



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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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 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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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: 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 -



Certificate

No. Q5 016316 0021 Rev. 01

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. 01

Report No.: 713198949

Valid from: 2021-02-22
Valid until: 2022-02-28

Date, 2021-02-22

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 016316 0021 Rev. 01

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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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



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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

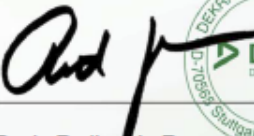
Revision status of the annex: 0 dated 2020-04-01

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).

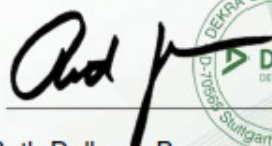
Certified location:

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



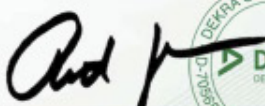
Annex to the Certificate No. 50593-14-01

Revision status: 0

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

The following locations / companies belong to the certificate above:

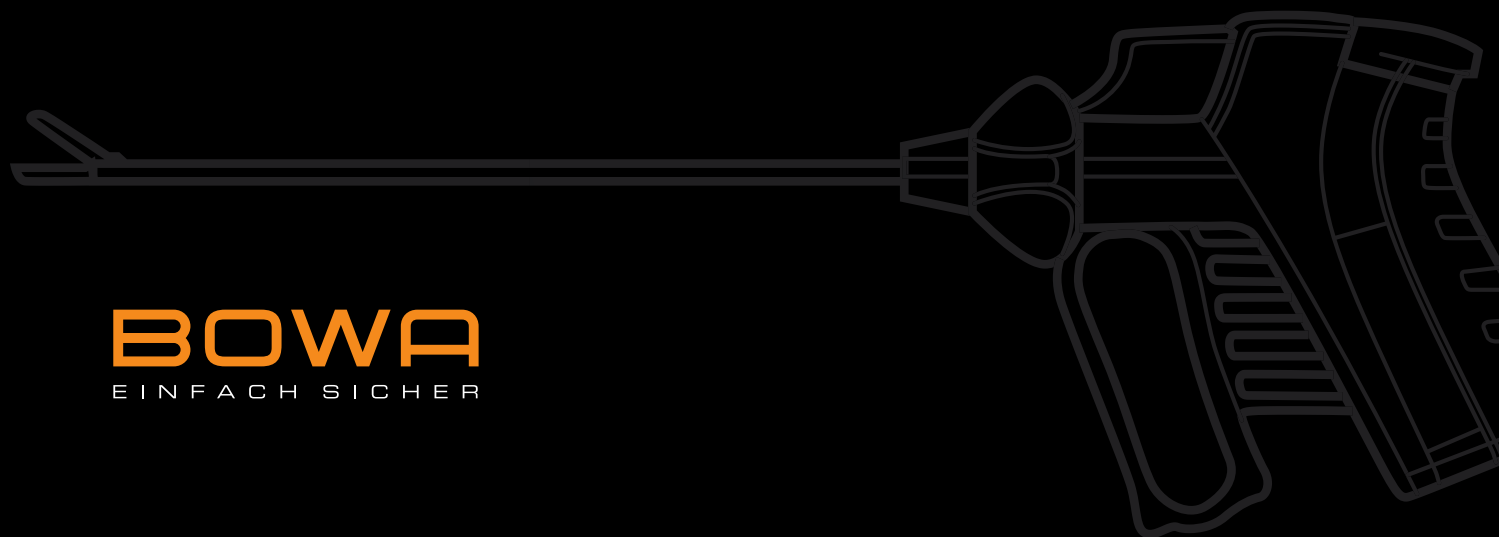
	Headquarter	Certified location	Scope of certification
	Richard Wolf GmbH	Pforzheimer Straße 32 75438 Knittlingen Deutschland	See page 1
	at the following locations / at the companies at the following locations		Scope of certification
1.	Richard Wolf GmbH	Reuchlinstraße 10-11 10553 Berlin Deutschland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



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



ELECTROSURGERY.
COMPLETE.



BOWA
EINFACH SICHER

2.2 Anschlusskabel bipolar Connecting cables bipolar Câbles de raccordement bipolaires Cables de conexión bipolares Cavi di collegamento bipolari

134°C
Autoclave
273°F

Geräteseitig / At the unit / Côté appareil / En el lado del aparato / Parte generatore					
					
BOWA Erbe International* Martin International Valleylab Conmed		Erbe VIO / ICC / ACC Erbe T-Serie		Erbe VIO International*	
BOWA-Pinzette Europäischer Flachstecker BOWA forceps Euro- pean flat connector Pince BOWA Fiche plate européenne Pinza BOWA conector europeo plano Pinze BOWA connettore piatto europeo 550V_P		351-040 (4.5 m)	101-040 (4 m)	353-040 (4.5 m)	287-040 (4.5 m)
EU-Pinzette Europäischer Flachstecker EU forceps European flat connector Pince UE Fiche plate européenne Pinza UE conector europeo plano Pinze UE connettore piatto europeo 550V_P		351-051 (4.5 m)	101-000 (4 m)	353-050 (4.5 m)	287-050 (4.5 m)
US-Pinzette US forceps Pince US Pinza E.E.U.U. Pinze USA 550V_P		351-045 (4.5 m)	101-045 (4 m)	353-045 (4.5 m)	287-045 (4.5 m)
BiZZER®, Ethicon Bipolare Scheren: Bipolar scissors: Ciseaux bipolaires Tijeras bipolares: Forbici bipolari: 300V_P		378-045 (4.5 m)	378-145 (4.5 m)	-	378-245 (4.5 m)
Lawton Bipolare Schere Bipolar scissors Ciseaux bipolaires Tijera bipolar Forbici bipolari 300V_P		401-051 (4.5 m)	401-052 (4.5 m)	-	-
* Abhängig von der jeweiligen Buchsenkonfiguration * Depending on the respective socket configuration * Dépend de la configuration de prise respective * Según la configuración de enchufes respectiva * In funzione della rispettiva configurazione della presa					