



# 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

## Product Information

**Name :** Face masks

**GMDN :** 35177

**Basic UDI-DI :** 697460865CP-002DK

**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: 唐仕贤

Date: 11-20-2023

Position: GM

Place: Shenzhen /China

