



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
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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

Product Information

Name: Face masks
GMDN: 35177
Basic UDI-DI: 697460865CPT-002SA
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: 唐仁贵

Position: GM

Date: 1-6-2025

Place: Shenzhen /China

