
 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-PJH-T002
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	Powder Jet Handpiece	Version	1.0

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, P.R.China
European Representative:	MedNet EC-REP GmbH Address: Borkstraße 10, 48163 Münster, Germany
Product Name:	Powder Jet Handpiece
Model:	iJet, iJet S
CND Code:	Z12119099
SRN:	CN-MF-000012204
Basic UDI-DI:	697156045PJHSB
Device Photograph:	Please refer to section 1.7 Device Photograph in RF-PJH-T004 Device Description and Specification.
Intended Use:	Powder Jet Handpiece is used for polishing denture or dental cast.
Risk Class:	Class I
Classification Rule:	Rule 13 in Chapter III of Annex VIII of the Regulation (EU) 2017/745
Conformity Assessment Route	Annex II & III 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:	See RF-PJH-T003 Applied Standard List
Notified Body:	/
Identification Number:	
Place, Date of Issue:	Guilin, Guangxi 2022-02-09
Signature:	 Name: Judong Chen Function: Management representative