



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
Netherlands
SRN: NL-AR-000000247

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

Remark

The declaration of conformity is valid in connection with the release technical document MDR-TCF-001.

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.

Manufacturer

Name: CHENGDU SANI MEDICAL EQUIPMENT CO., LTD.

Address: No. 408, Tengfei 4th Road, Southwest Airport Economic Development Zone, Shuangliu District, Chengdu, Sichuan Province, 610207, P.R. China

SRN: CN-MF-000011715

Product Information

Name: DENTAL MIRROR

Model: See Annex

EMDN: Q010504

Basic UDI-DI: 697060203DM0014W

Classification: Class I, According to Rule 5, Annex VIII, Regulation (EU) 2017/745

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: Foshan/China

Annex

Name	Model
DENTAL MIRROR	M-R-AG-02-Y, M-R-AG-04-Y, M-C-AG-02-Y, M-C-AG-04-Y, M-R-SG-02-Y, M-R-SG-04-Y, M-C-SG-02-Y, M-C-SG-04-Y, M-R-SS-01-Y, M-R-SS-03-Y, M-C-SS-01-Y, M-C-SS-03-Y, M-R-AG-02-N, M-R-AG-04-N, M-C-AG-02-N, M-C-AG-04-N, M-R-SG-02-N, M-R-SG-04-N, M-C-SG-02-N, M-C-SG-04-N, M-R-SS-01-N, M-R-SS-03-N, M-C-SS-01-N, M-C-SS-03-N, O-00-Y, O-0-Y, O-1-Y, O-2-Y, O-3-Y, O-4-Y, O-5-Y, O-6-Y, O-7-Y, O-8-Y, O-00-N, O-0-N, O-1-N, O-2-N, O-3-N, O-4-N, O-5-N, O-6-N, O-7-N, O-8-N