



EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 016316 0023 Rev. 00

Manufacturer: **BOWA-electronic GmbH & Co. KG**
Heinrich-Hertz-Strasse 4-10
72810 Gomaringen
GERMANY

SRN Manufacturer - DE-MF-000007801

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.

The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective aspects relating to

- establishing, securing, and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

If class IIa or class IIb devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.

If class III or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G15 016316 0023 Rev. 00

Report No.: 713356607
Preceding Certificate No.: G10 016316 0022 Rev. 00

Valid from: 2025-08-10
Valid until: 2030-08-09

Issue date: 2025-07-30

Christoph Dicks
Head of Certification/Notified
Body



EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 016316 0023 Rev. 00

Classification:	Class IIb
Device Group:	Z120109 - ELECTROSURGICAL INSTRUMENTS
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Classification:	Class IIb
Device Group:	K020101 - MONO- AND BIPOLAR SURGICAL INSTRUMENTS, SINGLE-USE
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Classification:	Class IIb
Device Group:	K020102 - ELECTROSURGERY PADS (NEUTRAL ELECTRODES) AND CABLES, SINGLE-USE
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Classification:	Class IIb
Device Group:	Z120309 - MEDICAL/MEDICINAL GAS PIPELINE SYSTEMS AND RELATED ACCESSORIES
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Classification:	Class IIb
Device Group:	K020480 - DEVICES FOR SURGERY WITH ARGON GAS GENERATOR, SINGLE-USE- ACCESSORIES
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Classification:	Class IIb
Device Group:	L180201 - OPEN ELECTROSURGERY SCISSORS, REUSABLE
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Classification:	Class IIb
Device Group:	L180301 - OPEN ELECTROSURGERY HANDPIECES, REUSABLE
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Classification:	Class IIb
Device Group:	L180401 - OPEN ELECTROSURGERY FORCEPS, REUSABLE
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Classification:	Class IIb
Device Group:	L180402 - ENDOSCOPIC ELECTROSURGERY FORCEPS, REUSABLE
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Classification:	Class IIb
Device Group:	L180602 - ENDOSCOPIC ELECTROSURGERY ELECTRODES, REUSABLE
Intended Purpose:	Electrosurgical equipment for cutting and coagulation of tissue
Classification:	Class IIb
Device Group:	K020401 - ARGON GAS SURGERY INSTRUMENTS, SINGLE-USE



EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 016316 0023 Rev. 00

Intended Purpose: Electrosurgical equipment for cutting and coagulation of tissue

Classification: Class IIb
Device Group: L180601 - OPEN ELECTROSURGERY ELECTRODES,
 REUSABLE

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 -

Revision History:

Rev.	Dated	Report	Description
00	2025-08-10	713356607	Renewal of certificate