



Cable, rubber return plate, international, 4.5 m

Cable for reusable neutral electrodes

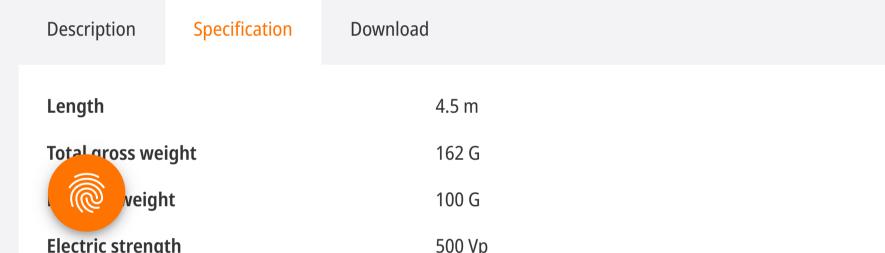
- > High voltage reliability
- > Autoclavable

Scope of delivery Incl. instructions for use Product number: 385-050 Unit: 1 piece

Device connection: 2 pin international NON-REM

D<u>Reset selection</u>

Inquiry





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Electric strength	500 vp
Monopolar / bipolar / passive	passive
Single-use / reusable	Reusable
Sterile / non-sterile	Non-sterile
Cleaning / Disinfecting	Autoclave
Preparation	200 cycles
Connector type	BOWA / Valleylab NON-REM
Permissible combinations	232-003, 242-003
Packaging unit	PCS (1 PCS)
Scope of delivery	Incl. instructions for use
CE conformity marking	YES
EU medical device classification	Ι
Manufacturer	BOWA-electronic GmbH & Co. KG

Do you still have any questions regarding the product?

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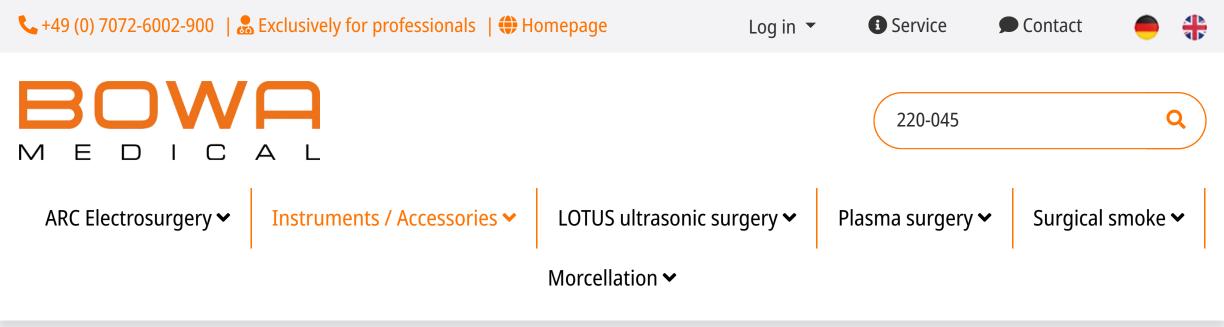
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JackKNIFE, 2 switches, shaft 2.4 mm, for 3pin, cable 4.5 m

Universal ergonomics in a modern design

Scope of delivery Incl. instructions for use Product number: 220-045

Unit: 1 piece

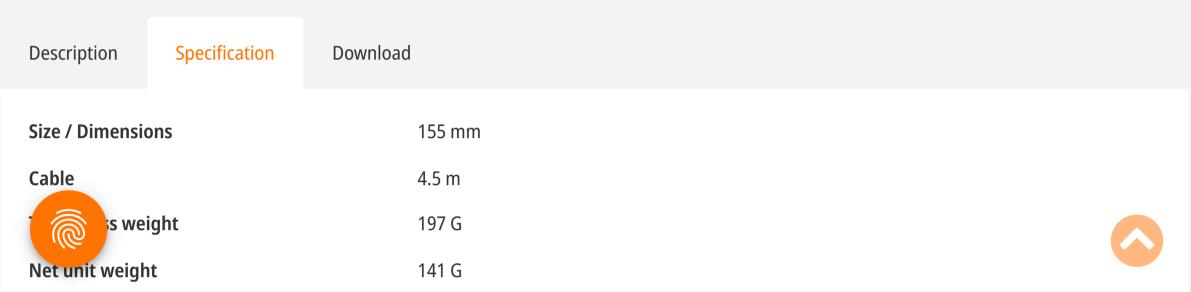
Electrode receiver: 2.4 mm

Socket type: 3-pin International

S Reset selection

Inquiry

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Electric strength	6000 Vp
Monopolar / bipolar / passive	Monopolar
Single-use / reusable	Mehrweg
Sterile / non-sterile	Unsteril
Cleaning / Disinfecting	Autoclave
Preparation	200 cycles
Connector type	3-pin International
Permissible combinations	2.4 mm electrodes
Packaging unit	PCS (1 PCS)
Scope of delivery	Incl. instructions for use
CE conformity marking	YES
Notified body	TÜV SÜD Product Service GmbH (0123)
EU medical device classification	IIb
Manufacturer	BOWA-electronic GmbH & Co. KG

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LLETZ electrodes Monopolar loop electrodes for conisati... **Electrodes, long** Reusable long electrodes for electrosu... **Electrodes, short** Reusable short electrodes for electrosu...

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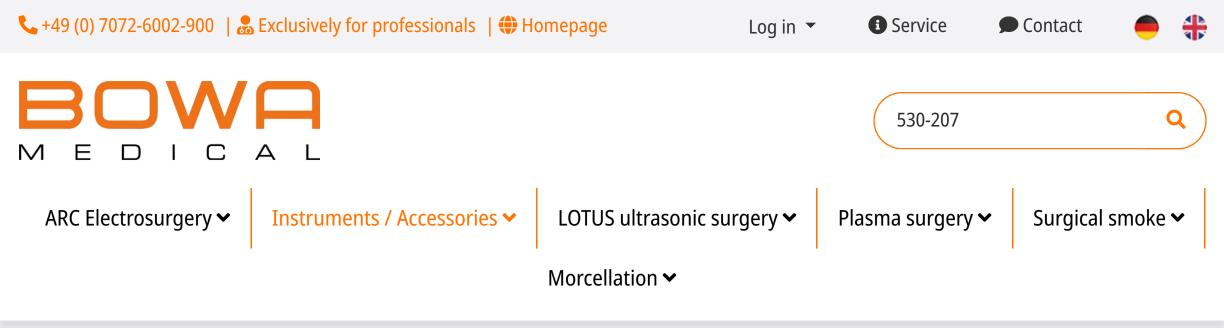
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BOVF MEDICA





Reusable short electrodes for electrosurgery

- > With heat-resistant safety insulation
- > Dielectric strength up to 5700 Vp
- > Reusable

Scope of delivery

Incl. instructions for use Product number: 530-207 Unit: 1 pack (5 pcs.)

Type: Knife electrode	•
Shape: Straight	•
Shaft diameter: 2.4 mm	•
D <u>Reset selection</u>	

Inquiry

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Description

Download

Specification

2.5 x 15 mm



Length	60 mm
Shape	Straight
Total gross weight	47 G
Net unit weight	2 G
Electric strength	5700 Vp
Monopolar / bipolar / passive	Monopolar
Single-use / reusable	Reusable
Sterile / non-sterile	Non-sterile
Cleaning / Disinfecting	Autoclave
Preparation	75 cycles
Permissible combinations	Reusable handles 2.4 mm, 105-045, 120-045, 218-045, 218-145, 220-045, 220-345, 327-045, 335-030
Packaging unit	PAC (5 PCS)
Scope of delivery	Incl. instructions for use
CE conformity marking	YES
Notified body	TÜV SÜD Product Service GmbH (0123)
EU medical device classification	IIb
Manufacturer	BOWA-electronic GmbH & Co. KG
Note	shaft Ø 2.4 mm

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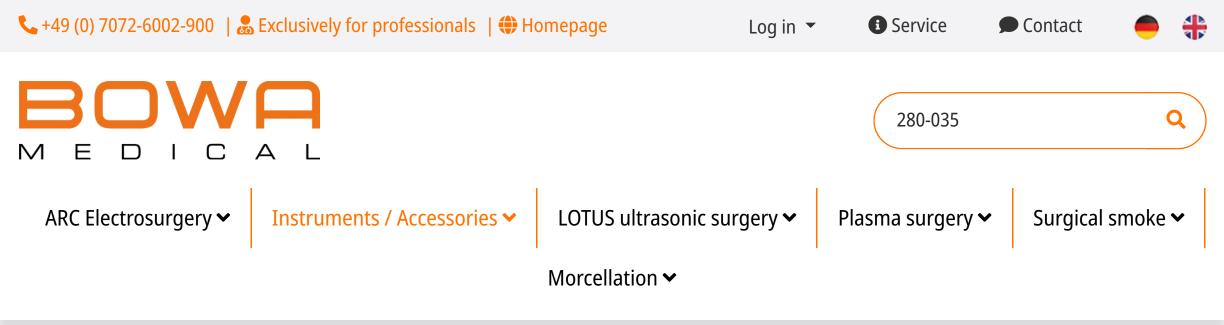
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Monopolar cable, arthroscopy and LAP electrode, for 4 mm, 4.5 m

Monopolar connection cable for electrosurgery

- > Robust plug with kink protection and strain relief
- > Ideal cleaning properties thanks to the round shape of the cable
- > Indelible laser marking for reliable identification
- > Extreme durability for up to 300 reprocessing cycles
- > For all common device types

Scope of delivery

Incl. instructions for use Product number: 280-035 Unit: 1 piece

Instrument type: BOWA MEDICAL LAP

Device connection: 4 mm Standard

D<u>Reset selection</u>

Inquiry



Download

Specification



Size / Dimensions	4 mm
Length	4.5 m
Total gross weight	166 G
Net unit weight	110 G
Electric strength	6000 Vp
Monopolar / bipolar / passive	Monopolar
Single-use / reusable	Reusable
Sterile / non-sterile	Non-sterile
Cleaning / Disinfecting	Autoclave
Preparation	300 cycles
Connector type	4 mm Standard
Permissible combinations	510-108, 510-109, 510-110, 510-112, 700-003, 700-004, 700-005, 700-006, 710-003, 710-004, 710-005, 710-006
Packaging unit	PCS (1 PCS)
Scope of delivery	Incl. instructions for use
CE conformity marking	YES
EU medical device classification	Ι
Manufacturer	BOWA-electronic GmbH & Co. KG

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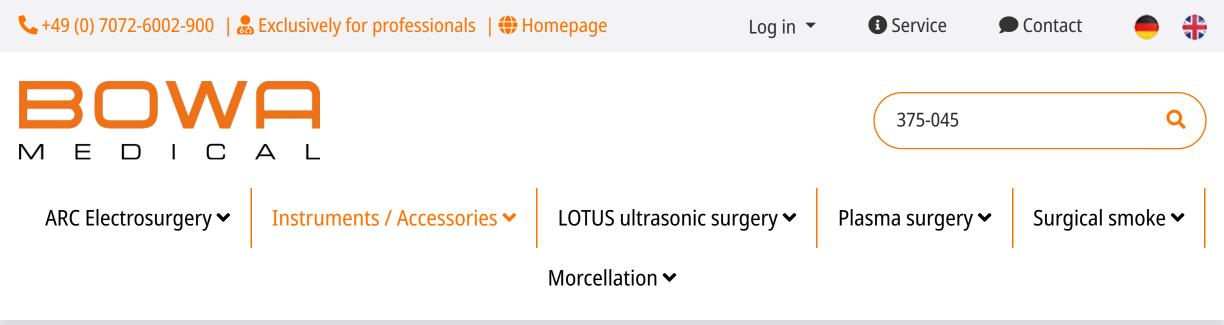
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Monopolar cable, 2 mm socket, for 8 mm Bovie, 4.5 m

Monopolar and bipolar cables for resectoscopes and hysteroscopes

Scope of delivery Incl. instructions for use Product number: 375-045 Unit: 1 piece

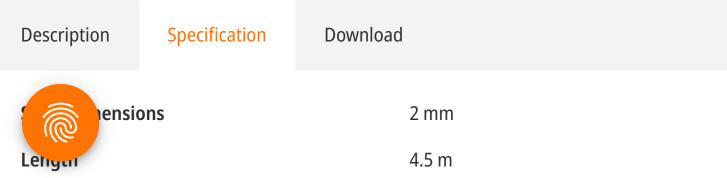
Mono-/bipolar: Monopolar

Instrument type: 2mm socket

Device connection: 8 mm Bovie jack

D<u>Reset selection</u>

Inquiry





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Total gross weight	179 G
Net unit weight	123 G
Electric strength	6000 Vp
Monopolar / bipolar / passive	Monopolar
Single-use / reusable	Reusable
Sterile / non-sterile	Non-sterile
Cleaning / Disinfecting	Autoclave
Preparation	300 cycles
Connector type	8 mm Bovie Jack
Permissible combinations	Resectoscopes with 2 mm connection socket
Packaging unit	PCS (1 PCS)
Scope of delivery	Incl. instructions for use
CE conformity marking	YES
EU medical device classification	Ι
Manufacturer	BOWA-electronic GmbH & Co. KG

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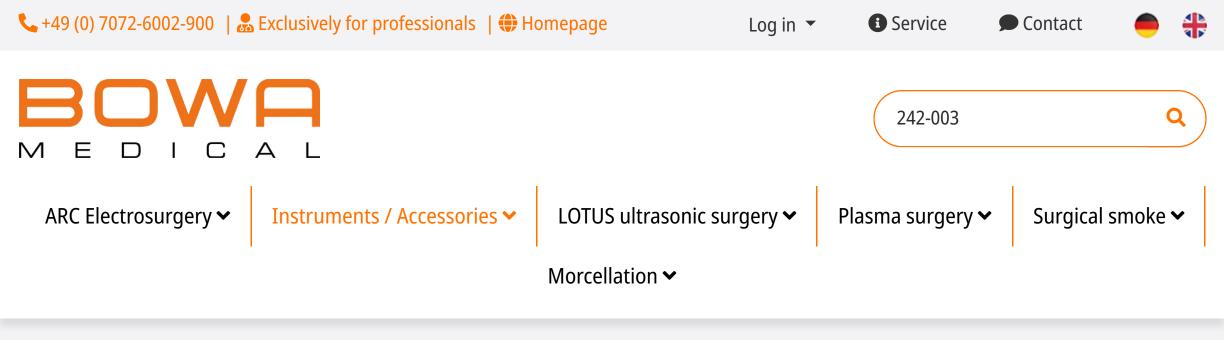
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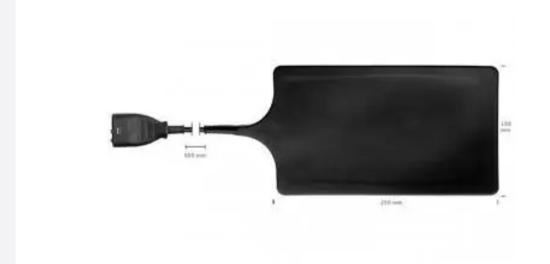
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Rubber return plate, adults, 250 x 150 mm, international

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-

Reusable neutral electrodes for simple procedures

Product number: 242-003

Unit: 1 piece

Use: Adults

Connection: International

D<u>Reset selection</u>

Inquiry

Description	Specification	Download	
Size / Dimensio	ons	375 cm ²	
Cable		0.5 m	
Total gross wei	ght	454 G	
N weigh	t	279 G	
M ar / bi	polar / passive	Passive	
Single-use / reu	usable	Reusable	
Sterile / non-st	erile	Non-sterile	
Cleaning / Disi	nfecting	Autoclave	
Preparation		75 cycles	
Permissible co	mbinations	194-075, 295-050, 385-050	
Packaging unit		PCS (1 PCS)	
CE conformity	marking	YES	
EU medical dev	vice classification	IIb	
Manufacturer		BOWA-electronic GmbH & Co. KG	
Note		non-split, for adults > 15 kg	

Do you still have any questions regarding the product?

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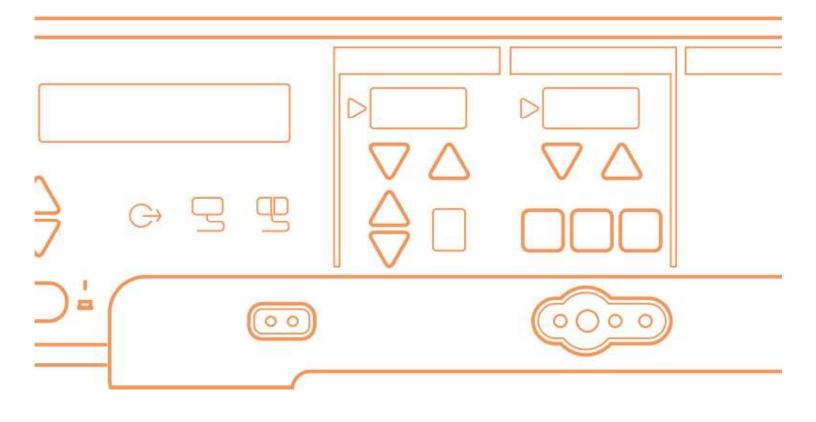
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SERVICE MANUAL ELECTROSURGICAL UNIT







3. Design and operating principle

The electrosurgical unit consists of several sub-assemblies connected together as blocks or modules:

- Power board (70151)
- Control board (70150)
- Autostart board (70200)
- Front panel (70128)
- LWL board (70099)

The block diagram gives an overview of the components and their functions.

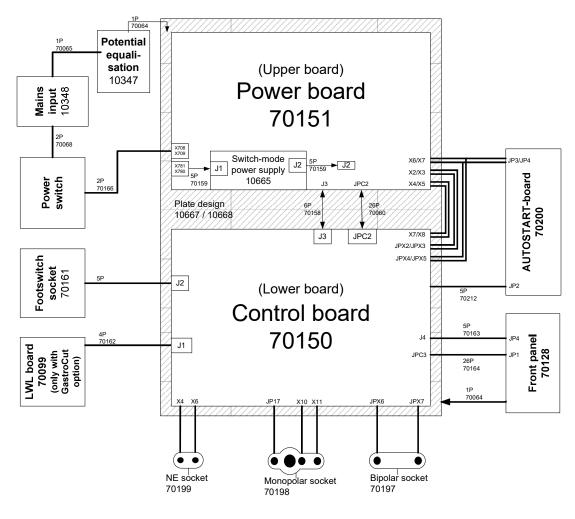


Figure 3-1: Block diagram



3.1. Power board

The power board contains all the circuits required to generate the HF power from mains-frequency current.

The power board is composed of various individual functions:

- Power rectifier (1)
- Power supply unit (2)
- Extra-low voltage power supply unit (3)
- Generator (4)
- Control electronics (5)

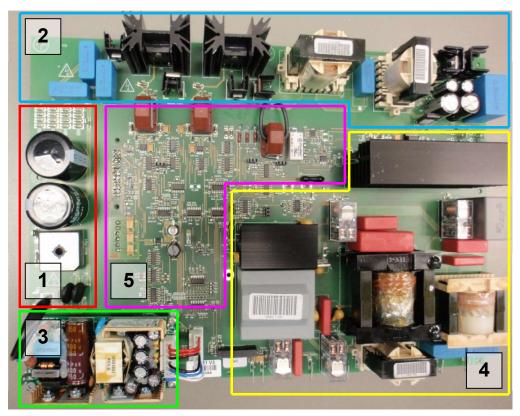


Figure 3-2: Power board (70151)

The management system of **BOWA-electronic GmbH & Co. KG**

Heinrich-Hertz-Strasse 4-10, DE 72810 Gomaringen

has been assessed and certified as meeting the requirements of **ISO 14001:2015**

For the following activities Development, production, and distribution of medical devices for electrosurgery (cables, injection moulded parts, instruments, electronic assembly, toolmaking)

This certificate is valid from 22 December 2022 until 21 December 2025 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 22 December 2022



Authorised by Michael Rath Head of Certification Body

SGS-TÜV Saar GmbH Am TÜV 1 66280 Sulzbach (Germany) t +49 (0)40 30.101.361 - www.sgs-tuev-saar.com





ppa. Alexander Hirschhäuser

Director KNS Germany

Authorised by





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Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten BS-MDR-099





EU Quality Management System Certificate (MDR) Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices) No. G10 016316 0022 Rev. 00

Manufacturer:

BOWA-electronic GmbH & Co. KG

Heinrich-Hertz-Strasse 4-10 72810 Gomaringen GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

Report No.:

713175396

Valid from: Valid until:

Issue date: 2020-08-10

2020-08-10 2025-08-09

Christoph Dicks Head of Certification/Notified Body



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EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 016316 0022 Rev. 00

Device Group:Z120109 - ELECTROSURGERY INSTRUMENTSClassification:IIbIntended Purpose:Generation of electrical power for monopolar and bipolar cutting
and coagulation on tissue structures in surgical operations

Device Group:

Classification: Intended Purpose: K020101 - ELECTROSURGICAL INSTRUMENTARY, MONO-AND BIPOLAR, SINGLE-USE IIb Electrosurgical equipment for cutting and coagulation of tissue

 Device Group:
 K020102 - ELECTROSURGICAL PADS AND CABLES

 Classification:
 IIb

 Intended Purpose:
 Electrosurgical equipment for cutting and coagulation of tissue

Device Group: Classification: Intended Purpose: K020480 - ARGON GAS SURGICAL DEVICES - ACCESSORIES IIb Electrosurgical equipment for cutting and coagulation of tissue

Device Group:

Classification: Intended Purpose: L180201 - SCISSORS, "OPEN SKY" ELECTROSURGICAL, REUSABLE IIb Electrosurgical equipment for cutting and coagulation of tissue

Device Group:

Classification: Intended Purpose: L180301 - HANDPIECES, "OPEN SKY" ELECTROSURGICAL, REUSABLE IIb Electrosurgical equipment for cutting and coagulation of tissue

Device Group:

Classification: Intended Purpose: L180401 - FORCEPS, "OPEN SKY" ELECTROSURGICAL, REUSABLE IIb Electrosurgical equipment for cutting and coagulation of tissue

Device Group:

L180402 - FORCEPS, ELECTROSURGICAL ENDOTHERAPY, REUSABLE

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BS-MDR-099



EU Quality Management System Certificate (MDR) Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices) No. G10 016316 0022 Rev. 00

Classification: llb **Intended Purpose:** Electrosurgical equipment for cutting and coagulation of tissue **Device Group:** L180602 - ELECTRODES, ELECTROSURGICAL ENDOTHERAPY, REUSABLE **Classification:** llb **Intended Purpose:** Electrosurgical equipment for cutting and coagulation of tissue **Device Group:** K020401 - ARGON GAS SURGICAL INSTRUMENTARY, SINGLE-USE **Classification:** llb **Intended Purpose:** Electrosurgical equipment for cutting and coagulation of tissue L180601 - ELECTRODES, "OPEN SKY" ELECTROSURGICAL, **Device Group:** REUSABLE **Classification:** llb **Intended Purpose:** Electrosurgical equipment for cutting and coagulation of tissue

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Certificate No. Q5 016316 0021 Rev. 02

Holder of Certificate:

BOWA-electronic GmbH & Co. KG

Heinrich-Hertz-Strasse 4-10 72810 Gomaringen GERMANY

Certification Mark:



Scope of Certificate:

Design and development, production and distribution of sterile and non-sterile medical devices: Electrosurgical Units and Accessories, Argon Coagulation Units and Accessories, Electrode Handles, Active Electrodes and Instruments, Monopolar and Bipolar Forceps, Endoscopic and Laparoscopic Instruments, Instruments for Vessel Sealing, Neutral Electrodes and Bipolar Scissors

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 016316 0021 Rev. 02

Report No.:

713229570

Valid from: Valid until: 2022-03-02 2025-03-01

Date.

2022-03-02

Christoph Dicks Head of Certification/Notified Body

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Certificate

No. Q5 016316 0021 Rev. 02

Applied Standard(s): EN ISO 13485:2016 Medical devices - Quality management systems -Requirements for regulatory purposes (ISO 13485:2016) DIN EN ISO 13485:2016

Facility(ies):

BOWA-electronic GmbH & Co. KG Heinrich-Hertz-Strasse 4-10, 72810 Gomaringen, GERMANY Design and development, production and distribution of sterile and non-sterile medical devices: Electrosurgical Units and Accessories,

Argon Coagulation Units and Accessories, Electrode Handles, Active Electrodes and Instruments, Monopolar and Bipolar Forceps, Endoscopic and Laparoscopic Instruments, Instruments for Vessel Sealing and Bipolar Scissors

Design and development and distribution of sterile and non-sterile medical devices: Neutral Electrodes

BOWA Polska Sp. zo. o. Zlotkowo, ul. Obornicka 10, 62-002 Suchy Las, POLAND

Production of sterile and non-sterile medical devices: Instruments for Vessel Sealing and Neutral Electrodes

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