



DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745



Manufacturer: XIANTAO RHYCOM NON WOVEN PRODUCTS CO.,LTD
Address: Chuangye Road, longhuashan Sub-district, Xiantao
 City, Hubei Province, China
EC Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name: Shoe Cover
Model: S,M,L,XL,XXL, XXXL, According to customer requirements
Classification: Class I
Rule: Rule 1, Annex VIII, Regulation (EU) 2017/745
Conformity Assessment Annex II+III of Regulation (EU) 2017/745
Procedure:
SRN: /
Basic UDI-DI: /

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the following harmonized standards.

EN ISO 14971:2012 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 62366-1:2015

*On behalf of SUNGO Europe office, I confirmed we are
 EU REP of the company who issue this document.*

Signature: Tom Wang

Name / Position: Tom Wang / GM

Date: 2020-8-18

Place: Hubei / China



Authorized Signature (S)