



# 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: 2012  
EN ISO 15223-1: 2016  
EN 1041:2008  
ISO 10993-1: 2018  
EN ISO 10993-5: 2009  
EN ISO 10993-10: 2013

## 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:** Micro applicator  
**Model:** MA-001(Superfine White), MA-002(Fine Mauve), MA-003(Fine Yellow),MA-004(Regular Blue), MA-005(Regular Green),MA-006(Regular Orange),MA-007(Regular Purple),MA-008(Cylinder Black)

**GMDN:** 33722

### Basic UDI-DI:

697460865MA-001CE(Superfine White)  
697460865MA-002CG(Fine Mauve)  
697460865MA-003CJ(Fine Yellow)  
697460865MA-004CL(Regular Blue)  
697460865MA-005CN(Regular Green)  
697460865MA-006CQ(Regular Orange)  
697460865MA-007CS(Regular Purple)  
697460865MA-008CU(Cylinder Black)

**Classification:** Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

## Declaration

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### Remark

*The declaration of conformity is valid in connection with the release technical document*

*CE/MDR-WM-03.*

*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.*

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: 2021-06-29

Position: GM

Place: Shenzhen /China

