

## EC Declaration of Conformity

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

Manufacturer: Zhejiang Hongyu Medical Commodity Co., Ltd.  
Address: No. 668 ChuanHua Road, Fotang Town Industrial  
Functional Area, 322002 Yiwu City, Zhejiang  
Province, PEOPLE'S REPUBLIC OF CHINA

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

Product Name: Disposable Medical Face Mask  
Mode: Ear Loop  
Type: 12\*7cm, 14.5\*9.5cm, 17.5\*9.5cm  
Classification: Class I (MDD, Annex IX), Rule 1  
UMDNS code: 12447

Conformity Assessment Route: Annex VII

We confirm our product can meet the requirement of Medical Device Direc-  
tive(93/42/EEC) and the following harmonized standards.

|                      |                      |
|----------------------|----------------------|
| EN ISO 14971:2012    | EN ISO 15223-1:2016  |
| EN 1041:2008+A1-2013 | EN ISO 10993-1:2018  |
| EN ISO 10993-5:2009  | EN ISO 10993-10:2013 |
| EN ISO 14683:2019    |                      |

Signature of General Director:  
Place, date of issue: Zhejiang, P.R. China, April 14th, 2020

Zhejiang Hongyu Medical Commodity Co., Ltd  
No. 668 ChuanHua Road, Fotang Town Industrial Functional Area, 322002 Yiwu City,  
Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

