EC DECLARATION OF CONFORMITY

Regulation (EU) 2016/425 - Personal Protective Equipment

Manufacturer:
Name: Xiantao Maosheng Plastic Products Co., LTD
Address: (No. 1 Factory Building), Zhennan Village, Zhanggou Town, Xiantao City, Hubei Province, China

Customer
Name: PROLIMAX HIGIENE INDUSTRIAL, S.L.
C/Jardines Nº7, Barcience, 45525 (Toledo)
Tel: 925 779 507 - Fax: 925 771 364

- **Product: Shoe Cover**

- **Codes: 68400, 68400B, 68400V**
  68600

We confirm that the article identified in Product is in conformity with the requirements of Regulation (EU) 2016/425 on Personal Protective Equipment, CAT I.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

XIANTAO MAOSHENG PLASTIC PRODUCTS CO.,LTD 仙桃市茂盛塑料制品有限公司

Signed:

Date: 2025.02.01

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: 2021
EN ISO 20417: 2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-T0208-09.

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. 1 Factory Building), Zhennan Village, Zhanggou Town, Xiantao City, Hubei Province, China
SRN: CN-MF-000009821

Product Information

Name: Shoe Cover
Model: XS，S，M，L，XL，XXL，XXL，XXXL, customized
EMDN: T0208
Basic UDI-DI: 697363561MSSC01SS(Non-woven)
697363561MSSC02SU(PE)
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: 2024.12.9

XIANTAO MAOSHENG PLASTIC PRODUCTS CO.,LTD 仙桃市茂盛塑料制品有限公司

Position: GM Place: Hubei/China

DECLARATION OF CONFORMITY

Customer
Name: PROLIMAX HIGIENE INDUSTRIAL, S.L.
C/Jardines Nº7, Barcience, 45525 (Toledo)
Tel: 925 779 507 - Fax: 925 771 364

Manufacturer:
Name: Xiantao Maosheng Plastic Products Co., LTD
Address: (No. 1 Factory Building), Zhennan Village, Zhanggou Town, Xiantao City, Hubei Province, China
SRN: CN-MF-000009821

European Authorised Representative:
Name: SUNGO Europe B.V.
Address: Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands
SRN: NL-AR-000000247

Product Name: Shoe Cover
BASIC UDI-DI: 697363561MSSC01SS

- 68400, 68400B, 68400V
- 68500, 68500A, 68500B
- 68600

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 .

XIANTAO MAOSHENG PLASTIC PRODUCTS CO.,LTD 仙桃市茂盛塑料制品有限公司

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

Date of issue : 02.01.2025