



# 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: 2021  
EN ISO 20417: 2021  
EN ISO 10993-1: 2020  
EN ISO 10993-5: 2009  
EN ISO 10993-10: 2013  
EN 14683:2019+AC:2019 Type II

### Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-T020604-01.*

*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:** Hubei Maiyue Non woven products Co.,Ltd.  
**Address:** Factory buliding no.12-1,zhanpeng Road, zhongling Industrial park,pengchang town, xiantao City.

## Product Information

**Name:** DISPOSABLE FACE MASK  
**Model:** 17.5\*9.5cm,14.5\*9.5cm  
**EMDN:** T020604  
**Basic UDI-DI:** /  
**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: 2022.01.19

Position: GM

Place: Hubei/China

