



# DECLARATION OF CONFORMITY

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

**Manufacturer:** Wuhan Orient Honest International Trade Co.,Ltd  
**Address:** No.274, zone A, 3rd floor, Hanyuan shopping mall, no451,Luoxishiroad,  
Hongshan district, Wuhan city, Hubei province

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

**Product Name:** Disposable medical mask  
**Specification:** 210mm\*95mm, 175mm\*95mm, 145mm\*90mm, 125mm\*85mm

**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) including Directive 2007/47/EC 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 10993-10:2018

EN 14683:2019+AC:2019

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

Signature: 纪昌琦

Name/ Position: Changzhen Ji/ GM

Date: 2020.5.29

Place: Hubei / China



Changzhen Ji

Authorized Signature (S)