

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 UDI	4250350186085E 4250350105566
CND	Z120109 ELECTROSURGERY INSTRUMENTS
Product code / REF	900-400
Device name	Electrosurgical unit 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 ISO 20417

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, 2023-05-12

Head of Quality Management /
Regulatory Affairs



Wolf-Rüdiger Fritz