



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-00000247

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

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
Brand Name: peppler Four Seasons - 717
GMDN: 35177
Basic UDI-DI: 697460865CP4-001FK(717HB)/
697460865CP4-003FP(717R)/
697460865CP4-004FR(717G)/
697460865CP4-006FV(717O)/
697460865CP4-008FZ(717HG)/
697460865CP4-009G3(717P)/
697460865CP4-010FL(717B)/
697460865CP4-011FN(717S)/
697460865CP4-012FQ(717BR)/
697460865CP4-014FU(717TG)/
697460865CP4-015FW(717GR)/
697460865CP4-016FY(717IG)/
697460865CP4-018G4(717RB)/
697460865CP4-019G6(717NB)/
697460865CP4-020FP(717OG)/
697460865CP4-021FR(717L).
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

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.

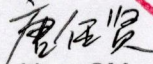
The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

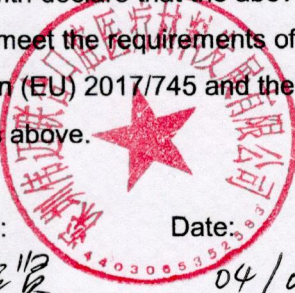
Declaration

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:


Position: GM


04/06/2022
Place: Shenzhen /China

