



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



Product Service

## 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:** 2020-08-10

**Valid until:** 2025-08-09

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2020-08-10



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<b>Device Group:</b>	Z120109 - ELECTROSURGERY INSTRUMENTS
<b>Classification:</b>	IIb
<b>Intended Purpose:</b>	Generation of electrical power for monopolar and bipolar cutting and coagulation on tissue structures in surgical operations
<b>Device Group:</b>	K020101 - ELECTROSURGICAL INSTRUMENTARY, MONO- AND BIPOLAR, SINGLE-USE
<b>Classification:</b>	IIb
<b>Intended Purpose:</b>	Electrosurgical equipment for cutting and coagulation of tissue
<b>Device Group:</b>	K020102 - ELECTROSURGICAL PADS AND CABLES
<b>Classification:</b>	IIb
<b>Intended Purpose:</b>	Electrosurgical equipment for cutting and coagulation of tissue
<b>Device Group:</b>	K020480 - ARGON GAS SURGICAL DEVICES - ACCESSORIES
<b>Classification:</b>	IIb
<b>Intended Purpose:</b>	Electrosurgical equipment for cutting and coagulation of tissue
<b>Device Group:</b>	L180201 - SCISSORS, "OPEN SKY" ELECTROSURGICAL, REUSABLE
<b>Classification:</b>	IIb
<b>Intended Purpose:</b>	Electrosurgical equipment for cutting and coagulation of tissue
<b>Device Group:</b>	L180301 - HANDPIECES, "OPEN SKY" ELECTROSURGICAL, REUSABLE
<b>Classification:</b>	IIb
<b>Intended Purpose:</b>	Electrosurgical equipment for cutting and coagulation of tissue
<b>Device Group:</b>	L180401 - FORCEPS, "OPEN SKY" ELECTROSURGICAL, REUSABLE
<b>Classification:</b>	IIb
<b>Intended Purpose:</b>	Electrosurgical equipment for cutting and coagulation of tissue
<b>Device Group:</b>	L180402 - FORCEPS, ELECTROSURGICAL ENDOTHERAPY, REUSABLE





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**No. G10 016316 0022 Rev. 00**

**Classification:** IIb  
**Intended Purpose:** Electrosurgical equipment for cutting and coagulation of tissue

**Device Group:** L180602 - ELECTRODES, ELECTROSURGICAL  
ENDOTHERAPY, REUSABLE

**Classification:** IIb  
**Intended Purpose:** Electrosurgical equipment for cutting and coagulation of tissue

**Device Group:** K020401 - ARGON GAS SURGICAL INSTRUMENTARY,  
SINGLE-USE  
**Classification:** IIb  
**Intended Purpose:** Electrosurgical equipment for cutting and coagulation of tissue

**Device Group:** L180601 - ELECTRODES, "OPEN SKY" ELECTROSURGICAL,  
REUSABLE  
**Classification:** IIb  
**Intended Purpose:** Electrosurgical equipment for cutting and coagulation of tissue

**The validity of this certificate depends on conditions and/or is limited to the following:** - none -