CE

DECLARATION OF CONFORMITY

According to REGULATION (EU) 2017/745 -Article 19, Annex II and Annex III.

Manufacturer:

Company name: Baru Foshan Medical Technology Co.,Limited

Address: Room 1107-1109, No.1 Building, Southern China Medical Expo, JichangRoad, Luncun, Nanhai District, Foshan City,Guangdong, China

Tel: +86-0757-81262021

E-mail： fiona@wwss-dent.com

SRN: CN-MF-000045880

Whose Authorized Representative:

Name:： JOYSUN GROUP S.L.U

Address: CALLE ORENSE, NUM 10. PLANTA 1.PUERTA 13,28020 MADRID, SPAIN.

E-mail： Joysun-yes@isosh.com

SRN： ES-AR-000043666

We, the manufacturer, herewith declare that the device covered by the present EU declaration is in conformity with the (EU) MDR 2017/745.

Product Name	Powder jet handpiece		
Model	BR-815/BR-816/BR-819/BR-819-2/BR-820/BR-821 /BR-821-2, BR-806/BR-807/BR-817/BR-817-2/BR-818/BR-818-2/BR-822/BR-824/BR-824-2		
Intend use	It mainly uses high-pressure spraying of abrasive particles to clean, decontaminate, remove rust, deburr, and roughen the surfaces of metals and non-metals to improve surface adhesion and provide a good foundation for subsequent coating, electroplating, and other processes. In the manufacturing industry, sandblasting guns are often used for surface pretreatment of automotive parts, aerospace components, marine equipment, etc. to ensure a strong and durable coating. At the same time, it is also suitable for architectural decoration, such as surface texture treatment of stone and glass, and fine grinding in art restoration, to meet diverse surface treatment needs.		
EMDN code	Q0199	**Basic UDI-DI**	697578373PJH001TQ
Classification and rule	I, rule 13	**Conformity Assessment Route**	Article 19, Annex II and Annex III

Applicable Standards and CS:

EN ISO 13485:2016 EN ISO 14971:2019

EN ISO 20417:2021 EN ISO 15223-1:2021

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION (EU) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process

Signed: John Kuang

Date: August 7, 2025

Place: Foshan, China

Name of authorized signatory: John Kuang

Position held in the company:
August 7, 2025

Baru Foshan Medical Technology Co., Limited