



# 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

## Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-T0299-02.*

*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:** Isolation gown  
**Model:** S,M,L,XL,XXL,XXXL  
**EMDN:** T0299  
**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

