

## 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:

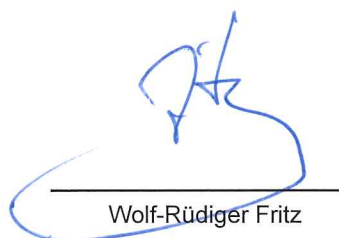
**Regulation (EU) 2017/745 relating to medical devices,**

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

Gomaringen, 2021-07-22

Head of Quality Management /  
Regulatory Affairs



Wolf-Rüdiger Fritz

**Article list for DoC  
class I**

REF	Product description	PG	CND	UDI	Basic UDI-DI
<b>K020480</b>	<b>ARGON GAS SURGICAL DEVICES - ACCESSORIES</b>		<b>K020480</b>		<b>4250350186107</b>
Intended Purpose	Electrosurgical equipment for cutting and coagulation of tissue				
932-146	Cable for flexible Argon probe COMFORT, 2.5 m	10-2	K020480	4250350108345	4250350186107
932-910	Rinsing adapter for flexible Argon probes (5 pcs.)	10-2	K020480	4250350104200	4250350186107
<b>L180402</b>	<b>FORCEPS, ELECTROSURGICAL ENDOTHERAPY, REUSABLE</b>		<b>L180402</b>		<b>4250350186114</b>
Intended Purpose	Electrosurgical equipment for cutting and coagulation of tissue				
723-050	ERGO 315R, cleaning adapter Set	16-3	L180402	4250350110225	4250350186114
723-051	ERGO 315R, cleaning adapter handle/jaw	16-3	L180402	4250350110232	4250350186114
723-052	ERGO 315R, cleaning adapter push rod	16-3	L180402	4250350110249	4250350186114
773-982	ERGO 315R, reprocessing basket	16-3	L180402	4250350110256	4250350186114
773-983	ERGO 315R, lid for basket	16-3	L180402	4250350110263	4250350186114
773-984	LOTUS reprocessing basket with lid 550x150x77 mm	16-3	L180402	4250350112038	4250350186114
773-985	LOTUS reprocessing basket with lid 640x150x77 mm	16-3	L180402	4250350112045	4250350186114
773-986	LOTUS reprocessing basket with lid for Series 5; 650x150x68 mm	16-3	L180402	4250350112687	4250350186114
773-987	LOTUS reprocessing basket with lid for Series 5; 730x150x68 mm	16-3	L180402	4250350112694	4250350186114
<b>Z120109</b>	<b>ELECTROSURGERY INSTRUMENTS</b>		<b>Z120109</b>		<b>4250350186121</b>
Intended Purpose	Electrosurgical equipment for cutting and coagulation of tissue				
101-000	Bipolar cable, E.U. forceps, for Erbe, 4 m	01	Z120109	4250350100110	4250350186121
101-003	Cable, rubber return plate, for Erbe, 4.5 m	01	Z120109	4250350100127	4250350186121
101-040	Bipolar cable, BOWA forceps, for Erbe, 4 m	01	Z120109	4250350100134	4250350186121
101-045	Bipolar cable, U.S. forceps, for Erbe, 4 m	01	Z120109	4250350100141	4250350186121
101-051	Monopolar cable, 4 mm socket, for Erbe, 4.5 m	01	Z120109	4250350100158	4250350186121
101-060	Monopolar cable, arthroscopy and LAP electrode, for Erbe, 4.5 m	01	Z120109	4250350100165	4250350186121
101-140	Bipolar cable, BOWA forceps, COMFORT, 4.5 m	01	Z120109	4250350108475	4250350186121
101-145	Monopolar cable, ErgoLAP, for Erbe, 4.5 m	01	Z120109	4250350100141	4250350186121
101-150	Cable, single-use return plate, for ALSA, Eschmann, 4.5 m	01	Z120109	4250350100189	4250350186121
101-245	Cable, ErgoLAP BIPOLAR, for Erbe, 4.5 m	01	Z120109	4250350100196	4250350186121
106-045	Monopolar cable, 2 mm socket, for Erbe, 4.5 m	01	Z120109	4250350100226	4250350186121
106-145	Monopolar cable, resectoscope Wolf/Storz, COMFORT, 4.5 m	01	Z120109	4250350108420	4250350186121
106-245	Monopolar cable, Storz resectoscope, COMFORT, 4.5 m	01	Z120109	4250350108413	4250350186121
106-345	Monopolar cable, resectoscope Olympus, COMFORT, 4.5 m	01	Z120109	4250350108437	4250350186121
111-000	Adapter monopolar, 3-pin instrument, for Erbe	01	Z120109	4250350100240	4250350186121
111-001	Adapter monopolar, 2 - 4 mm instrument, for Erbe, footswitched	01	Z120109	4250350100257	4250350186121
131-045	Monopolar cable, endoscopy 2.8 mm socket, for Erbe, 4.5 m	01	Z120109	4250350103739	4250350186121
131-145	Monopolar cable, endoscopy 2.8 mm socket, COMFORT, 4.5 m	01	Z120109	4250350108468	4250350186121
132-045	Monopolar cable, endoscopy 4 mm socket, for Erbe, 4.5 m	01	Z120109	4250350103753	4250350186121
193-008	Rubber return plate, adults, 250 x 150 mm, for Erbe	03	Z120109	4250350100271	4250350186121
193-016	Rubber return plate, children, 150 x 80 mm, for Erbe	03	Z120109	4250350100288	4250350186121
194-075	Rubber band with fixation button, 75 cm	03	Z120109	4250350110782	4250350186121
222-000	Adapter monopolar, 3-pin, for Martin	01	Z120109	4250350100394	4250350186121
232-003	Rubber return plate, children, 150 x 80 mm, international	03	Z120109	4250350100417	4250350186121
242-003	Rubber return plate, adults, 250 x 150 mm, international	03	Z120109	4250350100424	4250350186121
270-145	Cable, ErgoLAP MONOPOLAR, for Martin, 4.5 m	01	Z120109	4250350100431	4250350186121
280-031	Monopolar cable, U.K., for 4 mm, 4.5 m	01	Z120109	4250350100448	4250350186121
280-035	Monopolar cable, arthroscopy and LAP electrode, for 4 mm, 4.5 m	01	Z120109	4250350100455	4250350186121
280-050	Monopolar cable, 4 mm socket, for 4 mm, 4.5 m	01	Z120109	4250350100462	4250350186121
285-050	Monopolar cable, for Martin handles, 4.5 m	01	Z120109	4250350100479	4250350186121
287-040	Bipolar cable, BOWA forceps, for Martin, 4.5 m	01	Z120109	4250350100486	4250350186121
287-045	Bipolar cable, U.S. forceps, for Martin, 4.5 m	01	Z120109	4250350100493	4250350186121
287-050	Bipolar cable, E.U. forceps, for Martin, 4.5 m	01	Z120109	4250350100509	4250350186121
287-245	Cable, ErgoLAP BIPOLAR, for Martin, 4.5 m	01	Z120109	4250350100516	4250350186121
294-050	Cable, single-use return plate, for Erbe, 4.5 m	01	Z120109	4250350100523	4250350186121
295-050	Cable, rubber return plate, for Martin, 4.5 m	01	Z120109	4250350100530	4250350186121
331-045	Monopolar cable, endoscopy 2.8 mm, for 8 mm Bovie, 4.5 m	01	Z120109	4250350103760	4250350186121
332-045	Monopolar cable, endoscopy 4 mm socket, for 8 mm Bovie, 4.5 m	01	Z120109	4250350103777	4250350186121
333-001	Adapter monopolar, 2 - 4 mm instrument, for 8 mm Bovie	01	Z120109	4250350100578	4250350186121

**Article list for DoC  
class I**

REF	Product description	PG	CND	UDI	Basic UDI-DI
340-000	Adapter bipolar, 2-pin 28 mm, for Erbe	01	Z120109	4250350100608	4250350186121
350-245	Cable, ErgoLAP BIPOLAR, for 2-pin 22 mm, 4.5 m	01	Z120109	4250350100646	4250350186121
351-040	Bipolar cable, BOWA forceps, for 2-pin 28 mm, 4.5 m	01	Z120109	4250350100653	4250350186121
351-045	Bipolar cable, U.S. forceps, for 2-pin 28 mm, 4.5 m	01	Z120109	4250350100660	4250350186121
351-051	Bipolar cable, E.U. forceps, for 2-pin 28 mm, 4.5 m	01	Z120109	4250350100677	4250350186121
351-245	Cable, ErgoLAP BIPOLAR, for 2-pin 28 mm, 4.5 m	01	Z120109	4250350100684	4250350186121
351-345	Cable, ErgoLAP BIPOLAR, COMFORT, 4.5 m	01	Z120109	4250350100684	4250350186121
352-145	Bipolar cable, Storz resectoscope, COMFORT, 4.5 m	01	Z120109	4250350107737	4250350186121
352-245	Bipolar cable, Storz laparoscopy, COMFORT, 4.5 m	01	Z120109	4250350112014	4250350186121
353-040	Bipolar cable, BOWA forceps, for 2-pin 22 mm, 4.5 m	01	Z120109	4250350103999	4250350186121
353-045	Bipolar cable, U.S. forceps, for 2-pin 22 mm, 4.5 m	01	Z120109	4250350104002	4250350186121
353-050	Bipolar cable, E.U. forceps, for 2-pin 22 mm, 4.5 m	01	Z120109	4250350103951	4250350186121
354-145	Bipolar cable, Wolf resectoscope, COMFORT, 4.5 m	01	Z120109	4250350107713	4250350186121
355-030	Bipolar cable, E.U. forceps, for Valleylab, 3 m	01	Z120109	4250350100738	4250350186121
355-031	Bipolar cable, BOWA forceps, for Valleylab, 3 m	01	Z120109	4250350100745	4250350186121
355-145	Bipolar cable, Olympus resectoscope, COMFORT, 4.5 m	01	Z120109	4250350107720	4250350186121
360-050	Monopolar cable, 4 mm socket, for 8 mm Bovie, 4.5 m	01	Z120109	4250350100790	4250350186121
360-145	Cable, ErgoLAP MONOPOLAR, for 8 mm Bovie, 4.5 m	01	Z120109	4250350100806	4250350186121
360-245	Cable, ErgoLAP MONOPOLAR, COMFORT, 4.5 m	01	Z120109	4250350108482	4250350186121
365-030	Monopolar cable, U.K., for 8 mm Bovie, 4.5 m	01	Z120109	4250350100813	4250350186121
370-050	Monopolar cable, arthroscopy and LAP electrode, for 8 mm, 4.5 m	01	Z120109	4250350100820	4250350186121
375-045	Monopolar cable, 2 mm socket, for 8 mm Bovie, 4.5 m	01	Z120109	4250350100837	4250350186121
378-045	Cable, BiZZER / TissueSeal, 4.5 m	01	Z120109	4250350100844	4250350186121
378-145	Cable, BiZZER, for Erbe, 4.5 m	01	Z120109	4250350108543	4250350186121
378-245	Cable, BiZZER, for Martin, 4.5 m	01	Z120109	4250350108550	4250350186121
380-050	Cable, single-use return plate, international, 4.5 m	01	Z120109	4250350100851	4250350186121
385-050	Cable, rubber return plate, international, 4.5 m	01	Z120109	4250350100868	4250350186121
386-050	Cable, single-use return plate, international (NON-REM), 4.5 m	01	Z120109	4250350100875	4250350186121
405-045	Monopolar cable, 2 mm socket, for 4 mm, 4.5 m	01	Z120109	4250350100899	4250350186121
431-045	Monopolar cable, endoscopy, 2.8 mm socket, for 4 mm, 4.5 m	01	Z120109	4250350103722	4250350186121
432-045	Monopolar cable, endoscopy, 4 mm socket, for 4 mm, 4.5 m	01	Z120109	4250350103746	4250350186121
480-145	Cable, ErgoLAP MONOPOLAR, for 4 mm, 4.5 m	01	Z120109	4250350100905	4250350186121
901-210	Adapter bipolar, Erbe, for BOWA ARC	01	Z120109	4250350103265	4250350186121
901-220	Adapter bipolar, Martin, for BOWA ARC	01	Z120109	4250350103272	4250350186121
901-250	Adapter monopolar, Erbe, for BOWA ARC	01	Z120109	4250350103296	4250350186121
901-270	Adapter monopolar, Martin, for BOWA ARC	01	Z120109	4250350103302	4250350186121