

CE

Declaration of Conformity

Manufacturer:

Name: Anqing Jiaxin Medical Material Co, Ltd.

*Add: No. A-5, Yangtze River Bridge Economic Development Zone 246001
Anqing, Anhui PEOPLE'S REPUBLIC OF CHINA.*

Product Name : Medical face mask, Surgical mask

*Risk Class of the Device: The medical device has been assigned to class
I, rule 1 according to ANNEX VIII, Medical Device REGULATION (EU)
2017/745 and (EU) 93/42.*

*As a manufacturer, we declare that
The product concerned has been designed and manufactured under a quality
management system according to ANNEX IX of Medical Device REGULATION
(EU) 2017/745 and (EU) 93/42.*

*Following the procedure relating to the EC Declaration of Conformity set out in
ANNEX IX of Medical Device REGULATION (EU) 2017/745 and (EU) 93/42.*

*This Declaration of conformity is valid in connection with the release document
for the respective batch of produced devices*

Standards :

EN 14683 : 2019 Medical face masks - Requirements and test methods

European Representative:

*Name: Shanghai International Holding
Corp. GmbH (Europe)*

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Germany*

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*Manufacturer: ANQING JIAXIN MEDICAL MATE
CO., LTD
安庆市嘉欣医用材料有限公司
JIAXIN MEDICAL MATERIAL CO., LTD.*

date: MAR. 16, 2020