

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

Applicant

Name: Anhui JBH Medical Apparatus Co., Ltd
Address: No. 116 qicang Road, Mingguang City, Chuzhou, Anhui

EC Representative

Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Disposable medical mask

Type: 17.5*9.5cm

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 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

Signature:

Date:



2020.3.12