



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 :1000010123

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: 李文皓

Name/ Position: *Wenhao Li/ GM*

Date: 2021 / 1 / 13

Place: *Hubei/ China*

