



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel,
The 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 14683: 2019+AC: 2019 Type IIR

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-RF-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: Sword Xiantao Disposable Protective Products Factory
Address: Liukou Industrial Zone, Xiantao City, 433000, Hubei Province, China
SRN: CN-MF-000009766

Product Information

Name: Surgical Masks
Model: 17.5cm* 9.5cm, 14.5cm* 9.0cm, customizable
GMDN: 66199
Basic UDI-DI: 697163167SM2Z
Classification: Class I

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: 2022.9.15

Position: GM

Place: Hubei / China