

File No.: ZMN-YF-AV5-01-001-008

Version: B

EC Declaration of Conformity

Manufacturer: Guilin Woodpecker Medical Instrument Co., Ltd

Information Industrial Park, Guilin National High-Tech Zone, 541004 Guilin, Guangxi, PEOPLE'S

REPUBLIC OF CHINA

SRN of Manufacturer:

CN-MF-000009139

European Representative:

MedNet EC-REP GmbH

Borkstrasse 10, 48163 Muenster, Germany

SRN of European Representative:

DE-AR-000000002

Product Name:

Dental Air Polishing Handpiece

Models:

AP-H, AP-H Plus, AP-Mini, AP-Mini+, AP-P,

AP-P Pro

Classification:

II a / Rule 9 (MDR, Annex VIII)

CND Code:

Z121101

Basic UDI-DI:

694484360059KP

Conformity Assessment Route:

Annex IX Chapters I and III of (EU)2017/745, MDR

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Regulations and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the Declaration of Conformity.

General applicable regulations: Medical Device Regulation, (EU)2017/745.

Notified Body:

TÜV SÜD Product Service GmbH

Ridlerstraße 65 80339 Munich Country: Germany

NB Identification number:

C € 0123

(EC) Certificate(s):

G10 079900 0005 Rev. 00

Issue date:

2022-01-11

Expire date of the Certificate:

2027-01-10

Position: PRRC

Location: G

Signature: