

EC Declaration of Conformity

Regarding Medical Device Directive(93/42/EEC)

including Directive 2007/47/EC

Applicant

Name: Jiangsu NewValue Medical Products Co., Ltd.

Address: Building G35, No.1 Avenue, China Medical City, Taizhou, Jiangsu, 225300, China

EC Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Medical Face Mask

Type: 17.5*9.5cm, 14.5*9cm, 21*7cm, Round (according to customer requirement)

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 13485

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: 

Date: 2022.05.28

