



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
EN 13795-1: 2019

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-HBKN-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 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
Basic UDI-DI: 69474019GOWNS1XZ
Classification: Class I
Rule: Rule 1, Annex VIII, Regulation (EU) 2017/745

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Declaration



Authorized Signature (S)

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: 2021.12.01

Position: General Manager Place: Hubei / China

