



DECLARATION OF CONFORMITY

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

Manufacturer: Shandong Kaibo Medicinal Packaging Co., Ltd

Address: West Yanggan Road, Anqiu City(Guanwang Industrial Park), Shandong
Province, China.

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: Non-Sterile Disposable Medial Mask

Specification: 175mm*95mm

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) and the following harmonized standards.

EN ISO 14971:2012

EN ISO 15223-1:2016

EN1041:2008+A1:2013

EN 10993-1:2018

EN ISO 10993-5:2009

EN ISO 10993-10:2013

EN 14683:2019

Signature: 

Date: 2020.5.19

Place: CHINA/ZHEJIANG

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


Sungo
global service


Authorized Signature (S)



扫描全能王 创建