



# 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-T030502-01.*

*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 KANGNING PROTECTIVE PRODUCTS CO., LTD.  
**Address:** Special No. 1, Xuefu Road, 433000, Xiantao, Hubei, China  
**SRN:** CN-MF-000008961

## Product Information

**Name:** Medical sheet  
**Model:** customized  
**GMDN:** 47456  
**EMDN:** T030502  
**Basic UDI-DI:** 69474019SHEETWD  
**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: 2022.9.6

Position: GM

Place: Hubei/China

