



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
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SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure

Applicable Standards

EN ISO14971:2019
EN ISO15223-1:2021
EN ISO10993-1:2020
EN ISO10993-5:2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021
EN ISO 20417:2021
EN 62366-1:2015
ISO 11140-1:2014

Remark

The declaration of conformity is valid in connection with the release technical document [CE/MDR-S9099-01](#).

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: ANQING CLEAN DENTAL INSTRUMENT TECHNOLOGY CO.,LTD
Address: No. 1, Wuxiang Road, Yixiu District, Anqing City, Anhui Province, China
SRN: CN-MF-000026210

Product Information

Name: Sterilization indicator card

Model: Class 4, Class 5, Class 6

EMDN: S9099

Basic UDI-DI: 697543453C001EC

Classification: Class I, According to Rule 1, 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: 2024.3.20

Position: GM

Place: Anqing/China