



# DECLARATION OF CONFORMITY

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

**Manufacturer:** Zhangjiagang Xiehe Medical Apparatus and Instruments Co.,Ltd

**Address:** No.7th,Middle Xinzha Road,Zhashang Industrial Zone,Yangshe Town,Zhangjiagang City,Jiangsu  
215600,China

**EC Representative:** SUNGO Europe B.V.

**Address:** Olympisch Stadion 24, 1076DE Amsterdam,  
Netherlands

**Product Name:** Disposable Medical Face Mask

**Specification:** Ear Loop, 17.5\*9.5cm

**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 ISO14683: 2019

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

Signature: 

Name/ Position: Cindy/ GM

Date: \_15/05/2020\_

Place: Zhangjiagang/China



Authorized Signature (S)