

EC DECLARATION OF CONFORMITY

No.: 900-400

valid to 2022-03-08

Manufacturer:

Street, House No.:
Postal Code, City:
State/Federal State:

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

This declaration of conformity is issued under our sole responsibility (manufacturer).

Object of declaration (identification of product allowing traceability):

GMDN code and name: P 11490 – Electrosurgical diathermy system generator
UMDNS code and name: 11-490 - HF-Chirurgiegerät
Category code and category: 04 Electrical and mechanical medical devices
Classification rule and class: Rule 9 - Class IIb

Product name:

REF- /Order No.:

Electrosurgical unit ARC 400
REF 900-400 / M098-900400
as from SW-Release V 2.1.x

The object of the declaration described above is in conformity with the relevant Community harmonisation legislation:

Directive(s)_Date of last revision:

CD 93/42/EEC (MD)_2007-09-21
CD 2011/65/EU (RoHS)_2011-06-08

Conformity assessment procedure:

Annex II (Full Quality Assurance System) of CD 93/42/EEC (MD)

Relevant harmonised standards:

DIN EN 60601-1
DIN EN 60601-1-2
DIN EN 60601-2-2
DIN EN 1041
DIN EN ISO 14971

The notified body **TUEV SUED Product Service GmbH**, identification number **0123**, performed and issued the certificate(s):

Title of Certificate:

EC Certificate Full Quality Assurance System

Certificate No., issued on:

G1 17 02 16316 019, 2017-03-08, valid to 2022-03-08

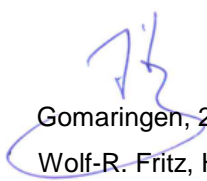
Certificate EN-13485:2012 + AC:2012 No.:

Q1N 16 02 16316 018, 2016-03-03, valid to 2019-02-28

Place, date of issue:

Gomaringen, 2017-03-08

Name, function and signature:


Wolf-R. Fritz, Head of Quality Management