EU Declaration of Conformity

TO REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Manufacturer:	Name: Guilin Refine Medical Instrument Co., Ltd. Address: No.8-3, Information Industrial Park, High-Tech Zone, Qixing District, 541004 Guilin, Guangxi, PEOPLE'S REPUBLIC OF CHINA SRN: CN-MF-000012204
European Representative:	Name: MedNet EC-REP C IIb GmbH Address: Borkstraße 10, 48163 Münster, Germany SRN: DE-AR-000011194
Product Name:	Ultrasonic Scaler
Model:	MaxPiezo1, DS1, MaxPiezo2, MaxPiezo2+, DS2, DS2+, MaxPiezo3, MaxPiezo3+, MaxPiezo5, MaxPiezo5+, MaxPiezo6, MaxPiezo6+, MaxPiezo7, MaxPiezo7+, DS3, DS3+, DS5, DS5+, DS6, DS6+, DS7, DS7+
GMDN Code:	39216
CND Code:	Z12119001
SRN:	CN-MF-000012204
Basic UDI-DI:	697156045USCTM
Device Photograph:	Please refer to section 1.7 Device Photograph in RF-MP3-T004 Device Description and Specification.
Intended Use:	The ultrasonic scaler is intended use in periodontology, for the removal of plaque and calculus, for the cleaning of tooth surfaces and root canals.
Risk Class:	Class II a
Classification Rule:	1st indent of Rule 9 in Chapter III of Annex VIII of the Regulation (EU) 2017/745
Conformity Assessment Route	Chapter I and III of Annex IX of the Regulation (EU) 2017/745
We herewith declare that the above-mentioned product(s) meet the Regulation (EU) 2017/745 of THE EUROPEAN PARLIAMENT AND OF THE COUNCIL and the transposition into national law. All supporting documentation is retained at the premises of the manufacturer. We, the manufacturer, are exclusively responsible for the DoC.	
Applied Standards:	EN ISO 13485:2016, MDR (EU) 2017/745, RoHS (Restriction of Hazardous Substances) 2011/65/EU, MEDDEV.2.7.1 Rev4, EN ISO 14971:2019, IEC 62304:2006+A1:2015, IEC 62366-1:2015, IEC

	60601-1-2:2014/A1:2020, IEC 60601-1:2005/A1:2012, IEC 80601-2-60:2019, EN ISO 18397:2016, EN ISO 9687:2015/A1:2018, EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 7405:2018, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2010, EN ISO 17664:2017, EN ISO 17665-1:2006, ISO/TS 17665-2:2009, IEC 62471:2006		
Notified Body:	TÜV SÜD Product Service GmbH Address: Ridlerstraße 65, 80339 MÜNCHEN, Germany Phone : +49 (89) 50084261 Fax : +49 (89) 50084230		
Identification Number:	0123		
(EC) Certificate(s):	G10 113957 0002 Rev.00	Valid until	2028-12-10
Start of CE-marking:	2023-12-11		
Place, Date of Issue:	Guilin, Guangxi 2023-12-12		
Signature:	Name: Yangwen Jiang Function: Management Representative		