



# 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  
EN 14683: 2014  
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

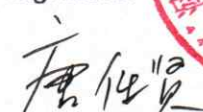
**Name:** Face masks  
**Brand name:** Mundschutz peppler protect – 719  
**GMDN:** 35177  
**Basic UDI-DI:** 697460865CP-001DH(719HB), 697460865CP-002DK(719W), 697460865CP-003DM(719R), 697460865CP-005DR(719G), 697460865CP-007DV(719L), 697460865CP-009DZ(719P),697460865CP-010DJ(719B).  
**Classification:** 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:

  
Position: GM

  
09/30/2021  
Place: Shenzhen /China