



# DECLARATION OF CONFORMITY

Regarding Medical Device Directive(93/42/EEC)  
including Directive 2007/47/EC

**Manufacturer:** Shantou Tang Mian Clothing Co., Ltd.  
**Address:** No. 81 Guangyuan Road Xiashan Chaonan District Shantou,  
Guangdong,CN

**EC Representative:** SUNGO Europe B.V.  
**Address:** Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

**Product Name:** Disposable Surgical Mask (non-sterile)  
**Specification:** Model 808, 17 cm x 9.5 cm

**Classification:** Class I (MDD, Annex IX)

## Conformity Assessment

**Procedure:** Annex VII of Medical Device Directive(93/42/EEC)

We herewith declare that the above-mentioned products meet the requirements of Medical Device Directive (93/42/EEC) and the following harmonized standards.

EN ISO 14971:2012

EN ISO 15223-1:2016

EN 1041:2008+A1:2013

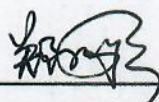
ISO 10993-1:2018

EN ISO 10993-5:2009

EN ISO 10993-10:2013

EN 14683:2019+AC:2019

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

Signature: 

Name/ Position: Zheng Xiaobin/ General Manager

Date: 2020.05.09

Place: China/Guangdong





Authorized Signature (S)