

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.*

