



# 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: 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. I confirmed we are  
On behalf of SUNGO Europe B.V., I confirmed we are  
EU REP of the company who issue this document.



Authorized Signature (S)

## Manufacturer

Name: XIANTAO ZHONGTAI PROTECTIVE  
PRODUCTS CO., LTD  
Address: 3#, Taizi Lake Industry Park, Pengchang  
Town, Xiantao City 433018 Hubei Province, P.R.  
China

## Product Information

Name : Isolation Gown

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

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

2021.6.25

Position: GM

Place: Hubei/China