Declaration of Conformity (DoC)

We

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

Digitally signed by Ceaicovschi Tudor
Date: 2023.06.11 16:12:41 EEST
Reason: MoldSign Signature
Location: Moldova

declare in sole responsibility that the medical device(s)

Basic UDI-DI UDI	4250350186084 4250350105566
CND	**Z120109** ELECTROSURGERY INSTRUMENTS
Product code / REF	**900-400**
Device name	**ARC 400**
Product group(s)	PG14-3
Intended purpose	Electrosurgical equipment for cutting and coagulation of tissue

to which this declaration relates is classified as **risk class IIb**, 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

and that the following Notified Body performed the intervention as described and issued the certificate

Notified Body name	TUEV-SUED Product Service GmbH
Address	Ridlerstr. 65, 80339 München
Country	Germany
Identification number	0123
Description of intervention	Conformity assessment to **Annex IX**
Number certificate	**G10 016316 0022 Rev. 00**
Date certificate	2020-08-10
Duration and conditions of validity of the examination certificate	2025-08-09

Gomaringen, 2022-10-18

Head of Quality Management /
Regulatory Affairs

Wolf-Rüdiger Fritz

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

Telefon +49 (0) 7072-6002-0
Telefax +49 (0) 7072-6002-33
info@bowa-medical.de | bowa-medical.de

Registergericht: Stuttgart HRA 381478
Geschäftsführer: Jens Kröber
Martin Heinrich