DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

CE

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.

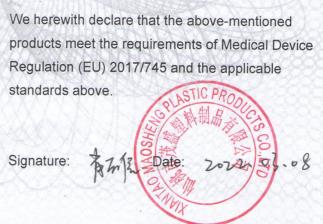
Manufacturer

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



Position: GM

Place: Hubei/China

DECLARATION OF CONFORMITY

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: Xianta Maosheng Rustic Products Co., LTD

Date of issue : 01.12.2022