

# EC Declaration of Conformity

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

### including Directive 2007/47/EC

#### Applicant

Name: ESound Medical Device Co., Ltd.

Address: High-Tech Medical Equipment Industrial Park, Changyuan County, China

#### EC Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

#### Product

Name: Medical Face Mask

Type: Planar, Large Size (Surgical Face Mask);

Folded (Medical Protective Mask)

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 14683: 2019

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.*



*Authorized Signature (S)*

Signature: *Xiang Ya Wei*

Date: 2020.4.1.

