



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
EN14683:2019+AC: 2019 Type I

Remark

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

Product Information

Name : Disposable Medical Face Mask (TYPE I)

Model: 17.5cm*9.5cm,14.5*9.5cm

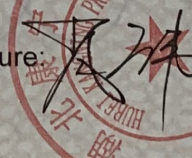
GMDN : 35177

Basic UDI-DI : 69474019MASK01R4

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: 2020.09.30

Position: GM

Place: Hubei / China

