File No.: ZMN-YF-DOC-MDR2
Version: A

EC Declaration of Conformity

Manufacturer:	**Guilin Woodpecker Medical Instrument Co.,Ltd.** Information Industrial Park, Guilin National High-Tech Zone, Guilin, 541004 Guangxi, P.R. 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、AP-P Plus
Classification:	II a / Rule 9 (MDR Annex VIII)
EMDN Code:	Z121101
Basic UDI-DI:	694484360059KP
Conformity Assessment Route:	Annex IX Chapters I and III of (EU)2017/745, MDR
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Country: Germany NB Identification number: 0123
CE Certificate No.:	G10 079900 0005 Rev. 00
Effective date:	2022-01-11
Expire date :	2027-01-10

File No.: ZMN-YF-DOC-MDR2
Version: A

Product Name:	Dental Electric Motor
Models:	MT2、 MT3、 ES5、ES5+、ES5 Pro、ES5 Pro+、M2、M2 Pro、M3
Classification:	II a / Rule 9 (MDR Annex VIII)
EMDN Code:	Z121101
Basic UDI-DI:	694484360517KY
Conformity Assessment Route:	Annex IX Chapters I and III of (EU)2017/745, MDR
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Country: Germany NB Identification number: 0123
CE Certificate No.:	G10 079900 0005 Rev. 00
Effective date:	2022-01-11
Expire date :	2027-01-10

Product Name:	Dental Low Speed Handpiece
Models:	WJ-45/WJ-45L/WJ-45T/WJ-45TL/WJ-SG45/WJ-SG45L/WJ-SG45T/WJ-SG45TL/WJ-SG45C/WJ-SG45CL/WJ-SG15/WJ-SG15L
Classification:	II a / Rule 9 (MDR Annex VIII)
EMDN Code:	Z121101
Basic UDI-DI:	694484360047KG
Conformity Assessment Route:	Annex IX Chapters I and III of (EU)2017/745, MDR
Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 Munich Country: Germany NB Identification number: 0123
CE Certificate No.:	G10 079900 0005 Rev. 00
Effective date:	2022-01-11
Expire date :	2027-01-10

File No.: ZMN-YF-DOC-MDR2
Version: A

Product Name:	Digital Intraoral X-ray Sensor
Models:	i-Sensor H1, i-Sensor H2， i-Sensor H1.5
Classification:	II a / Rule 17, (MDR, Annex VIII)
EMDN Code:	Z1103040102
Basic UDI-DI:	694484369018M8
Conformity Assessment Route:	Annex IX Chapters I and III of (EU)2017/745, MDR
Notified Body:	DEKRA Certification B.V. Meander 1051 / 6825 MJ Arnhem / P.O. Box 5185 / 6802 ED Arnhem Country : Netherlands NB Identification number: 0344
CE Certificate No.:	6092943CE01
Effective date:	2022-12-02
Expire date :	2027-12-01

We, the manufacturer, herewith declare under our sole responsibility that the above mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR) and other relevant Union legislation that provides for the issuing of an EU declaration of conformity. All supporting documentations are retained under the premises of the manufacturer.

Name: Ning Jiakang

Position: PRRC

Location: Guilin, China

陈燕 2024.5.18
Complied by:

王祝涛 2024.5.18
Reviewed by:

Signature: 2024.5.18