

# EC Declaration of Conformity

## Regarding Medical Device Directive(93/42/EEC)

### including Directive 2007/47/EC

#### Applicant

Name: HENAN LANTIAN MEDICAL SUPPLIES CO., LTD.  
Address: Changyuan Industry Area, Henan Province, China

#### EC Representative

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

#### Product

Name: Surgical Face Mask (Non - Sterile)  
Type: Flat type

Classification: Class I (MDD, Annex IX), Rule 1(All non-invasive devices are in class I)  
Conformity Assessment Route: Annex VII

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

EN ISO 14971:2012  
EN ISO 15223-1:2016  
EN 1041:2013  
EN ISO 10993-1:2009/AC:2010  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013

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

Signature:



Date:

2020.5.28



Authorized Signature (S)

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