



# 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: 2016  
EN 1041:2008+A1:2013  
ISO 10993-1: 2018  
EN ISO 10993-5: 2009  
EN ISO 10993-10: 2013  
EN 13795-1:2019

### Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-ZT-05*

*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:** XIANTAO ZHONGTAI PROTECTIVE PRODUCTS CO., LTD

**Address:** 3#, Taizi Lake Industry Park, Pengchang Town, Xiantao City 433018 Hubei Province, P.R. China

**SRN:** CN-MF-000008476

## Product Information

**Name:** Isolation Gown

**Model:** S,M,L,XL,XXL, customized

**EMDN:** T0299


**GMDN:** 35492

**Basic UDI-DI:** 697443606C000169

**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: 2023. 8. 1

Position: GM

Place: Hubei/China

