



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

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 60601-1:2006+A13:2024
EN 60601-1-2:2015+A1:2021

Product Information

Name: DENTAL MICROSCOPE
Model: EM8, EM8 PRO, EM9, EM9 PRO
EMDN: Z12120108
Basic UDI-DI: 697999159DM001TB
Classification: Class I, according to Rule10, Annex
VIII, Regulation (EU) 2017/745

Declaration

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.*

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