



DECLARATION OF CONFORMITY

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

Manufacturer: Changzhou Baidelin Health Material Co., Ltd

Address: No.218, Sanhe road, Sanhekou Development Zone, Zhenglu Town,
Changzhou City, Tianning District, Jiangsu Province,
China

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: Disposable Medical Face Mask

Specification: Planar earloop (17.5cmx9.5cm, 14.5cmx9.5cm)

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) including Directive 2007/47/EC and the following harmonized standards.

EN ISO 14971:2012

EN ISO 15223-1:2016

EN 1041:2008+A1:2013

ISO 10993-1:2018

EN ISO 10993-5:2009

EN ISO 10993-10:2013

EN 14683:2019+AC:2019

Signature: 

Name/ Position: Lu Jinde/ GM

Date: 2020.5.29

Place: Changzhou City/ China