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
EN ISO 15223-1: 2021
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021
EN14683:2019
EN 62366-1:2015
ISO 13485: 2016

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-WM-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: Wellmed Dental Medical Supply Co., Ltd

Address: 301 Zhongxing Science and Technology Building, No.64, Xin'an 2nd Road, Baoan District, Shenzhen, China

SRN: CN-MF-000003243

Product Information

Name: Face masks

GMDN: 35177

Basic UDI-DI: 697460865FLS-001RU, 697460865FLS-002RW, 697460865FLS-003RY

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: 17/03/2026

Position: GM Place:Shenzhen /China