

 桂林市锐锋医疗器械有限公司 Guilin Refine Medical Instrument CO.,LTD.	EU Declaration of Conformity	Document No.	RF-UST-T002
		Page	Page 1 of 3
	Ultrasonic Scaler Tip	Version	1.1

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

Manufacturer:	Guilin Refine Medical Instrument Co., Ltd. Address: No.8-3, Information Industrial Park, High-Tech Zone, Qixing District, Guilin, Guangxi, 541004, PEOPLE'S REPUBLIC OF CHINA
European Representative:	Name: MedNet EC-REP C IIb GmbH Address: Borkstraße 10, 48163 Münster, Germany SRN: DE-AR-000011194
Product Name:	Ultrasonic Scaler Tip
Model:	201, 202, 203, A1, A2, E0, E1, E10, E10D, E11, E11D, E12D, E14, E14D, E15, E15D, E2, E3, E3D, E4, E4D, E5, E5D, E6, E7, E8, E9, E60, E62, ED62, E93, E96, E98, ED0, ED1, ED10, ED10D, ED11, ED11D, ED12D, ED14, ED14D, ED15, ED15D, ED2, ED3, ED3D, ED4, ED4D, ED5, ED5D, ED6, ED7, ED8, ED9, EK8, ES0, ES1, ES10, ES11, ES14, ES15, ES2, ES3, ES4, ES5, ES8, ES9, E0T, E10DT, E10T, E11DT, E11T, E14DT, E14T, E15DT, E15T, E1T, E2T, E32D-S, E3DT, E3T, E4DT, E4T, E5DT, E5T, E8T, E9T, EA1, EA2, ED0T, ED10DT, ED10T, ED11DT, ED11T, ED14DT, ED14T, ED15DT, ED15T, ED1T, ED2T, ED3DT, ED3T, ED4DT, ED4T, ED5DT, ED5T, ED60, ED8T, ED9T, EK1, EK2, EK9, ES10DT, ES11DT, ES14DT, ES15DT, ES1T, ES2T, ES3DT, ES3T, ES4DT, ES4T, ES5DT, ES5T, ET20, ET25, G1, G10, G11, G12, G2, G20, G21, G28, G3, G30, G31, G32, G33, G4, G5, G6, G7, G8, G9, GC1, GC2, GD1, GD10, GD12, GD2, GD20, GD21, GD28, GD3, GD30, GD31, GD32, GD33, GD4, GD5, GD6, GD7, GD8, GD9, GK1, GK2, GK3, GK4, GK5, GK6, GK7, GS1, GS2, GS3, GS4, GS5, GS6, GS7, GS8, GS9, G10T, G1-S, G1T, G28T, G2T, G3T, G4T, G5T, G6T, G7T, G8T, G9T, GD10T, GD11, GD1T, GD28T, GD2T, GD3T, GD4T, GD5T, GD6T, GD7T, GD8T, GD9T, GK14, GK16, GK18, GK20, GK21, GK67, GKG1, GKG2, GKG4, GKP1, GS1T, GS20, GS21, GS2T, GS3T, GS4T, GS5T, GS6T, P1, P10, P11, P12, P14L, P14R, P18, P2, P20, P20L, P20R, P21L, P21R, P22L, P22R, P2L, P2LD, P2R, P2RD, P3, P3D, P4, P4D, P5, P6, P7, P8, PC1, PD1, PD10, PD11, PD12, PD14L, PD14R, PD18, PD2, PD20, PD20L, PD20R, PD21L, PD21R, PD22L, PD22R, PD2L, PD2LD, PD2R, PD2RD, PD3, PD3D, PD4, PD4D, PD5,

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		Page	Page 2 of 3
	Ultrasonic Scaler Tip	Version	1.1

	PD6, PD7, PD8, PS1, PS3, PS3D, PS4, PS4D, P10T, P11T, P12T, P14LT, P14RT, P18T, P1T, P2DT, P2LDT, P2LT, P2RDT, P2RT, P3-1, P33, P3DT, P3T, P42, P4DT, P4T, P51LT, P51RT, P53L, P53LT, P53R, P53RT, P50RT, P56T, P52T, P50LT, P59T, P90T, P5T, P67, P6T, P7T, P8T, P94, P95, P96L, P96R, PD12T, PD1T, PD2DT, PD2LDT, PD2LT, PD2RDT, PD2RT, PD3DT, PD3T, PD42, PD4DT, PD4T, PD67, PD90, PD90T, PD94, PD95, PD96L, PD96R, PP1, PPL, PPR, PS2, PS2L, PS2R, PS3DT, PS4DT, SB1, SB2, SB3, SBD1, SBD2, SBD3, SBDL, SBDT, SBL, SBR, SB4, SB5, SB6, SB7L, SB7R, SB1T, SB2T, SB3T, SBD1T, SBD4, SBD5, SBD6, SBD7L, SBD7R, SBLT, SBRT, SBS1, SBS2, SBS3, SBSL, SBSR, 2, 10P, 10X, 1-D5, 20A, 21A, 3#, 5A, 6A, 7A, A, A1T, A2T, BI23, C, H3-1, K1, K2, K3, QXP, S1, S2, S3, STIP1006
CND Code:	A010699
SRN:	CN-MF-000012204
Basic UDI-DI:	697156045USTUP
Device Photograph:	Please refer to section 1.8 Device photograph in RF-UST-T004 Device Description and Specification.
Intended Use:	The Ultrasonic Scaler Tip connected with the ultrasonic scaler are intended used to clean and shape the teeth surface, root canal.
Risk Class:	Class IIa
Classification Rule:	Rule 5 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, EN ISO 14971:2019, MEDDEV.2.7.1 Rev4, EN ISO 9687:2015/A1:2018, EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 18397:2016, EN ISO 7405:2018, EN ISO 10993-1:2020, EN ISO 10993-5:2009, ISO 10993-10:2021, EN ISO 10993-11:2018, ISO 10993-23:2021, RoHS 2011/65/EU , RoHS (EU) 2015/863 , REACH (EC) 1907/2006, ISO 11014-2009 , EN ISO 17664-1:2021, EN ISO 17665-1:2006, IEC 62366-1:2015+A1:2020, ISTA-2A, EN 62506:2013, EN ISO 6508-1:2016, EN ISO 9227:2017
Notified Body:	TÜV SÜD Product Service GmbH Address: Ridlerstraße 65, 80339 MÜNCHEN, Germany Phone : +49 (89) 50084261 Fax : +49 (89) 50084230
Identification Number:	0123

 桂林市锐锋医疗器械有限公司 Guilin Refine Medical Instrument CO.,LTD.	EU Declaration of Conformity	Document No.	RF-UST-T002
		Page	Page 3 of 3
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(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 2023-12-10		
Signature:	 Name: Yangwen Jiang Function: Management Representative		