



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
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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 1041: 2008
EN ISO 15223-1: 2016
EN ISO 20417:2021
EN ISO 10993-1: 2018
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-T0209-01.

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: Xiantao Maosheng Plastic Products Co., Ltd
Address: NO.3 of Xinmin Road III, Zhanggou Town, Xiantao City, Hubei, China
SRN: CN-MF-000009821

Product Information

Name: Isolation Gown
Model: 05/02/033S-PP 35 gown, with back closure, blue color
Basic UDI-DI: 697363561MSIG01R8
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: 2023.3.8

Position: GM

Place: Hubei/China