DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
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Capelle aan den IJssel, The Netherlands
SRN: NL-AR-000000247

Manufacturer

Name: SUZHOU ESCO MEDICAL EQUIPMENT CO.,LTD
Address:4F, Bldg. 3, No. 58 Nanhu Rd., Wuzhong District., Suzhou, China
SRN: CN-MF-000052833

Conformity Assessment

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

Applicable Standards
EN ISO 14971: 2019+A11:2021
EN ISO 15223-1:2021+A1:2025
EN ISO 20417:2021
EN ISO 10993-1: 2025
EN ISO 10993-5: 2009+A11:2025
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021+A1:2025
EN 60601-1:2006+A13:2024
EN 60601-1-2:2015+A1:2021
EN 60825-1:2014
EN 62471:2008

Product Information

Name: INTRA ORAL SCANNER
Model: E3, E5,E6
EMDN: Z11030402
Basic UDI-DI: 697999159IOS00155
Classification: Class I, according to Rule 5 Rule 13, 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:2026.4.8

Position: GM Place: Jiangsu/ China

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.

File No.: MDR-TCF-001-08