



# 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  
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-KN-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: Hubei Kangning Protective Products Co., Ltd.  
Address: Special No. 1, Xuefu Road, 433000, Xiantao, Hubei, China  
SRN: CN-MF-000008961

## Product Information

Name: Disposable gown  
Model: Non-sterile, customized  
GMDN: 35492  
EMDN: T0299  
Basic UDI-DI: 69474019GOWNP1XQ  
Classification: Class I, 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: 08.09.2022

Position: GM Place: Hubei / China

