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

TÜV SÜD 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

Digitally signed by Ceaicovschi Tudor
Date: 2021.12.02 16:06:09 EET
Reason: MoldSign Signature
Location: Moldova

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(Class IIa and Class IIb Devices)

No. G10 016316 0022 Rev. 00

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

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(Class IIa and Class IIb Devices)

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 -

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