

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 C Iib GmbH
 Borkstrasse 10, 48163 Muenster, Germany

SRN of European Representative: DE-AR-000011194

Product Name:	Ultrasonic Scalers
Models:	U600, U600 LED, D600, D600 LED, D3, D3 LED, UDS-K, UDS-K LED, D5, D5 LED, UDS-A, UDS-A LED, UDS-P, UDS-P LED, D6, D6 LED, D7, D7 LED, UDS-E, UDS-E LED, UDS-L, UDS-L LED, U6, U6 LED, S6, S6 LED, PT 8, UDS-T LED , D8 LED
Classification:	II a / Rule 9 (MDR Annex VIII)
EMDN Code:	Z121101
Basic UDI-DI:	694484360006K2
Conformity Assessment Route:	Annex IX Chapters I and III of (EU)2017/745, MDR
Notified Body:	TÜV Rheinland LGA Products GmbH Tillystraße 2 · 90431 Nürnberg Country: Germany NB Identification number: 0197
CE Certificate No.:	HZ 2158053-1
Effective date:	2023-07-31
Expire date :	2028-07-30

File No.: ZMN-YF-DOC-MDR1
 Version: A

Product Name:	Ultrasonic Scalers
Models:	UDS-N2, UDS-N2 LED, V2, V2 LED, UDS-N3, UDS-N3 LED, V3, V3 LED, UDS-N6, UDS-N6 LED, V6, V6 LED
Classification:	II a / Rule 9 (MDR Annex VIII)
EMDN Code:	Z121101
Basic UDI-DI:	694484360073KH
Conformity Assessment Route:	Annex IX Chapters I and III of (EU)2017/745, MDR
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Product Name:	Dental Scaler and Air Polisher
Models:	PT-A, PT-B, AP-A, AP-B, PT-E
Classification:	II a / Rule 9 (MDR Annex VIII)
EMDN Code:	Z121101
Basic UDI-DI:	694484360008K6
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Product Name:	Ultrasonic Periodontal Treatment Device
Models:	PT-3, PT-5
Classification:	II a / Rule 9 (MDR Annex VIII)
EMDN Code:	Z121101
Basic UDI-DI:	694484360006K2
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Product Name:	Endo Motor
Models:	Ai-Motor, MotoPex,Endo Matic, Endo Smart Pro, Rooter X3000, BAE380R, CanalPro X-Move, Endo Space, Smart A, 812MT, E-COM, E-Com+,Endo Smart, Endo Smart+, Endo Pace, Endo Free, i-Polish, K-Po, Endo Radar Plus, Endo Radar Pro, Endo Radar
Classification:	II a / Rule 9 (MDR Annex VIII)
EMDN Code:	Z121101
Basic UDI-DI:	694484360018K9
Conformity Assessment Route:	Annex IX Chapters I and III of (EU)2017/745, MDR
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Product Name:	Apex Locator
Models:	Woodpex I, Dpex I, Woodpex III, Dpex III, Woodpex X, DPEX X, Woodpex V, DPEX V, Ai-Pex, Minipex, Smart-Pex
Classification:	II a / Rule 9 (MDR Annex VIII)
EMDN Code:	Z121101
Basic UDI-DI:	694484360080KE
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Product Name:	Piezo Bone Surgery
Models:	Ai-surgery, Surgic smart, Surgery-X, Surgery-X LED, Surgic Touch, Surgic Touch LED, US-II, US-II LED, DS-II, DS-II LED, ULTRASURGERY, ULTRASURGERY LED, Surgical Master, Surgic Star, Surgical Master SE, Surgic Star SE
Classification:	II a / Rule 9 (MDR Annex VIII)
EMDN Code:	Z121101
Basic UDI-DI:	694484360027KA
Conformity Assessment Route:	Annex IX Chapters I and III of (EU)2017/745, MDR
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Product Name:	Ultrasonic Endo Activator Device
Models:	Endo 1, Endo 3
Classification:	II a / Rule 9 (MDR Annex VIII)
EMDN Code:	Z121101
Basic UDI-DI:	694484360033K5
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Product Name:	Gutta Percha Obturation Device
Models:	Fi-P, Fi-G, Fi-E
Classification:	II a / Rule 9 (MDR Annex VIII)
EMDN Code:	Z121101
Basic UDI-DI:	694484360037KD
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Product Name:	Dental Handpieces
Models:	CA161, CA161-RR, CA361-H, CA161-20CA001-G,CA221,CA1471
Classification:	II a / Rule 9 (MDR Annex VIII)
EMDN Code:	Z121101
Basic UDI-DI:	694484360043K8
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Product Name:	Handpieces of Piezo Bone Surgery
Models:	HB-1, HB-1 LED, HB-2, HB-2 LED
Classification:	II a / Rule 9 (MDR Annex VIII)
EMDN Code:	Z121101
Basic UDI-DI:	694484360048KJ
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Product Name:	Handpieces of Ultrasonic Scaler
Models:	HW-3H、HD-7H、HW-5L、HD-7L, HW-6、HD-8H、HW-6L、HD-8L、YZ-1L
Classification:	II a / Rule 9 (MDR Annex VIII)
EMDN Code:	Z121101
Basic UDI-DI:	694484360053KB
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Product Name:	Handpieces of Dental Scaler and Air Polisher
Models:	YZ-2L,YD-2L
Classification:	II a / Rule 9 (MDR Annex VIII)
EMDN Code:	Z121101
Basic UDI-DI:	694484360053KB
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Product Name:	Air Polisher Headpiece
Models:	AP-1, AP-2
Classification:	II a / Rule 9 (MDR Annex VIII)
EMDN Code:	Z121101
Basic UDI-DI:	694484360049KL
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Product Name:	Dental Handpieces
Models:	WP-1、WP-1L、WJ-15L、WJ-15、WJ-11、WJ-11L
Classification:	II a / Rule 9 (MDR Annex VIII)
EMDN Code:	Z121101
Basic UDI-DI:	694484360085KQ
Conformity Assessment Route:	Annex IX Chapters I and III of (EU)2017/745, MDR
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Product Name:	Dental Turbine Handpiece
Models:	HP33-M4,HP33-B2,HP33Q-M4,HP33F-M4,HP33FQ-M4, HP13-M4,HP13-B2,HL11-M4,HL11-B2,HP11-M4,HP11-B2, Ti33-NL,Ti33-N,Ti33-KL,Ti33-K,Ti33-M4, HPMini-NL, HPMini-N, HPMini-KL, HPMini-K, HPMini-M4, HPMini-B2, HP45SG-NL,HP45SG-N,HP45SG-KL,HP45SG-M4,HP45-NL, HP45-N,HP45-KL,HP45-K,HP33-NL,HP33-N,HP33-KL, HP33-K,HP22-NL,HP22-N,HP22-KL,HP22-K,HP22-M4, HP22-B2,Ti22-NL,HP11-NL,HP11-N,HP11-KL,HP11-K,Ti11-NL
Classification:	II a / Rule 9 (MDR Annex VIII)
EMDN Code:	Z121101
Basic UDI-DI:	694484360071KD
Conformity Assessment Route:	Annex IX Chapters I and III of (EU)2017/745, MDR
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Product Name:	Dental Implant Unit
Models:	Implant NX、Implant Smart、Implant Air、Implant Pilot、 Implanter LED、Implanter、Implant-X LED、Implant-X
Classification:	II a / Rule 9 (MDR Annex VIII)
EMDN Code:	Z121101
Basic UDI-DI:	694484360032K3
Conformity Assessment Route:	Annex IX Chapters I and III of (EU)2017/745, MDR
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Product Name:	Dental X-Ray Generator
Models:	Ai Ray, Mini Ray, Master Ray, Smart Ray
Classification:	II b / Rule 10, subclause 2 of MDR Annex VIII
EMDN Code:	Z110304
Basic UDI-DI:	694484360060K8
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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.



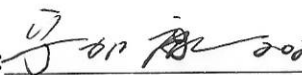
Name: Ning Jiakang

Position: PRRC

Location: Guilin, China

陳燕 2024.5.18
Complied by:

王设伟 2024.5.18
Reviewed by:

Signature:  2024.5.18

