



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-T0208-01

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: Shoe Cover
Size: 16", 18"
EMDN: T0208
GMDN: 15056
Basic UDI-DI : 697363561MSSC01SS,
697363561MSSC02SU
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: 2024.07.08



Position: GM

Place: Hubei/China

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Customer

Name: PROLIMAX HIGIENE INDUSTRIAL, S.L.
C/Jardines N°7, Barcience, 45525 (Toledo)
Tel: 925 779 507 - Fax: 925 771 364

Manufacturer:

Name: Xiantao Maosheng Plastic Products Co., LTD
Address: No. 3 of Xinmin Road III, Zhanggou Town, Xiantao City,
433000 Hubei, China

European Authorised Representative:

Name: SUNGO Europe B.V.
Address: Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel,
The Netherlands

Product Name: Shoe Cover
BASIC UDI-DI: 697363561MSSC02SU

- 68300, 68301, 68302, 68303, 68304
- 68304, 68340A
- 68305, 68307

Classification: Class I, According to Rule 1, Annex VIII, Medical Device
Regulation (EU)2017/745

Conformity assessment procedure: Annex II+III

We confirm our products meets the requirements of Medical Device
Regulation(EU) 2017/745 .



Signed for and on behalf of: Xiantao Maosheng Plastic Products Co., LTD

Date of issue : 01.12.2022