm / Loop electrode, 15 x 10mm, L: 120mm, handle 4mm	Ib	16-860
	524-900	Elektroda pętla, 20 x 8mm, dł. 120mm, uchwyt 4mm / Loop electrode, 20 x 8mm, L: 120mm, handle 4mm	Ib	16-860
	525-000	Elektroda pętla, 20 x 15mm, dł. 120 mm, uchwyt 4mm / Loop electrode, 20 x 15mm, L: 120mm, handle 4mm	Ib	16-860
	525-100	Elektroda pętla, 20 x 20mm, dł. 120 mm, uchwyt 4mm / Loop electrode, 20 x 20mm, L: 120mm, handle 4mm	Ib	16-860
	525-200	Elektroda pętla, 25 x 20mm, dł. 120 mm, uchwyt 4mm / Loop electrode, 25 x 20mm, L: 120mm, handle 4mm	Ib	16-860
	525-800	Elektroda pętla, 10mm, dł. 120mm, uchwyt 4mm / Loop electrode, 10mm, L: 120mm, handle 4mm	Ib	16-860
	525-900	Elektroda pętla, 15mm, dł. 120mm, uchwyt 4mm / Loop electrode, 15mm, L: 120mm, handle 4mm	Ib	16-860
	526-000	Elektroda pętla, 20mm, dł. 120mm, uchwyt 4mm / Loop electrode, 20mm, L: 120mm, handle 4mm	Ib	16-860
	526-100	Elektroda pętla, 25mm, dł. 120mm, uchwyt 4mm / Loop electrode, 25mm, L: 120mm, handle 4mm	Ib	16-860
	526-200	Elektroda żagielek, 15 x 25mm, dł. 115mm, uchwyt 4mm / Triangle loop electrode, 15 x 25mm, L: 115mm, handle 4mm	Ib	16-860
	526-300	Elektroda żagielek, 20 x 25mm, dł. 115mm, uchwyt 4mm / Triangle loop electrode, 20 x 25mm, L: 115mm, handle 4mm	Ib	16-860
	526-400	Elektroda żagielek, 10 x 25mm, dł. 115mm, uchwyt 4mm / Triangle loop electrode, 10 x 25mm, L: 115mm, handle 4mm	Ib	16-860
	527-000	Elektroda igła zagięta, z izolowanym trzpieniem, 1,8 x 1mm, dł. 100mm, uchwyt 4mm / Needle electrode, angled, insulated pin, 1.8 x 1mm, L: 100mm, handle 4mm	Ib	16-860
	527-100	Elektroda kulka zagięta, z izolowanym trzpieniem, 2mm, dł. 100mm, uchwyt 4mm / Ball electrode, angled, insulated pin, 2mm, L: 100mm, handle 4mm	Ib	16-860

Juzwiak

Jowita Juzwiak

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Certification body for medical devices

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Raport nr / Report No.: PL4919/2021-03

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Ważny od / Valid from 21-04-2020

Ważny do / Valid until 20-04-2023

Typ / Type	Nr Ref	Wyroby / Products	Klasa Class	UMDNS
Akcesoria elektrochirurgiczne: Elektrody aktywne/	527-500	Przedłużacz do elektrod standardowych 4mm, dł.100mm, uchwyt 4mm / Extension for electrodes 4mm, L:100mm, handle 4 mm	IIb	16-860
Electrosurgical accessories: Active electrodes	527-550	Przedłużacz do elektrod standardowych 4mm, dł.150mm, uchwyt 4mm / Extension for electrodes 4mm, L:150mm, handle 4 mm	IIb	16-860
	528-650	Elektroda igła do mikrodysekcji, wolfram, giętka, 0,25mm x 4mm, dł. 45mm, uchwyt 4mm / Microdissection needle electrode, tungsten, flexible, 0.25 mm x 4 mm, L: 45mm, handle 4mm	IIb	16-860
	528-660	Elektroda igła do mikrodysekcji, kątowna 45°, giętka, wolfram, 0,25 x 4mm, dł. 45mm, uchwyt 4mm / Microdissection needle electrode, tungsten, angled 45°, flexible, 0.25 x 4mm, L: 45mm, handle 4mm	IIb	16-860
	528-770	Elektroda igła wolframowa, kątowna, z izolacją ceramiczną, 0,5 x 5mm, uchwyt 4mm / Tungsten needle electrode, angled, with ceramic insulation, 0.5 x 5mm, handle 4mm	IIb	16-860
	528-780	Elektroda igła wolframowa, prosta, z izolacją ceramiczną, 0,5 x 4mm, uchwyt 4mm / Tungsten needle electrode, straight, with ceramic insulation, 0.5 x 4mm, handle 4mm	IIb	16-860
	529-000	Elektroda igła do mikrodysekcji, wolfram, giętka, 0,25 x 4mm, dł. 20mm, uchwyt 4mm / Microdissection needle electrode, tungsten, flexible, 0.25 x 4mm, L: 20mm, handle 4mm	IIb	16-860
	529-050	Elektroda igła do mikrodysekcji, kątowna 45°, giętka, wolfram, 0,25 x 4mm, dł. 20mm, uchwyt 4mm / Microdissection needle electrode, tungsten, angled 45°, flexible, 0.25 x 4mm, L: 20mm, handle 4mm	IIb	16-860
	529-350	Adapter elektrod 2,4 mm do uchwytu 4mm / Adaptor for 2,4mm electrodes to handle 4mm	IIb	16-860
	529-360	Adapter elektrod 1,6mm do uchwytu 4mm / Adaptor for 1,6mm electrodes to handle 4mm	IIb	16-860
	530-000	Elektroda szpatuła owalna, prosta, 2 x 24mm, uchwyt 2,4mm / Spatula electrode, oval shape, 2 x 24mm, handle 2.4mm	IIb	16-860
	530-100	Elektroda nóż prosty, 25 x 3,5mm, uchwyt 2,4mm / Knife electrode straight, 25 x 3.5mm, handle 2.4mm	IIb	16-860
	530-310	Elektroda igła prosta, 0,5mm, uchwyt 2,4mm / Needle electrode straight, 0.5mm, handle 2.4mm	IIb	16-860
	530-320	Elektroda igła prosta, 0,7mm, uchwyt 2,4mm / Needle electrode straight, 0.7mm, handle 2.4mm	IIb	16-860
	530-370	Elektroda igła prosta, 0,5mm, uchwyt 2,4mm / Needle electrode straight, 0.5mm, handle 2.4mm	IIb	16-860
	530-510	Elektroda kulka prosta, 2mm, uchwyt 2,4mm / Ball electrode straight, 2mm, handle 2.4mm	IIb	16-860
	530-520	Elektroda kulka prosta, 4mm, uchwyt 2,4mm / Ball electrode straight, 4mm, handle 2.4mm	IIb	16-860
	530-530	Elektroda kulka prosta, 6mm, uchwyt 2,4mm / Ball electrode straight, 6mm, handle 2.4mm	IIb	16-860
	530-580	Elektroda kulka kątowna, 2 mm, uchwyt 2,4mm / Ball electrode angled, 2mm, handle 2.4mm	IIb	16-860
	530-590	Elektroda kulka kątowna, 4mm, uchwyt 2,4mm / Ball electrode angled, 4mm, handle 2.4mm	IIb	16-860
	530-610	Elektroda pętla druciana, 5mm, uchwyt 2,4mm / Wire loop electrode, 5mm, handle 2.4mm	IIb	16-860
	530-620	Elektroda pętla druciana, 10mm, uchwyt 2,4mm / Wire loop electrode, 10mm, handle 2.4mm	IIb	16-860
	530-630	Elektroda pętla druciana, 14mm, uchwyt 2,4mm / Wire loop electrode, 14mm, handle 2.4mm	IIb	16-860
	530-720	Elektroda pętla taśmowa, 10mm, uchwyt 2,4mm / Ribbon loop electrode, 10mm, handle 2.4mm	IIb	16-860
	530-730	Elektroda pętla taśmowa, 14mm, uchwyt 2,4mm / Ribbon loop electrode, 14mm, handle 2.4mm	IIb	16-860
	530-800	Elektroda lancet kątowny, 1,5 x 17mm, uchwyt 2,4mm / Lancet electrode angled, 1.5 x 17mm, handle 2.4mm	IIb	16-860
	530-820	Elektroda lancet kątowny, romboidalny, 1,6 x 19mm, uchwyt 2,4mm / Lancet electrode angled, rhombic, 1.6 x 19mm, handle 2.4mm	IIb	16-860
	532-300	Elektroda igła prosta wolframowa, izolowana, 0,5 x 20mm, uchwyt 2,4mm / Tungsten needle electrode, straight, insulated, 0.5 x 20mm, handle 2.4mm	IIb	16-860
	532-400	Elektroda igła kątowna wolframowa, izolowana, 0,5 x 20mm, uchwyt 2,4mm / Tungsten needle electrode, angled, insulated, 0.5 x 20mm, handle 2.4mm	IIb	16-860


Jowita Juźwiak
Jednostka Certyfikująca Wyroby Medyczne /
Certification body for medical devices

Katowice, 24-05-2021

Jednostka notyfikowana Numer identyfikacyjny 2274
Notified Body ID. No. 2274

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do certyfikatu numer rejestracyjny / to Certificate Registration No.:

Raport nr / Report No.: PL4919/2021-03

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Ważny od / Valid from 21-04-2020

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Typ / Type	Nr Ref	Wyroby / Products	Klasa Class	UMDNS
Akcesoria elektrochirurgiczne: Elektrody aktywne/ Electrosurgical accessories: Active electrodes	533-900	Przedłużacz do elektrod standardowych 2,4mm, dł. 100mm, uchwyt 2,4mm / Extension for electrodes 2,4mm, L: 100mm, handle 2,4 mm	IIb	16-860
	533-950	Przedłużacz do elektrod standardowych 2,4mm, dł. 150mm, uchwyt 2,4mm / Extension for electrodes 2,4mm, L: 150mm, handle 2,4 mm	IIb	16-860
	534-000	Elektroda szpatuła prosta, dł. 100mm, uchwyt 2,4mm / Spatula electrode straight, L: 100mm, handle 2,4mm	IIb	16-860
	534-030	Elektroda kulka prosta, 6mm, dł. 100mm, uchwyt 2,4mm / Ball electrode straight, 6mm, L: 100mm, handle 2,4mm	IIb	16-860
	534-050	Elektroda noż kątowny 45°, 20mm, dł. 100mm, uchwyt 2,4mm / Knife electrode angled 45°, 20mm, L: 100mm, handle 2,4mm	IIb	16-860
	534-100	Elektroda noż prosty, 25mm, dł. 100mm, uchwyt 2,4mm / Knife electrode straight, 25mm, L: 100mm, handle 2,4mm	IIb	16-860
	534-210	Elektroda igła prosta, 0,8 x 12mm, dł. 100mm, uchwyt 2,4mm / Needle electrode straight, 0,8 x 12mm, L: 100mm, handle 2,4mm	IIb	16-860
	534-220	Elektroda igła prosta, 0,7 x 12mm, dł. 100mm, uchwyt 2,4mm / Needle electrode straight, 0,7 x 12mm, L: 100mm, handle 2,4mm	IIb	16-860
	534-410	Elektroda kulka prosta, 2mm, dł. 100mm, uchwyt 2,4mm / Ball electrode straight, 2mm, L: 100mm, handle 2,4mm	IIb	16-860
	534-420	Elektroda kulka prosta, 4mm, dł. 100mm, uchwyt 2,4mm / Ball electrode straight, 4mm, L: 100mm, handle 2,4mm	IIb	16-860
	534-430	Elektroda kulka kątowna, 6mm, dł. 100mm, uchwyt 2,4mm / Ball electrode angled, 6mm, L: 100mm, handle 2,4mm	IIb	16-860
	534-450	Elektroda kulka kątowna, 4mm, dł. 100mm, uchwyt 2,4mm / Ball electrode angled, 4mm, L: 100mm, handle 2,4mm	IIb	16-860
	534-460	Elektroda pętla, 10 x 10mm, dł. 120mm, uchwyt 2,4mm / Loop electrode, 10 x 10mm, L: 120mm, handle 2,4mm	IIb	16-860
	535-000	Elektroda pętla, 20 x 15mm, dł. 120mm, uchwyt 2,4mm / Loop electrode, 20 x 15mm, L: 120mm, handle 2,4mm	IIb	16-860
	535-100	Elektroda pętla, 20 x 20mm, dł. 120mm, uchwyt 2,4mm / Loop electrode, 20 x 20mm, L: 120mm, handle 2,4mm	IIb	16-860
	535-200	Elektroda pętla, 25 x 20mm, dł. 120mm, uchwyt 2,4mm / Loop electrode, 25 x 20mm, L: 120mm, handle 2,4mm	IIb	16-860
	535-800	Elektroda pętla, 10mm, dł. 100mm, uchwyt 2,4mm / Loop electrode, 10mm, L: 100mm, handle 2,4mm	IIb	16-860
	535-900	Elektroda pętla, 15mm, dł. 120mm, uchwyt 2,4mm / Loop electrode, 15mm, L: 120mm, handle 2,4mm	IIb	16-860
	536-000	Elektroda pętla, 20mm, dł. 120mm, uchwyt 2,4mm / Loop electrode, 20mm, L: 120mm, handle 2,4mm	IIb	16-860
	536-100	Elektroda pętla, 25mm, dł. 120mm, uchwyt 2,4mm / Loop electrode, 25mm, L: 120mm, handle 2,4mm	IIb	16-860
	536-200	Elektroda żagielek, 15 x 25mm, dł. 115mm, uchwyt 2,4mm / Triangle loop electrode, 15 x 25mm, L: 115mm, handle 2,4mm	IIb	16-860
	536-300	Elektroda żagielek, 20 x 25mm, dł. 115mm, uchwyt 2,4mm / Triangle loop electrode, 20 x 25mm, L: 115mm, handle 2,4mm	IIb	16-860
	536-400	Elektroda żagielek, 10 x 25mm, dł. 115mm, uchwyt 2,4mm / Triangle loop electrode, 10 x 25mm, L: 115mm, handle 2,4mm	IIb	16-860
	540-100	Elektroda igła prosta, 0,2mm, uchwyt 1,6mm / Needle electrode, straight, 0,2mm, handle 1,6mm	IIb	16-860
	540-110	Elektroda igła izolowana, prosta, 0,2mm, uchwyt 1,6mm / Needle electrode straight, insulated, 0,2mm, handle 1,6mm	IIb	16-860
	540-200	Elektroda igła kątowna 45°, uchwyt 1,6mm / Needle electrode, angled 45°, handle 1,6mm	IIb	16-860
	540-400	Elektroda pętla druciana, 3mm, uchwyt 1,6mm / Wire loop electrode, 3mm, handle 1,6mm	IIb	16-860
	540-500	Elektroda pętla druciana, 5mm, uchwyt 1,6mm / Wire loop electrode, 5mm, handle 1,6mm	IIb	16-860
	540-600	Elektroda pętla druciana, 8mm, uchwyt 1,6mm / Wire loop electrode, 8mm, handle 1,6mm	IIb	16-860
	540-800	Elektroda pętla druciana, wydłużona, zakrzywiona, 7 x 1,5mm, uchwyt 1,6mm / Wire loop, elongated, angled, 7,0 x 1,5 mm, handle 1,6mm	IIb	16-860
	541-600	Elektroda igła kątowna 30°, 1,7mm, uchwyt 1,6mm / Needle electrode, angled 30°, 1,7mm, handle 1,6mm	IIb	16-860
	541-700	Elektroda kulka kątowna, 1,7mm, uchwyt 1,6mm / Ball electrode angled, 1,7mm, handle 1,6mm	IIb	16-860
	541-710	Elektroda kulka prosta, 1,7mm, uchwyt 1,6mm / Ball electrode straight, 1,7mm, handle 1,6mm	IIb	16-860
	541-800	Elektroda kulka kątowna, 3mm, uchwytu 1,6mm / Ball electrode, angled, 3mm, handle 1,6mm	IIb	16-860


Jowita Juźwiak

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Ważny od / Valid from 21-04-2020

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Typ / Type	Nr Ref	Wyroby / Products	Klasa Class	UMDNS
Akcesoria elektrochirurgiczne: Elektrody aktywne/ Electrosurgical accessories: Active electrodes	541-810	Elektroda kulka prosta, 3mm, uchwyt 1,6mm / Ball electrode, straight, 3mm, handle 1.6mm	IIb	16-860
	541-900	Elektroda do koagulacji, prosta, uchwyt 1,6mm / Coagulation electrode, straight, handle 1.6mm	IIb	16-860
	542-200	Elektroda szpatuła prosta, 2 x 16mm, dł. 40mm, uchwyt 1,6mm / Spatula electrode straight, 2 x 16 mm, L: 40mm, handle 1.6mm	IIb	16-860
	548-200	Elektroda szpatuła prosta, 2 x 6mm, dł. 55mm, uchwyt 1,6mm / Spatula electrode straight, 2 x 6 mm, L: 55mm, handle 1.6mm	IIb	16-860
	580-210	Elektroda igła kątowna 90°, 0,6 x 1,5mm, dł. 115mm, uchwyt 4mm / Needle electrode, angled 90°, 0.6 x 1.5mm, L: 115mm, handle 4mm	IIb	16-860
	580-220	Elektroda igła kątowna 90°, 0,6 x 4mm, dł. 115mm, uchwyt 4mm / Needle electrode, angled 90°, 0.6 x 4mm, L: 115mm, handle 4mm	IIb	16-860
	580-240	Elektroda nóż kątowny 45°, 0,4 x 3mm, dł. 115mm, uchwyt 4mm / Knife electrode, angled 45°, 0.4 x 3mm, L: 115mm, handle 4mm	IIb	16-860
	580-250	Elektroda klawiszowa kątowna 90°, 1,5 x 3mm, dł. 115mm, uchwyt 4mm / Keying electrode, angled 90°, 1.5 x 3mm, L: 115mm, handle 4mm	IIb	16-860
	580-260	Elektroda okrągła, szczoteczka, dł. 115mm, uchwyt 4mm / Round electrode, brush, L: 115mm, handle 4mm	IIb	16-860
	580-270	Elektroda kulka prosta, 3mm, dł. 115mm, uchwyt 4mm / Ball electrode straight, 3mm, L: 115mm, handle 4mm	IIb	16-860
	580-280	Elektroda okrągła, wklęsła, dł. 115mm, uchwyt 4mm / Round electrode, hollow, L: 115mm, handle 4mm	IIb	16-860
	580-290	Elektroda okrągła, płaska, dł. 115mm, uchwyt 4mm / Round electrode, flat, L: 115mm, handle 4mm	IIb	16-860
	587-010	Elektroda bipolarna, igła, zagięta 90°, 0,6 x 1,5mm, dł. 115mm / Bipolar needle electrode, angled 90°, 0.6 x 1.5mm, L: 115mm	IIb	16-860
	587-011	Elektroda bipolarna, pętla "Cobra", dł. 170mm / Bipolar loop electrode "Cobra", L: 170mm	IIb	16-860
	587-020	Elektroda bipolarna, igła zagięta 90°, 0,6 x 4mm, dł. 115mm / Bipolar needle electrode, angled 90°, 0.6 x 4mm, L: 115mm	IIb	16-860
	587-030	Elektroda bipolarna, igła, zagięta 90°, 0,6 x 1,5mm, dł. 170 mm / Bipolar needle electrode angled 90°, 0.6 x 1.5mm, L: 170mm	IIb	16-860
	587-040	Elektroda bipolarna, klawiszowa, zagięta 90°, 1,5 x 4mm, dł. 115mm / Bipolar button electrode, angled 90°, 1.5 x 4mm, L: 115mm	IIb	16-860
	587-060	Elektroda bipolarna, igła, zagięta 90°, 0,6 x 4mm, dł. 170mm / Bipolar needle electrode, angled 90°, 0.6 x 4mm, L: 170mm	IIb	16-860
	587-090	Elektroda bipolarna, pętla "Cobra", dł. 115mm / Bipolar loop electrode "Cobra", L: 115mm	IIb	16-860
	587-110	Elektroda bipolarna do waporyzacji -Phazer, wypukła, zagięcie 70°, śr. kulki 2,4 mm, dł. 115mm / Bipolar vaporization electrode, Phazer, convex, angled 70°, ball 2.4mm, L: 115mm	IIb	16-860
	587-140	Elektroda bipolarna do waporyzacji -Phazer, wypukła, zagięcie 70°, śr. kulki 2,4 mm, dł. 170mm / Bipolar vaporization electrode, Phazer, convex, angled 70°, ball 2.4 mm, L: 170mm	IIb	16-860
	587-920	Elektroda bipolarna do waporyzacji, okrągła, VAP, dł. 170mm / Bipolar vaporization electrode, VAP, L: 170mm	IIb	16-860
	587-930	Elektroda bipolarna do waporyzacji, okrągła, VAP, dł. 115mm / Bipolar vaporization electrode, VAP, L: 115mm	IIb	16-860
	58S-920	Elektroda bipolarna do waporyzacji, okrągła, VAP, dł. 170mm, kabel SDS 3 m / Bipolar vaporization electrode, VAP, L: 170mm, SDS cable 3m	IIb	16-860
	58S-930	Elektroda bipolarna do waporyzacji, okrągła, VAP, dł. 115mm, kabel SDS 3 m / Bipolar vaporization electrode, VAP, L: 115mm, SDS cable 3m	IIb	16-860
	58S-010	Elektroda bipolarna, igła, zagięta 90°, 0,6 x 1,5mm, dł. 115mm, kabel SDS 3m / Bipolar needle electrode, angled 90°, 0.6 x 1.5mm, L: 115mm, SDS cable 3m	IIb	16-860
	58S-011	Elektroda bipolarna, pętla "Cobra", dł. 170mm, kabel SDS 3m / Bipolar loop electrode "Cobra", L: 170mm, SDS cable 3m	IIb	16-860
	58S-020	Elektroda bipolarna, igła zagięta 90°, 0,6 x 4mm, dł. 115mm, kabel SDS 3m / Bipolar needle electrode, angled 90°, 0.6 x 4mm, L: 115mm, SDS cable 3m	IIb	16-860
	58S-030	Elektroda bipolarna, igła, zagięta 90°, 0,6 x 1,5mm, dł. 170mm, kabel SDS 3m / Bipolar needle electrode, angled 90°, 0.6 x 1.5mm, L: 170mm, SDS cable 3m	IIb	16-860
	58S-040	Elektroda bipolarna, klawiszowa, zagięta 90°, 1,5 x 4mm, dł. 115mm, kabel SDS 3m / Bipolar button electrode, angled 90°, 1.5 x 4mm, L: 115mm, SDS cable 3m	IIb	16-860


Jowita Juzwiak
Jednostka Certyfikująca Wyroby Medyczne /
Certification body for medical devices

Jednostka notyfikowana Numer identyfikacyjny 2274
Notified Body ID. No. 2274

Katowice, 24-05-2021

TÜV NORD Polska Sp. z o.o.
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ZAŁĄCZNIK nr 1, strona 12 z 12 / ANNEX No. 1, page 12 of 12

do certyfikatu numer rejestracyjny / to Certificate Registration No.:

Raport nr / Report No.: PL4919/2021-03

TNP/MDD/0320/4919/2020

Ważny od / Valid from 21-04-2020

Ważny do / Valid until 20-04-2023

Typ / Type	Nr Ref	Wyroby / Products	Klasa Class	UMDNS
Akcesoria elektrochirurgiczne: Elektrody aktywne/ Electrosurgical accessories: Active electrodes	58S-060	Elektroda bipolarna, igła zagięta 90°, 0,6 x 4mm, dł. 170mm, kabel SDS 3m / Bipolar needle electrode, angled 90°, 0,6 x 4mm, L: 170mm, SDS cable 3m	IIb	16-860
	58S-090	Elektroda bipolarna, pętla "Cobra", dł. 115mm, kabel SDS 3m / Bipolar loop electrode "Cobra", L: 115mm, SDS cable 3m	IIb	16-860
	58S-110	Elektroda bipolarna do waporyzacji -Phazer, wypukła, zagięcie 70°, śr. kulki 2,4 mm, dł. 115mm, kabel SDS 3m / Bipolar vaporization electrode, Phazer, convex, angled 70°, ball 2.4mm, L: 115mm, SDS cable 3m	IIb	16-860
	58S-140	Elektroda bipolarna do waporyzacji -Phazer, wypukła, zagięcie 70°, śr. kulki 2,4 mm, dł. 170mm, kabel SDS 3m / Bipolar vaporization electrode, Phazer, convex, angled 70°, ball 2.4 mm, L: 170mm, SDS cable 3m	IIb	16-860
	840-440	Elektroda jednorazowa, kulka 4mm, do uchwytu 2,4mm, sterylna. / Disposable electrode, ball 4mm, for 2.4mm handle, sterile	IIb	16-860
	840-441	Elektroda jednorazowa, kulka 4mm, nieklejąca, do uchwytu 2,4mm, sterylna. / Disposable electrode, ball 4mm, non-stick, for 2.4mm handle, sterile.	IIb	16-860
	840-450	Elektroda jednorazowa, nóż, do uchwytu 2,4mm, sterylna / Disposable electrode, knife, for 2.4mm handle, sterile	IIb	16-860
	840-451	Elektroda jednorazowa, nóż, nieklejąca, do uchwytu 2,4mm, sterylna / Disposable electrode, knife, non-stick, for 2.4mm handle, sterile.	IIb	16-860
	840-460	Elektroda jednorazowa, igła, do uchwytu 2,4mm, sterylna / Disposable electrode, needle, for 2.4mm handle, sterile.	IIb	16-860
	840-461	Elektroda jednorazowa, igła, nieklejąca, do uchwytu 2,4mm, sterylna / Disposable electrode, needle, non-stick, for 2.4mm handle, sterile.	IIb	16-860
	932-031	Elektroda argonowa sztywna do koagulacji, dł. robocza 25mm, śr. 5mm / Argon electrode, rigid, insulated shaft, 25mm w. length, dia. 5mm	IIb	16-860
	932-032	Elektroda argonowa sztywna do koagulacji, dł. robocza 100mm, śr. 5mm / Argon electrode, rigid, insulated shaft, 100mm w. length, dia. 5mm	IIb	16-860
	932-034	Elektroda argonowa sztywna do koagulacji, dł. robocza 320mm, śr. 5mm / Argon electrode, rigid, insulated shaft, 320mm w. length, dia. 5mm	IIb	16-860
	932-044	Igła prosta 14mm argonowa sztywna, dł. robocza 115mm, śr. 5mm / Argon needle 14mm, rigid, insulated shaft, 115mm w. length, dia. 5mm	IIb	16-860
	932-054	Igła prosta 14mm, argonowa sztywna, dł. robocza 40mm, śr. 5mm / Argon needle 14mm, rigid, insulated shaft, 40mm w. length, dia. 5mm	IIb	16-860
	932-056	Lancet prosty 14mm argonowy sztywny, dł. robocza 115mm, śr. 5mm / Argon lancet 14mm, rigid, insulated shaft, 115mm w. length, dia. 5mm	IIb	16-860
	932-057	Lancet prosty 14mm argonowy sztywny, dł. robocza 40mm, śr. 5mm / Argon lancet 14mm, rigid, insulated shaft, 40mm w. length, dia. 5mm	IIb	16-860
	932-058	Lancet prosty 14mm argonowy sztywny, dł. robocza 320mm, śr. 5mm / Argon lancet 14mm, rigid, insulated shaft, 320mm w. length, dia. 5mm	IIb	16-860
	932-060	Elektroda argonowa sztywna z wysuwaniem nożem, dł. robocza 40mm, śr. 5mm / Argon electrode, rigid, with adjustable knife, 40mm w. length, dia. 5mm	IIb	16-860
	932-061	Elektroda argonowa sztywna z wysuwaniem nożem, dł. robocza 115mm, śr. 5mm / Argon electrode, rigid, with adjustable knife, 115mm w. length, dia. 5mm	IIb	16-860
	932-062	Elektroda argonowa sztywna z wysuwaniem nożem, dł. robocza 350mm, śr. 5mm / Argon electrode, rigid, with adjustable knife, 350mm w. length, dia. 5mm	IIb	16-860
	932-063	Elektroda argonowa sztywna z wysuwaniem igłą, dł. robocza 115mm, śr. 5mm / Argon electrode, rigid, with adjustable needle, 115mm w. length, dia. 5mm	IIb	16-860
	932-148	Giętka sonda argonowa, wielorazowa, TBS, śr. 1,5mm, dł. 1,5m / Flexible argon probe, reusable, TBS, dia. 1.5mm, L: 1.5m	IIb	16-206
	932-149	Giętka sonda argonowa, wielorazowa, GIT, śr. 2,3mm, dł. 2,2m / Flexible argon probe, reusable, GIT, dia. 2.3mm, L: 2.2m	IIb	16-206
	932-150	Giętka sonda argonowa, wielorazowa, GIT, śr. 3,2mm, dł. 2,2m / Flexible argon probe, reusable, GIT, dia. 3.2mm, L: 2.2m	IIb	16-206
	932-151	Giętka sonda argonowa, wielorazowa, TBS, śr. 1,5mm, dł. 3m / Flexible argon probe, reusable, TBS, dia. 1.5mm, L: 3m	IIb	16-206
	932-152	Giętka sonda argonowa, wielorazowa, GIT, śr. 2,3mm, dł. 3m / Flexible argon probe, reusable, GIT, dia. 2.3mm, length 3m	IIb	16-206


Jowita Juzwiak

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Katowice, 24-05-2021

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CERTIFICATE

Management system as per
PN-EN ISO 13485:2016-04
Medical devices - Quality management systems - Requirements for regulatory purposes

In accordance with TÜV NORD Polska Sp. z o.o. procedures, it is hereby certified that

EMED SP. Z O.O. SP.K.
ul. Ryżowa 69a, PL / 05-816 Opacz-Kolonia

with the locations / sites according to the annex



applies a management system in line with the above standard for the following scope

**Design, production, sales and service of electrosurgical units,
accessories and endoscopic irrigation pump.**

Regardless of the fact that TÜV NORD Polska Sp. z o.o. is a notified body No. 2274 in the area of medical devices, this Certificate is not a Certificate of Conformity within the meaning of Directive 93/42/EEC and is not a basis for CE marking.

Certificate Registration No. **AC090 MD/1952/4919/2020**
Audit Report No. PL4919/2020

Valid from **21-04-2020**
Valid until **20-04-2023**



Manager of Certification Body
TÜV NORD Polska Sp. z o.o.

Katowice, 21-04-2020

This certification was conducted in accordance with the TÜV NORD Polska Sp. z o.o. auditing and certification procedures and is subject to regular surveillance audits.

TÜV NORD Polska Sp. z o.o.

ul. Mickiewicza 29

40-085 Katowice

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AC 090

ANNEX

to Certificate Registration No.: **AC090 MD/1952/4919/2020**

EMED SP. Z O.O. SP.K.
ul. Ryżowa 69a, PL / 05-816 Opacz-Kolonia



Certificate Registration No.
AC090 MD/1952/4919/2020-001

Location
EMED SP. Z O.O. SP.K.
ul. Ryżowa 69, PL / 05-816 Opacz-Kolonia

Scope
Design, production and service of
electrosurgical units, accessories and
endoscopic irrigation pump.

AC090 MD/1952/4919/2020-002

EMED SP. Z O.O. SP.K.
ul. Ryżowa 84b, PL / 05-816 Opacz-Kolonia

Design and production of electrosurgical units,
accessories and endoscopic irrigation pump.

End of the List



Manager of Certification Body
TÜV NORD Polska Sp. z o.o.

Katowice, 21-04-2020

TÜV NORD Polska Sp. z o.o.

ul. Mickiewicza 29

40-085 Katowice

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AC 090

ENDOCAM Logic HD

Camera controller

ENDOCAM

1



- Various equipment variants. The variants exclusively refer to the configuration of output and input signals
- Digital signal processing
- Outstandingly wide range of application due to integration of various applied parts and diagnostic methods
- updates can be applied at any time via USB port
- Storage of high-resolution images and HD videos on USB storage media
- Integration of further image signals via picture-in-picture port (3G-SDI)
- Specialized for use in integrated operating rooms as a central **core nova module**

- User-friendly. Clinically-devised presets are pre-programmed for various disciplines. This includes applications using standard and fiber endoscopes as well as sensor endoscopes with chip-on-the-tip technology. Personal settings can easily be saved as well
- Maximum flexibility: The resolution of all signal outputs can be adapted individually to the connected system
- Patient data can be entered using the connected USB keyboard
- Direct printing possible
- Modern, clearly arranged on-screen menu
- Dialog function:
 1. Control of connected ENDOLIGHT light source for optimum illumination with maximum protection for the endoscope
 2. Monitor display of major device parameters for further devices (pressure indication, set flow, residual gas display, etc.)

ENDOCAM Logic HD controller bndl

Comprising:

1x ENDOCAM Logic HD controller	552510x
1x hand-held remote control USB	5525401
1x USB flash memory 8 GB	56540028
1x CAN-BUS terminator	5590.989
1x HDMI / DVI-D cable, lockable, 3.0 m	103843
1x power cable	2440.03

Controller equipment variants:

2x HDMI out	55251011
2x HDMI out / 2x 3G-SDI out	55251051
2x HDMI out / 2x 3G-SDI out / PIP in	55251061
2x HDMI out / 2x 3G-SDI out / analog out	55251071
2x HDMI out / 2x 3G-SDI out / PIP in / analog out	55251081

ENDOCAM Logic HD

Technical data of camera controller

Camera controller		552510x	
Device properties			
Type of controls	Touchscreen		
Max. video signal resolution	1920 x 1200 pixels		
White balance, color temperature range	2300 K to 7000 K		
Noise level	34 dB to 48 dB max.		
Digital zoom	1.5x max.		
Individually configurable profiles	at least 5 profiles		
Brightness control	Automatic shutter control + automatic gain control		
Image format of saved pictures / videos	JPEG, TIFF (max. 1920 x 1080) / MPEG4 (max. 1920 x 1080)		
Operating conditions	+10°C to +40°C, 30% to 75% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa		
Operating mode	Continuous operation		
Equipment			
IP rating	IP20		
Cooling method	Controlled fan		
Power supply			
Mains + frequency	100-240 VAC, 50/60 Hz		
Power consumption	100 VA		
Current rating	max. 1.0 A		
Regulatory standards			
Safety	US/ CA: UL 2601-1 / CSA C22.2 NO.601.1, EU: EN 60601		
EMC	EN 60601-1-2 / IEC 601-1-2		
Medical device class	Class 1		
Classification of applied part	CF		
Interfaces			
Video outputs	2x 3G-SDI, 2x HDMI, 1x YC, 1x CV		
PiP input	1x 3G-HD-SDI		
Remote output	2 x 3.5 mm jack, stereo		
USB port (on front panel, for external storage media)	USB 2.0 (FAT32/NTFS formatting)		
Resolution (HDMI output)	Adjustable in the user menu 1280 x 1024/60P (5:4)1920 x 1080/60P (16:9)1920 x 1200/60P (16:10)		
Resolution (3G-SDI output) also supports HD-SDI	Adjustable in the user menu 1280 x 720/50P (16:9)1280 x 720/60P (16:9)1920 x 1080/50I (16:9)1920 x 1080/60I (16:9)1920 x 1080/50P (16:9)1920 x 1080/60/P (16:9)		
Resolution of SD outputs for video (Composite) and S-Video (Y/C)	Adjustable in the user menu PAL 720 x 576/50/I (4:3) NTSC 720 x 486/59.94/I (4:3)		
Resolution of picture-in-picture input (3G-SDI)	1280 x 720/50P (16:9)1280 x 720/60P (16:9)1920 x 1080/50I (16:9)1920 x 1080/60I (16:9)1920 x 1080/50P (16:9)1920 x 1080/60P (16:9)		
Dimensions and weights			
Weight	6.2 kg		
Dimensions (W x H x D)	300 x 120 x 416 mm		

ENDOCAM Logic HD

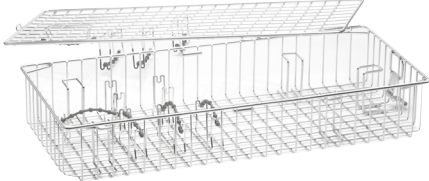
3-chip HD camera head



- Digital image processing and digital signal transmission
- 2 programmable camera head buttons with 4 available functions
- Universal C-Mount lens connection
- Cable outlet angled at 30°
- Camera head cable can be replaced in the hospital by technicians
- Steam-sterilizable
- Can be reprocessed by machine
- Suitable for low-temperature procedure

ENDOCAM Logic HD camera head **85525922**

3-chip type, cable length 3 m

Recommended accessories		Product no.
RIWO lens	C-Mount, f = 14 mm	85261144
	C-Mount, f = 24 mm	85261244
RIWO zoom lens	C-Mount, f = 13 - 29 mm	85261504
	Perforated basket for camera head (L x W x H) 448 x 200 x 73 mm	38002

ENDOCAM Logic HD

Technical data of camera head

Camera head 85525922	
Device properties	
Sensor	3x 1/3" CCD
Operation	2 programmable head buttons with 4 functions
Operating conditions	+10°C to +30°C, 20% to 75% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa
Equipment	
Thread for objective lens	C-Mount
Degree of protection against the ingress of moisture	IPX7
Service	Cable and eyepiece snap-in coupling can be replaced on site
Dimensions and weight	
Camera head weight (without cable)	170 g
Housing dimensions (W x H) - without cable and anti-kink protection	43 x 53 mm
Camera head length (without cable)	105 mm
Cable length	3 m / 5 m
Cable outlet	30°

RIWO lenses

RIWO zoom lens with snap-on mechanism and C-Mount thread, steam-sterilizable and reprocessable by machine			Product no.
 AUTOCLAVE 134° C / 273° F	RIWO zoom lens f = 21 - 36 mm		85261.501
RIWO zoom lens with snap-on mechanism and C-Mount thread, steam-sterilizable and reprocessable by machine			
 AUTOCLAVE 134° C / 273° F	RIWO zoom lens f = 13 - 29 mm		85261504
RIWO zoom lens with snap-on mechanism and C-Mount thread, reprocessable by machine and suitable for low-temperature procedure			
	RIWO zoom lens f = 13 - 29 mm		5261504
RIWO lens with snap-on mechanism and C-Mount thread, steam-sterilizable and reprocessable by machine			
 AUTOCLAVE 134° C / 273° F	RIWO lens f = 14 mm		85261144
	RIWO lens f = 24 mm		85261244
RIWO lens with snap-on mechanism and C-Mount thread, steam-sterilizable and reprocessable by machine			
 AUTOCLAVE 134° C / 273° F	RIWO lens f = 27 mm		85261.272
	RIWO lens f = 32 mm		85261.322

ENDOLIGHT LED 2.2

LED light source



- The light output is comparable to a 300-watt xenon illuminant
- The LED service life is at least 30,000 hours
- The LED light source reduces power consumption by up to 80% compared to an equivalent xenon light source
- Extremely quiet heatpipe ventilation concept at only 25 dB(A) noise level
- Light cables from different manufacturers (Richard Wolf, Storz, Olympus, ACMI) can directly be connected to the multi-port socket

- Automatic dimming of the light cable socket if the light cable is removed
- Very homogenous illumination of the endoscopic surgical area. No drop in brightness in the peripheral area and no "black spot" in the center
- Very stable color temperature (6500 Kelvin) over the entire LED service life
- Dialog function in conjunction with ENDOCAM Logic camera systems
- Compatible with core nova

Light source ENDOLIGHT LED 2.2 bndl 51640011

Comprising:

1x ENDOLIGHT LED 2.2	5164001
1x patch cable, RJ45 SFTP, 0.5 m	72325378
1x power cable	2440.03

ENDOLIGHT LED 2.2

Technical data

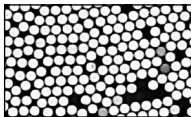
ENDOLIGHT LED 2.2		5164001
Device properties		
Type and number of lamps	1x high-power LED	
Lamp service life	30,000 h	
Brightness in Lumen	1900 lm	
Light output compared to xenon in W	300 W	
Color temperature	6500 K	
Brightness control	0 - 100%	
Noise level	25 dB(A)	
Operating mode	Continuous operation	
Operating conditions	+10°C to +40°C, 30% to 75% rel. humidity, atmospheric pressure 700 hPa to 1060 hPa	
Equipment		
Supported light cables	Wolf, Storz, Olympus, ACMI	
IP rating	IP20	
Cooling method	Passive heatpipe, fan	
Power supply		
Mains + frequency	100-240 VAC, 50/60 Hz	
Power consumption	150 VA	
Current rating	1.1-0.6 A	
Regulatory standards		
Safety	EU: EN 60601-1	
EMC	EN 60601-1-2 / IEC 601-1-2	
Medical device class	Class 1	
Classification	CF	
Dimensions and weight		
Weight	10.5 kg	
Dimensions (W x H x D)	300 x 160 x 421 mm	

fusion Fiber light cable

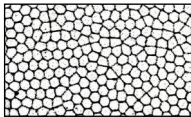


Anti-kink protection under the sheath for optimum hygiene properties

"Snap" quick release coupling



Standard
Light cables with adhesive



fusion
High-temperature-resistant light cables



Innovative color coding system

The color ring **system** for the handle at the endoscope side allows you to easily and quickly assign the matching light cable to the endoscope in use.

- Improved light transmission thanks to a special design
- High-performance fiber optic material "made in Germany"
- Fast "snap-on" precision connection between endoscope and light cable
- Anti-kink protection made of steel allows for a particularly high number of usage cycles
- Suitable for low-temperature procedure
- Steam-sterilizable
- Adapters for compatibility with light sources and endoscopes from different manufacturers
- Standardized color coding of light cables and endoscopes based on their diameters



fusion

Fiber light cable are exclusively available with 5.0 mm fiber diameter

Fusion Fiber light cable

Fusion Fiber light cable, complete	Color coding on endoscope side	Ø of fiber bundle and color code	Length	Fiber light cable without adapter Product no.	Complete Product no.
 Fiber light cable, bndl Comprising: Fiber light cable, Adapter, projector side (8095.07), and adapter, endos- cope side (809509)		5.0 mm gray	2.3 m	80655023*	806550231
			3.0 m	80655030*	806550301
			3.5 m	80655035*	806550351

* The ***Fusion*** light cables can also be ordered without adapter.
Adapters for connecting products from other manufacturers are
offered as separate items in our product range.

Universal device cart RIWomobil



All RIWomobil variants

have the following properties in common:

- Integrated cable duct
- 3 shelf units (width 370 mm), 2 of which continuously adjustable
- 4 double casters, 2 of which with dual-function locking (directional locking/freewheeling/full locking)
- Side profiles made of aluminum with mounting points for installing swivel arms and attaching a wide range of accessories
- Dimensions (W x H x D): 720 x 1518 x 700 mm
- 2 casters with dual conductivity
- Color: White, RAL 9016

RIWomobil features the following advantages:

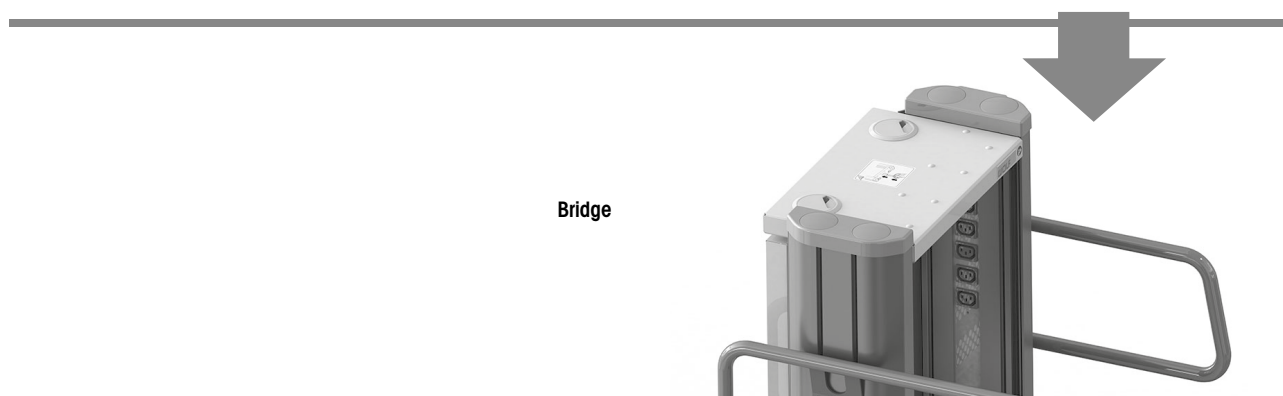
- Order-specific production
Each cart is configured and built according to the customer's individual demands.
Any additionally selected shelf units and drawers are installed, adjusted and tested directly in the production process.
- Quality and value preservation
All components are designed for longevity and high loads.
- Safety
All mechanical and electrical components are subjected to our permanent quality control process.
- Ergonomics
On all RIWomobil variants, the monitor position can be adapted to the demands of the operating team.
Height-adjustable shelf units and device handles on the cart provide individual adaptation options.

Universal device cart RIWomobil

Your optimum RIWomobil in just 3 steps

1. Where to place the monitors?

RIWomobil provides the option of positioning a swivel arm either in the center on the bridge or laterally in the side profile. As an alternative, a monitor mount can also be used to position a monitor in the center of the bridge.



2. Which electrics variant?

The **baseline electrics** with a **main switch** integrated in the aluminum profile, distributor strip with 12 device connections.

The **premium electrics** variant for highest demands includes the following elements in addition to the baseline equipment: isolating transformer and insulation monitoring unit with safety monitoring.

3. Which operating voltage?

RIWomobil with premium electrics

(for accessories, see section Device cart accessories)

Comprising:

Basic housing (premium version) with integrated isolating transformer, insulation monitoring unit, socket strip with main switch module, insulation monitor display and 12 sockets, 6 device connection cables, power cable 5.5 m,

Isolating transformer 220-230V, 2000VA **32116015**

Isolating transformer 100-120V, 1700VA **32116013**

RIWomobil with baseline electrics

(for accessories, see section Device cart accessories)

Comprising:

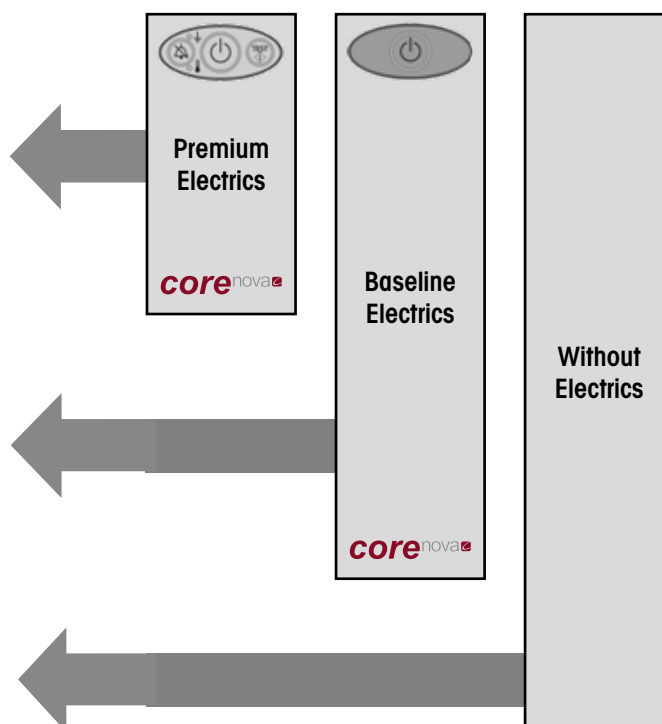
Basic housing (baseline version), socket strip with 12 sockets and integrated main switch module, 6 device connection cables, power cable 5.5 m,

Version with 220-240V, 2000VA **32116014**

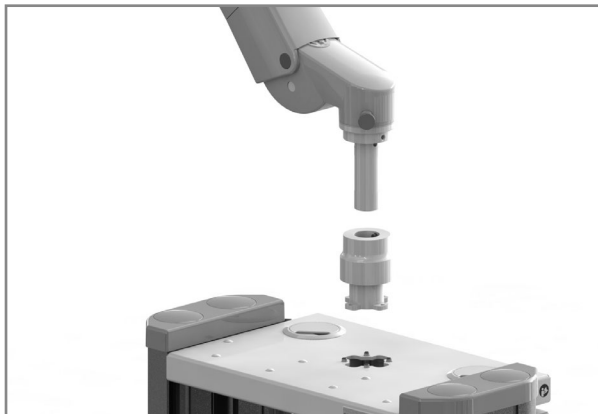
Version with 100-120V, 1700VA **32116012**

RIWomobil without electrical equipment

For mounting swivel arms..... **32116011**

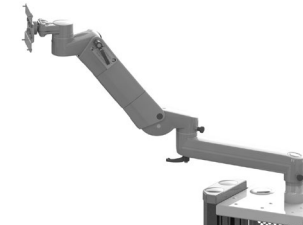


RIWomobil Swivel arm for bridge



All **Flexion-Port** models for mounting on the bridge have the following properties in common:

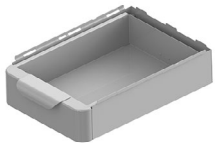
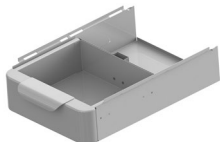
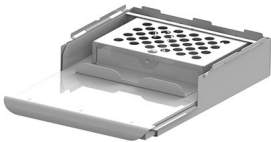
- VESA 100 mount
- Integrated cable duct
- Mechanical locking
- Swiveling range 340°. The area of the swiveling range can be defined individually during assembly
- Durable powder coating in white (RAL 9016)
- The specified length refers to the effective length between the swivel points
- Adapter for mounting on the bridge (32116474) is included in the set

Product no.		
	FLEXION-PORT 300 (58 cm) bndI Load capacity: 3 - 10 kg Comprising: 1x FLEXION-PORT 300 (58 cm) 32116058 1x swivel arm mount for bridge 32116474	321160582
	FLEXION-PORT 400 (68 cm) bndI Load capacity: 8 - 14 kg Comprising: 1x FLEXION-PORT 400 (68 cm) 32116068 1x swivel arm mount for bridge 32116474	321160682
	FLEXION-PORT 350+300 (93 cm) bndI Load capacity: 8 - 12 kg Comprising: 1x FLEXION-PORT 350+300 (93 cm) 32116093 1x swivel arm mount for bridge 32116474	321160932
	FLEXION-PORT 350+400 (103 cm) bndI Load capacity: 3 - 9 kg Comprising: 1x FLEXION-PORT 350+400 (103 cm) 32116103 1x swivel arm mount for bridge 32116474	321161032

RIWomobil Accessories

The accessories listed on this page is available in two variants:

1. Mounting, adjustment and final check during the production process
2. Retrofit kit for assembly by customer

Drawers		Product no.
	Assembly during RIWomobil production Drawer	32116412
	Retrofit kit Drawer	321164121
	Assembly during RIWomobil production Drawer, short, with compartment for power supply unit	32116414
	Retrofit kit Drawer, short, with compartment for power supply unit	321164141
	Pull-out keyboard with mousepad	32116413
	Retrofit kit Pull-out keyboard with mousepad	321164131
Shelf unit to accommodate large devices		
 Dimensions: width: 370 mm, depth: 526 mm	Assembly during RIWomobil production Shelf unit	32116401
	Retrofit kit Shelf unit	321164011
 Dimensions: width: 370 mm, depth: 626 mm	Assembly during RIWomobil production Shelf unit, long	32116402
	Retrofit kit Shelf unit, long	321164021

RIWomobil Accessories

Infusion bottle holder		Product no.
		Infusion bottle holder adjustable from 1.6 m to 2.6 m, load capacity max. 8 kg 32114.521
CO ₂		
 CO ₂ bottle holder, 1 L  CO ₂ bottle holder, 10 L	CO₂ bottle holder, 1 L for bottle ø up to max. 90 mm, load capacity max. 5 kg 32114.531	
	CO₂ bottle holder, 10 L for bottle ø up to max. 160 mm, load capacity max. 35 kg 32114.535	
Lateral holder		
		Holder for hand-held remote control or camera head connector 64030.106
Footswitch tray and bracket		
 Footswitch tray  Universal holder	Footswitch tray load capacity max. 3 kg 32114.541	
	Universal holder load capacity max. 3 kg 32114.545	

Rolling rack UNI-Cart



Equipment cart UNI-Cart 32113202

Mechanically height-adjustable

■ Device cart UNI-CART

Base rack, monitor mount, handle, power supply unit bracket, IEC socket strip cable winder, power cable with Schuko plug and IEC socket, IEC cable

Device cart	32113202
Basic rack	with 4 double casters, Ø=100 mm
Monitor mount	VESA 75/100
Holding bracket for power supply unit	large, for supply units with max. 420 mm circumference
IEC socket strip	3 sockets with switch
IEC socket	Length 5 m
IEC cable	Length 1.5 m
max. load	14 kg
Adjustment range (VESA top edge)	1330 - 1630 mm, mechanically height-adjustable
Dimensions (W x H x D)	540 x 1690 x 580 mm

INSUFFLATOR Highflow 45 BASIC

INSUFFLATOR Highflow 45 BASIC



- ☐ 6.5" Color display
- ☐ Touchscreen
- ☐ Max. flow rate 45 l / min
- ☐ Functional and user-friendly design
- ☐ Optional configurable software modules

INSUFFLATOR Highflow 45 BASIC Set

consisting of:

INSUFFLATOR Highflow 45 Basic (2235001),
insufflation tube, Ø 5 mm, 2.5 m long (8170.101),
hygiene filter, sterile PACK=10 PCS (4171.111),
power cable 3 m long (2440.03) **22350011**

Necessary accessories:

Connecting hose CO₂ 1,5m NIST-NIST **74021038**

with

Pressure reducer CO₂

DIN 477-1 74007.054

DIN EN ISO 407 74007.055

ISO 5145 74007.056

or

Connecting hose CO₂ 5,0m DIN

for central CO₂ gas supply (Air Liquide) 74021039

Connecting hose CO₂ 5,0m NF

for central CO₂ gas supply (Air Liquide) 74021040

Optional accessories:

Insufflation tube, disposable

with integrated hygiene filter,

PACK=10 PCS, in individual sterile packs 4170.501

High-flow insufflation tube*,

Ø 8 mm, autoclavable 8170.232

*recommended in conjunction with high-flow trocar sleeves

Optional software module:

Software module CAN-BUS, integrated core 2235101

Software module BABY-MODE 2235102

Software module VIDEO-DISPLAY 2235103

- ☐ 6,5" Farbdisplay
- ☐ Touchscreen
- ☐ Max. Flowrate 45 l / min
- ☐ Funktionelles und anwenderfreundliches Design
- ☐ Optional konfigurierbare Software-Module

INSUFFLATOR Highflow 45 BASIC Set

bestehend aus:

INSUFFLATOR Highflow 45 Basic (2235001),
Insufflationsschlauch, Ø 5 mm, 2,5 m lang (8170.101),
Hygiene-Filter, VE=10 ST, steril verpackt (4171.111),
Netzkabel 3 m lang (2440.03) 22350011

Erforderliches Zubehör:

Verbindungsschlauch CO₂ 1,5m NIST-NIST 74021038

mit

Druckminderer CO₂

DIN 477-1 74007.054

DIN EN ISO 407 74007.055

ISO 5145 74007.056

oder

Verbindungsschlauch CO₂ 5,0m DIN

für zentrale CO₂-Gasversorgung (Dräger) 74021039

Verbindungsschlauch CO₂ 5,0m NF

für zentrale CO₂-Gasversorgung (Air Liquide) 74021040

Optionales Zubehör:

Insufflationsschlauch, zum Einmalgebrauch

mit integriertem Hygienefilter,

VE=10 ST, einzeln steril verpackt 4170.501

High-Flow-Insufflationsschlauch*,

Ø 8 mm, autoklavierbar 8170.232

*in Verbindung mit High-Flow-Trokarhülsen empfohlen

Optionale Software-Module:

Softwaremodul CAN-BUS, Integration in core 2235101

Softwaremodul BABY-MODE 2235102

Softwaremodul VIDEOEINBLENDUNG 2235103

INSUFFLATOR

Highflow 45 BASIC

Technical data

INSUFFLATOR

Highflow 45 BASIC

Technische Daten

Schutzklasse nach IEC / EN 60601-1 ; (UL 60601-1 / CSA C22.2 No.601.1 - für USA) <i>Protection class complying with IEC / EN 60601-1 ; (UL 60601-1 / CSA C22.2 No.601.1 - for USA)</i>	1
Elektromagnetische Verträglichkeit (EMV) <i>Electromagnetic compatibility (EMC)</i>	gemäß IEC / EN 60601-1-2 <i>according to EN 60601-1-2</i>
Richtlinie über Medizinprodukte 93/42/EWG <i>Medical Device Directive 93/42/EEC</i>	Klasse IIb <i>Class IIb</i>
Schutz gegen elektrischen Schlag <i>Protection against electric shock</i>	Anwendungsteil des Typs CF <i>Application part of Type CF</i>
Schutzgrad gegen Eindringen von Flüssigkeit <i>Degree of protection against penetration of liquids</i>	IP 20 (nicht geschützt) <i>IP 20 (not protected)</i>
Betriebsart <i>Duty cycle</i>	Dauerbetrieb <i>Continuous operation</i>
Schutzgrad bei Anwendung in Gegenwart von brennbaren Gemischen <i>Degree of protection when flammable mixtures are present</i>	Gerät ist nicht explosionsgeschützt (Gerät nicht in zündfähiger Atmosphäre betreiben) <i>This device is not protected against explosions (Do not operate this device in areas where explosive substances are present)</i>
Gewicht <i>Weight</i>	8,9 kg (19,5 lbs) <i>8.9 kg (19.5 lbs)</i>
Abmessungen (B x H x T) <i>Dimensions (W x H x D)</i>	300 mm x 160 mm x 455 mm
Spannung <i>Voltage</i>	100 - 240 V~ / a.c.
Frequenz <i>Frequency</i>	50 / 60 Hz
Leistungsaufnahme <i>Power consumption</i>	60 VA
Sicherung <i>Fuse</i>	T 3,15 H <i>T 3.15 H</i>
Stromaufnahme <i>Power rating</i>	0,6 - 0,2 A <i>0.6 - 0.2 A</i>

Relevante Anwendungsparameter / Relevant application parameters:

Insufflationsmedium <i>Insufflation medium</i>	med. CO ₂ (Reinheitsgrad > 99,5 %) <i>med. CO₂ (purity > 99,5 %)</i>
Intraabdominalen Druck <i>Intra-abdominal pressure</i>	3 mmHg bis / to 25 mmHg, (± 2 mmHg) <i>vorwählbar / preselectable in 1 mmHg - Schritten / Steps</i>
Gasflussrate: - Primärfüllung - High Flow <i>Gas flow rate: - primary filling - high flow</i>	1 l/min. (± 50 %) 2 l/min. bis 45 l/min. (± 20 %) <i>vorwählbar in 1 l/min Schritten 1 l/min. 2 l/min. to 45 l/min. (± 20 %) preselectable in 1 l/min steps</i>
Verbrauchsanzeige <i>Consumption display</i>	0 l bis 9999 l (± 20 %) <i>0 l to 9999 l (± 20 %)</i>

EndoVue® 32"

Value Endoscopy Visualization



- Optimized for endoscopy applications
- Outstanding image quality
- Multi-modality imaging capabilities
- Low power consumption and fanless cooling
- Robust and reliable
- Minimum cost of ownership

For the medical professional seeking to maximize their capital investment and upgrade their aging monitor, the EndoVue® series delivers the image performance of a high-end endoscopy display at a value price.

EndoVue is a versatile visualization platform, supporting multi-modality medical imaging requirements. It is plug-and-play compatible with endoscopic camera systems from leading manufacturers. Designed and built for medical use, it is FDA listed, TUV certified, and CE marked, offering patient safety, clinical performance, and durability compared to non-medical grade displays.

The EndoVue display accommodates standard analog and digital high-definition signals from a variety of medical imaging sources, including ultrasound, PACS, and patient monitor vital signs. It features a fanless cooling design to minimize the risk of spreading airborne contaminants within the sterile field, and industry-leading LED backlight technology for reduced power consumption.

EndoVue® 32"

Value Endoscopy Visualization

SPECIFICATIONS

Screen Size	31.5" diagonal
Image Size	27.5" x 15.5"/698 x 393 mm (WxH)
Resolution	1920 x 1080
Aspect Ratio	16:9
View Angle	178°
Luminance	400 cd/m ² typical
Contrast Ratio	1,000:1 (typical)
Numbers of Colors	16.7 Million (8-bit)
Response Time	8ms
Latency	20ms
Video Inputs	DVI-D, RGBS/VGA/YPbPr (HD-15 or DVI-I via adapter), S-Video, Composite
Video Output	DVI-D
Warranty	1 Year standard, optional extended 1 year
Dimensions	29.7" x 19.1" x 3.9"/753 x 485 x 98 mm (WxHxD)
Weight	21.3 lbs/9.7 kg
Shipping Weight*	29 lbs/13.1 kg
Shipping Dimensions	35" x 9" x 27"/89 x 23 x 69 cm
Green Compliance	REACH, RoHS-2, WEEE, Conflict Minerals
Regulatory Compliance	ANSI/AAMI ES60601-1, CAN/CSA C22.2 No. 60601-1, CAN ICES-3(B)/NMB-3(B), FCC Class B, EN60601-1, EN60601-1-2, CE, MDR 2017/745, EAC, CCC, Class I Medical Device
Supplied Accessories	Power Supply, 100-240 VAC, 50-60 Hz to 24 VDC, 2.7 A AC power cord, region appropriate

*Shipping weights are approximate.

ORDER INFORMATION

EndoVue 32

90K0080	EndoVue 32" - North America
90K0081	EndoVue 32" - South America
90K0082	EndoVue 32" - Japan
90K0083	EndoVue 32" - China
90K0084	EndoVue 32" - Emerging Market**
90K0085	EndoVue 32" - Europe

OPTIONAL ACCESSORIES

35X0100	Fiber Converter 5 VDC Power Cable
73A1016	EndoVue 32" Extended 1 Year Warranty

**Emerging Market model eligible countries (non-eligible countries will void the warranty)

Bahrain | Bangladesh | Botswana | Bulgaria | Côte d'Ivoire | Croatia | Cyprus | Czech Republic | Egypt | Estonia | Ghana | Hungary | India | Indonesia | Jordan | Kenya | Lithuania | Macedonia | Malaysia | Malta | Mauritius | Morocco | Nigeria | Oman | Pakistan | Philippines | Poland | Qatar | Romania | Russia | Serbia | Slovakia | Slovenia | South Africa | Sri Lanka | Taiwan | Thailand | Tunisia | Turkey | UAE | Vietnam



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NDS Quality System

ISO 13485
FDA Registration #2954921



SPECTRUM – TECHNICAL SPECIFICATIONS

Electrosurgery
Argon
ThermoStapler®

SmartDevice System
- detects and identifies
the connected instrument

10 inches touch screen

Wireless footswitch

Voice communication

Different languages
available

Possibility of storing up to
105 programs under
different names

Remote program change

Special endoscopic modes

ThermoStapler® - bipolar
sealing of blood
vessels - up to 7mm

Power monitor

Easy software upgrade

SpectrumLine trolley



SAFETY FEATURES

Protection against electric shock:
Class / Grade I / CF

Low-frequency leakage currents in accordance with EN 60601-1

High-frequency leakage currents in accordance with EN 60601-2-2

Generator working frequency 333 kHz

Defibrillation proof in accordance with EN 60601-2-2

NEM System neutral electrode control

optical indication 7 levels, required resistance < 240 Ω

MONOPOLAR CIRCUIT

Mono Cut (300Ω)	9 effects/400W
Precise Cut (300Ω)	9 effects/50W
Mixed Cut (60Ω)	9 effects/150W
Polipo Cut (50Ω) (S)	9 levels/400W
Papillo Cut (60Ω) (S)	9 levels/400W
Arthro Cut (300Ω) (S)	9 levels/400W
Uro Cut (300Ω) (S)	9 levels/400W
Hystero Cut (300Ω) (S)	9 levels/400W
Argon Cut (200Ω) (S)	9 effects/350W
Muco Cut (100Ω) (S)	9 levels/400W

MONOPOLAR COAGULATION

Soft Coag (50Ω)	9 effects/200W
Forced Coag (300Ω)	9 effects/200W
Spray Coag (1250Ω)	80W
Hybrid Coag (300Ω)	9 effects/200W
Endo Spray (1250Ω) (S)	30W
Standard Argon (1250Ω) (S)	80W
Endo Argon (1250Ω) (S)	40W
Pulse Argon (1250Ω) (S)	80W
Uro Coag (60Ω) (S)	9 levels/200W
Arthro Coag (60Ω) (S)	9 levels/200W
Hystero Coag (60Ω) (S)	9 levels/200W

BIPOLAR CUTTING

Bi-Cut (300Ω) (S)	9 effects/120W
Uro Bi-Cut (200Ω) (S)	9 effects/400W
Hystero Bi-Cut (200Ω) (S)	9 effects/400W
Arthro Bi-Cut (50Ω) (S)	9 levels/400W
Uro Bi-Vapor (200Ω) (S)	9 effects/400W

BIPOLAR COAGULATION

Soft Bi-Coag (50Ω)	9 effects/120W
	AutoStart/AutoStop
Forced Bi-Coag (300Ω)	9 effects/120W
Uro Bi-Coag (10Ω) (S)	9 effects/400W
Hystero Bi-Coag (10Ω) (S)	9 effects/400W
Arthro Bi-Coag (10Ω) (S)	9 effects/400W
Sciss Bi-Coag (25Ω) (S)	9 effects/350W

ARGON

Argon grade	4.8 (99,998%) or higher
Gas input pressure	4-5 Bar
Gas outflow	0.1-10.0 [l/min], regulated 0.1 [l/min] in whole range
Pressure	Regulator with an 0.45 MPa (4.5 Bar) manometer on the argon cylinder

ThermoStapler® bipolar blood vessel sealing system (10Ω)	9 effects/300W
ThermoStapler® LAP laparoscopic bipolar blood vessel sealing system (10Ω)	9 effects/60W

OTHER FEATURES

SpectrumResult system	automatic power regulation
Program memory	105 different memory locations in 7 groups
Wireless footswitch	easy operation, without a cable
Outputs	various configuration of the sockets available

WEIGHT AND DIMENSIONS

Length	495 mm
Width	415 mm
Height	225 mm
Weight	12,2 kg

POWER SUPPLY

Supply voltage	220-240 [V] +/- 10% 50/60 [Hz] or 110-120 [V] +/- 10% 50/60 [Hz]
Rated power input	1350 [VA]

(S) - Specialized mode available only for dedicated SDS cable / instrument connected

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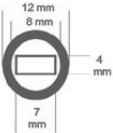
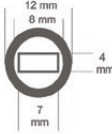
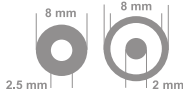
monopolar cables

kable monopolarne

SDS plug wtyk SDS	Ref. No. Kod	cable length dł. kabla		
	280-03S 280-05S	3 m 5 m	4mm female gniazdo żeńskie 4 mm	Monopolar laparoscopic cable Kabel monopolarny do laparoskopu
	 Ø 4 mm			
	281-03S	3 m	3mm female gniazdo żeńskie 3 mm	Monopolar endoscopic cable Kabel monopolarny do narzędzi endoskopowych
	 Ø 3 mm			
	405-04S	4.5 m	2mm male wtyk męski 2 mm	Monopolar cable for resectoscope Kabel monopolarny do resektoskopu
	 Ø 2 mm 			
	408-14S	4.5 m	angled connector złącze kątowe	Monopolar cable for STORZ resectoscope Kabel monopolarny do resektoskopu STORZ
				
	409-04S	4.5 m	3 mm male wtyk męski 3 mm	Monopolar cable for OLYMPUS resectoscope Kabel monopolarny do resektoskopu OLYMPUS
	 			

bipolar cables

kable bipolarne

SDS plug wtyk SDS	Ref. No. Kod	cable length dł. kabla	
	351-03S 351-05S	3 m 5 m	Bipolar cable, straight connector Kabel bipolarny, złącze proste
	 		
	351-13S 351-15S	3 m 5 m	Bipolar cable, angled connector Kabel bipolarny, złącze kątowe
	 		
	401-03S 401-05S	3 m 5 m	Bipolar cable 2x2.6mm, for ThermoStapler® clamps Kabel bipolarny 2x2,6mm, do klemów ThermoStapler®
			
	348-04S	4.5 m	Bipolar cable for STORZ resectoscope Kabel bipolarny do resektoskopu STORZ
			
	354-04S	4.5 m	Bipolar cable for resectoscope Kabel bipolarny do resektoskopu
	 		

reusable neutral electrodes

elektrody neutralne wielokrotnego użycia

	Ref. No. Kod	dimensions wymiały	cable length dł. kabla	plug wtyk	
	242-008	30x17 cm	4 m	EMED plug wtyk EMED	Neutral silicone electrode, reusable, for adults Elektroda neutralna silikonowa, wielorazowa, dla dorosłych
					
	242-003	30x17 cm	0.5 m		Neutral silicone electrode, reusable, for adults Elektroda neutralna silikonowa, wielorazowa, dla dorosłych
					

footswitches

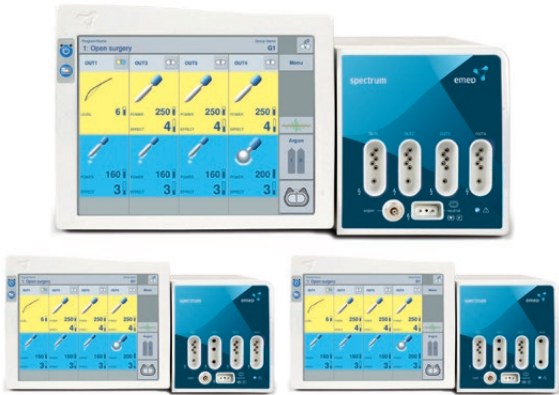
włączniki nożne

		Ref. No. Kod	cable length dł. kabla	
		100-336		Three-pedal footswitch, MultiSwitch, wireless Włącznik nożny 3-przyciskowy, MultiSwitch, bezprzewodowy
		100-316	5 m	Three-pedal footswitch, 6-pin plug Włącznik nożny 3-przyciskowy, wtyk 6-pinowy
		100-313		MultiSwitch, two-pedal footswitch, wireless Włącznik nożny 2-przyciskowy MultiSwitch, bezprzewodowy
		100-303	5 m	MultiSwitch, two-pedal footswitch, 6-pin plug Włącznik nożny 2-przyciskowy MultiSwitch, wtyk 6-pinowy
		100-302	5 m	Two-pedal footswitch, 6-pin plug Włącznik nożny 2-przyciskowy, wtyk 6-pinowy
		100-315		One-pedal footswitch, for COAGULATION, wireless Włącznik nożny 1-przyciskowy, do KOAGULACJI, bezprzewodowy
		100-305	5 m	One-pedal footswitch, for COAGULATION, 6-pin plug Włącznik nożny 1-przyciskowy, do KOAGULACJI, wtyk 6-pinowy
		100-314		One-pedal footswitch, for CUTTING, wireless Włącznik nożny 1-przyciskowy, do CIĘCIA, bezprzewodowy
		100-304	5 m	One-pedal footswitch, for CUTTING, 6-pin plug Włącznik nożny 1-przyciskowy, do CIĘCIA, wtyk 6-pinowy
		100-311		One-pedal footswitch, wireless Włącznik nożny 1-przyciskowy, bezprzewodowy
		100-301	5 m	One-pedal footswitch, 6-pin plug Włącznik nożny 1-przyciskowy, wtyk 6-pinowy

For ES120 unit and WATERFALL pump
Do aparatu ES120 i pompy WATERFALL

EMED electrosurgical units

aparaty elektrochirurgiczne EMED

	Ref. No. Kod	
 The SPECTRUM unit features a large touchscreen display showing multiple output channels (OUT1, OUT2, OUT3, OUT4) with settings for voltage (e.g., 6V, 250V, 100V) and current (e.g., 4A, 3A). The unit is white with a blue and yellow interface.	100-013	Electrosurgical unit SPECTRUM Aparat elektrochirurgiczny SPECTRUM
 The ATOM unit has a black touchscreen display with four main modes: POLYPOUT (4), MONO OUT (7), ENDO SPRAY (5), and FORCED COAG (6). It also shows a 2.0 output. The unit is black with white and blue accents.	100-620	Electrosurgical unit ATOM Aparat elektrochirurgiczny ATOM
 The ENDO unit features a black touchscreen display with modes for CUT, COAG, PLASMA, and ENDO COAG. It also shows an EFFECT P slider. The unit is black with white and blue accents.	100-600	Electrosurgical unit ENDO Aparat elektrochirurgiczny ENDO
 The ARTRO unit has a black touchscreen display with modes for CUT, EFFECT, and COAG. It also shows a 3 output. The unit is black with white and blue accents.	100-610	Electrosurgical unit ARTRO Aparat elektrochirurgiczny ARTRO