

Declaration of Conformity (DoC)

We

BOWA-electronic GmbH & Co. KG
Heinrich-Hertz Strasse 4-10
72810 Gomaringen / Germany
SRN manufacturer: **DE-MF-000007801**

declare in sole responsibility that the medical device(s)

Basic UDI-DI	see attached list
CND	see attached list
Product code / REF	see attached list
Device name	see attached list (product description)
Product group(s)	see attached list (PG)
Intended purpose	Electrosurgical equipment for cutting and coagulation of tissue

to which this declaration relates is classified as **risk class I**, according to the rules as set out in **Annex VIII** is in conformity with the following relevant European Union harmonization legislation:

Regulation (EU) 2017/745 relating to medical devices,

and that the device(s) is/are in conformity with the following standards and/or other normative documents

EN ISO 14971 / EN ISO 60601-1 / EN ISO 60601-2-2 / EN ISO 10993-1 / EN ISO 13485 /
DIN EN 1041

This declaration is valid until: 2025-03-01

Gomaringen, 2022-10-07

Head of Quality Management /
Regulatory Affairs


BOWA-electronic GmbH & Co. KG
Heinrich-Hertz-Strasse 4-10
72810 Gomaringen | Germany

Wolf-Rüdiger Fritz

Article List class I

REF	Product description	PG	CND	UDI	Basic UDI-DI
K020480	ARGON GAS SURGICAL DEVICES - ACCESSORIES		K020480		4250350186014Y
Intended Purpose	Electrosurgical equipment for cutting and coagulation of tissue				
932-146	Cable for flexible Argon probe COMFORT, 2.5 m	10-2	K020480	04250350108345	4250350186014Y
932-910	Rinsing adapter for flexible Argon probes (5 pcs.)	10-2	K020480	04250350104200	4250350186014Y
L180402	FORCEPS, ELECTROSURGICAL ENDOTHERAPY, REUSABLE		L180402		42503501860558
Intended Purpose	Electrosurgical equipment for cutting and coagulation of tissue				
723-050	ERGO 315R, cleaning adapter Set	16-3	L180402	04250350110225	42503501860558
723-051	ERGO 315R, cleaning adapter handle/jaw	16-3	L180402	04250350110232	42503501860558
723-052	ERGO 315R, cleaning adapter push rod	16-3	L180402	04250350110249	42503501860558
773-982	ERGO 315R, reprocessing basket	16-3	L180402	04250350110256	42503501860558
773-983	ERGO 315R, lid for basket	16-3	L180402	04250350110263	42503501860558
773-984	Lotus reprocessing basket with lid 550x150x77 mm	16-3	L180402	04250350112038	42503501860558
773-985	Lotus reprocessing basket with lid 640x150x77 mm	16-3	L180402	04250350112045	42503501860558
773-986	LOTUS reprocessing basket with lid for Series 5; 650x150x68 mm	16-3	L180402	04250350112687	42503501860558
773-987	LOTUS reprocessing basket with lid for Series 5; 730x150x68 mm	16-3	L180402	04250350112694	42503501860558
Z120109	ELECTROSURGERY INSTRUMENTS		Z120109		4250350186085E
Intended Purpose	Electrosurgical equipment for cutting and coagulation of tissue				
101-000	Bipolar cable, E.U. forceps, for Erbe, 4 m	01	Z120109	04250350100110	4250350186085E
101-003	Cable, rubber return plate, for Erbe, 4.5 m	01	Z120109	04250350100127	4250350186085E
101-040	Bipolar cable, BOWA forceps, for Erbe, 4 m	01	Z120109	04250350100134	4250350186085E
101-045	Bipolar cable, U.S. forceps, for Erbe, 4 m	01	Z120109	04250350100141	4250350186085E
101-051	Monopolar cable, 4 mm socket, for Erbe, 4.5 m	01	Z120109	04250350100158	4250350186085E
101-060	Monopolar cable, arthroscopy and LAP electrode, for Erbe, 4.5 m	01	Z120109	04250350100165	4250350186085E
101-140	Bipolar cable, BOWA forceps, COMFORT, 4.5 m	01	Z120109	04250350108475	4250350186085E
101-145	Monopolar cable, ErgoLAP, for Erbe, 4.5 m	01	Z120109	04250350100172	4250350186085E
101-150	Cable, single-use return plate, for ALSA, Eschmann, 4.5 m	01	Z120109	04250350100189	4250350186085E
101-245	Cable, ErgoLAP BIPOLAR, for Erbe, 4.5 m	01	Z120109	04250350100196	4250350186085E
101-345	Bipolar cable, Karl Storz Robi, for Erbe, 4.5 m	01	Z120109	04250350112854	4250350186085E
101-445	Bipolar cable, Aesculap forceps, for Erbe, 4.5 m	01	Z120109	04250350112885	4250350186085E
102-045	Monopolar cable, electrode handle, for Erbe, 4.5 m	01	Z120109	04250350112915	4250350186085E
103-045	Monopolar cable, electrode handle, for 3-pin, 4.5 m	01	Z120109	04250350112922	4250350186085E
106-045	Monopolar cable, 2 mm socket, for Erbe, 4.5 m	01	Z120109	04250350100226	4250350186085E
106-145	Monopolar cable, resectoscope Wolf/Storz, COMFORT, 4.5 m	01	Z120109	04250350108420	4250350186085E
106-245	Monopolar cable, Storz resectoscope, COMFORT, 4.5 m	01	Z120109	04250350108413	4250350186085E
106-345	Monopolar cable, resectoscope Olympus, COMFORT, 4.5 m	01	Z120109	04250350108437	4250350186085E
111-000	Adapter monopolar, 3-pin instrument, for Erbe	01	Z120109	04250350100240	4250350186085E
111-001	Adapter monopolar, 2 - 4 mm instrument, for Erbe, footswitched	03	Z120109	04250350100257	4250350186085E
131-045	Monopolar cable, endoscopy 2.8 mm socket, for Erbe, 4.5 m	03	Z120109	04250350103739	4250350186085E
131-145	Monopolar cable, endoscopy 2.8 mm socket, COMFORT, 4.5 m	03	Z120109	04250350108468	4250350186085E
132-045	Monopolar cable, endoscopy 4 mm socket, for Erbe, 4.5 m	01	Z120109	04250350103753	4250350186085E
222-000	Adapter monopolar, 3-pin, for Martin	01	Z120109	04250350100394	4250350186085E
270-145	Cable, ErgoLAP MONOPOLAR, for Martin, 4.5 m	01	Z120109	04250350100431	4250350186085E
280-031	Monopolar cable, U.K., for 4 mm, 4.5 m	01	Z120109	04250350100448	4250350186085E
280-035	Monopolar cable, arthroscopy and LAP electrode, for 4 mm, 4.5 m	01	Z120109	04250350100455	4250350186085E
280-045	Monopolar cable, 4 mm socket, for 3-pin, 4.5 m	01	Z120109	04250350112953	4250350186085E
280-050	Monopolar cable, 4 mm socket, for 4 mm, 4.5 m	01	Z120109	04250350100462	4250350186085E
285-050	Monopolar cable, for Martin handles, 4.5 m	01	Z120109	04250350100479	4250350186085E
287-040	Bipolar cable, BOWA forceps, for Martin, 4.5 m	01	Z120109	04250350100486	4250350186085E
287-045	Bipolar cable, U.S. forceps, for Martin, 4.5 m	01	Z120109	04250350100493	4250350186085E
287-050	Bipolar cable, E.U. forceps, for Martin, 4.5 m	01	Z120109	04250350100509	4250350186085E
287-245	Cable, ErgoLAP BIPOLAR, for Martin, 4.5 m	01	Z120109	04250350100516	4250350186085E
294-050	Cable, single-use return plate, for Erbe, 4.5 m	01	Z120109	04250350100523	4250350186085E
295-050	Cable, rubber return plate, for Martin, 4.5 m	01	Z120109	04250350100530	4250350186085E
331-045	Monopolar cable, endoscopy 2.8 mm, for 8 mm Bovie, 4.5 m	01	Z120109	04250350103760	4250350186085E
332-045	Monopolar cable, endoscopy 4 mm socket, for 8 mm Bovie, 4.5 m	01	Z120109	04250350103777	4250350186085E
333-001	Adapter monopolar, 2 - 4 mm instrument, for 8 mm Bovie	01	Z120109	04250350100578	4250350186085E
340-000	Adapter bipolar, 2-pin 28 mm, for Erbe	01	Z120109	04250350100608	4250350186085E
350-245	Cable, ErgoLAP BIPOLAR, for 2-pin 22 mm, 4.5 m	01	Z120109	04250350100646	4250350186085E
351-040	Bipolar cable, BOWA forceps, for 2-pin 28 mm, 4.5 m	01	Z120109	04250350100653	4250350186085E
351-045	Bipolar cable, U.S. forceps, for 2-pin 28 mm, 4.5 m	01	Z120109	04250350100660	4250350186085E
351-051	Bipolar cable, E.U. forceps, for 2-pin 28 mm, 4.5 m	01	Z120109	04250350100677	4250350186085E
351-245	Cable, ErgoLAP BIPOLAR, for 2-pin 28 mm, 4.5 m	01	Z120109	04250350100684	4250350186085E
351-345	Cable, ErgoLAP BIPOLAR, COMFORT, 4.5 m	01	Z120109	04250350108499	4250350186085E
351-445	Bipolar cable, Aesculap forceps, for 2-pin 28 mm, 4.5 m	01	Z120109	04250350112892	4250350186085E

Article List class I

REF	Product description	PG	CND	UDI	Basic UDI-DI
351-545	Bipolar cable, Karl Storz Robi, for 2-pin 28 mm, 4.5 m	01	Z120109	04250350112861	4250350186085E
352-145	Bipolar cable, Storz resectoscope, COMFORT, 4.5 m	01	Z120109	04250350107737	4250350186085E
352-245	Bipolar cable, Storz laparoscopy, COMFORT, 4.5 m	01	Z120109	04250350112014	4250350186085E
353-040	Bipolar cable, BOWA forceps, for 2-pin 22 mm, 4.5 m	01	Z120109	04250350103999	4250350186085E
353-045	Bipolar cable, U.S. forceps, for 2-pin 22 mm, 4.5 m	01	Z120109	04250350104002	4250350186085E
353-050	Bipolar cable, E.U. forceps, for 2-pin 22 mm, 4.5 m	01	Z120109	04250350103951	4250350186085E
354-145	Bipolar cable, Wolf resectoscope, COMFORT, 4.5 m	01	Z120109	04250350107713	4250350186085E
355-030	Bipolar cable, E.U. forceps, for Valleylab, 3 m	01	Z120109	04250350100738	4250350186085E
355-031	Bipolar cable, BOWA forceps, for Valleylab, 3 m	01	Z120109	04250350100745	4250350186085E
355-145	Bipolar cable, Olympus resectoscope, COMFORT, 4.5 m	01	Z120109	04250350107720	4250350186085E
360-050	Monopolar cable, 4 mm socket, for 8 mm Bovie, 4.5 m	01	Z120109	04250350100790	4250350186085E
360-145	Cable, ErgoLAP MONOPOLAR, for 8 mm Bovie, 4.5 m	01	Z120109	04250350100806	4250350186085E
360-245	Cable, ErgoLAP MONOPOLAR, COMFORT, 4.5 m	01	Z120109	04250350108482	4250350186085E
365-030	Monopolar cable, U.K., for 8 mm Bovie, 4.5 m	01	Z120109	04250350100813	4250350186085E
370-050	Monopolar cable, arthroscopy and LAP electrode, for 8 mm, 4.5 m	01	Z120109	04250350100820	4250350186085E
375-045	Monopolar cable, 2 mm socket, for 8 mm Bovie, 4.5 m	01	Z120109	04250350100837	4250350186085E
378-045	Cable, BiZZER / TissueSeal, 4.5 m	01	Z120109	04250350100844	4250350186085E
378-145	Cable, BiZZER, for Erbe, 4.5 m	01	Z120109	04250350108543	4250350186085E
378-245	Cable, BiZZER, for Martin, 4.5 m	01	Z120109	04250350108550	4250350186085E
378-345	Bipolar cable, Karl Storz Robi, for Martin, 4.5 m	01	Z120109	04250350112878	4250350186085E
378-445	Bipolar cable, Aesculap forceps, for Martin, 4.5 m	01	Z120109	04250350112908	4250350186085E
380-050	Cable, single-use return plate, international, 4.5 m	01	Z120109	04250350100851	4250350186085E
380-145	Y-cable, Ultravision, single-use return plate, international, 4.5 m	01	Z120109	04250350112939	4250350186085E
380-245	Y-cable, Ultravision, single-use return plate, for Erbe, 4.5 m	01	Z120109	04250350112946	4250350186085E
385-050	Cable, rubber return plate, international, 4.5 m	01	Z120109	04250350100868	4250350186085E
386-050	Cable, single-use return plate, international (NON-REM), 4.5 m	01	Z120109	04250350100875	4250350186085E
405-045	Monopolar cable, 2 mm socket, for 4 mm, 4.5 m	01	Z120109	04250350100899	4250350186085E
431-045	Monopolar cable, endoscopy, 2.8 mm socket, for 4 mm, 4.5 m	01	Z120109	04250350103722	4250350186085E
432-045	Monopolar cable, endoscopy, 4 mm socket, for 4 mm, 4.5 m	01	Z120109	04250350103746	4250350186085E
480-145	Cable, ErgoLAP MONOPOLAR, for 4 mm, 4.5 m	01	Z120109	04250350100905	4250350186085E
901-210	Adapter bipolar, Erbe, for BOWA ARC	01	Z120109	04250350103265	4250350186085E
901-220	Adapter bipolar, Martin, for BOWA ARC	01	Z120109	04250350103272	4250350186085E
901-250	Adapter monopolar, Erbe, for BOWA ARC	01	Z120109	04250350103296	4250350186085E
901-270	Adapter monopolar, Martin, for BOWA ARC	01	Z120109	04250350103302	4250350186085E