



# DECLARATION OF CONFORMITY

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

**Manufacturer:** HUBEI HONGRUI PLASTICS CO.,LTD  
**Address:** Group 6 of Huangjing Village, Longban, Xiantao city

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

**Product Name:** Medical Face Mask (non-sterile)  
**Specification:** 17.5\*9.5cm, Model NO :1999903629

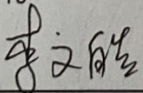
**Classification:** Class I (MDD, Annex IX)

## 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 10993-10:2013
EN 14683:2019	

**Signature:** 

*Name/ Position: Wenhao Li/ GM*

**Date:** 2021 / 1 / 13

*Place: Hubei/ China*

