DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

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Manufacturer

Name: CHENGDU SANI MEDICAL EQUIPMENT CO., LTD.
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SRN: CN-MF-000011715

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2019
ISO 15223-1: 2021/Amd 1:2025
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021

Product Information

Name：DENTAL INSTRUMENTS
Model ： Composite Instrument 、 Spreader 、 Condenser
EMDN： Q01010299
Basic UDI-DI： 697060203DI00142
Classification: Class I, According to Rule 5, Annex VIII, Regulation (EU) 2017/745

Remark

The declaration of conformity is valid in connection with the release technical document MDR-TCF-002.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: Date: 2025.6.10

Position: GM Place: Chengdu/China

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