

## Declaration of Conformity (DoC)

We

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

declare in sole responsibility that the medical device(s)

Basic UDI-DI UDI	4250350186084 4250350108574
CND	<b>Z120109</b> ELECTROSURGERY INSTRUMENTS
Product code / REF	<b>900-351</b>
Device name	<b>ARC 350</b>
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 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 <b>Annex IX</b>
Number certificate	<b>G10 016316 0022 Rev. 00</b>
Date certificate	2020-08-10
Duration and conditions of validity of the examination certificate	2025-08-09

Gomaringen, 2020-08-10

Head of Quality Management /  
Regulatory Affairs



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Wolf-Rüdiger Fritz