



# 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:** Disposable Sleeve

**Model:** S,M,L,XL,XXL, XXXL,XXXXL, 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	

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

Name / Position: Tom Wang / GM

Date: 2020-8-18

Place: Hubei / China



*Authorized Signature (S)*