



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, 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: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN14683:2019+AC:2019
EN 62366-1:2015

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: 697460865MCPM-0057S/
697460865ISM-002UA/697460865BLO-005NL/
697460865MCPM-0067U/697460865RM-004JR
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:

Position: GM

Date:

Place: Shenzhen /China

