

Ningbo Jianxiang Packaging Material Technology Co., Ltd. CE Technical Documentation	Document No.: CE-SM-03	Edition: A0	page: 1/2
	Declaration of Conformity	Effective Date: 2020-02-20	

Manufacturer:

Name: Ningbo Jianxiang Packaging Material Technology Co., Ltd

Add: No. 19-2, Miaofeng Road, Taoyuan street, Ningbo, Zhejiang, People's republic of China

European Representative:

CMC Medical Devices & Drugs S.L

C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain

Product Name: Surgical mask

Model/Size:

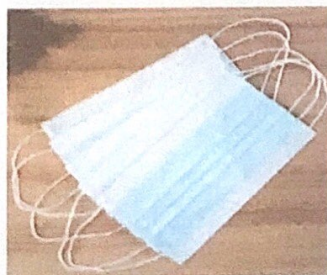
Model	Size
Plain face mask	17.5cm×9.5cm; 16.5cm×8.5cm; 16cm×8cm; 14cm×8cm; 12cm×7cm; 10cm×6cm.
Cup mask	L、M、L

Intended use:

It is worn by clinical medical staff during the invasive operation, covering the mouth, nose and mandible of users, providing physical barrier to prevent the direct penetration of pathogens, microorganisms, body fluids, particles, etc.

Product Picture:

Plain face 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.

UMDNS code: 12458

UDI-DI:

The product meets the provisions of Medical Device REGULATION (EU) 2017/745 which apply to

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them.

The medical device has been assigned to class I according to ANNEX VIII, Medical Device REGULATION (EU) 2017/745. It bears the mark



The product concerned has been designed and manufactured under a quality management system according to ANNEX IX of Medical Device REGULATION (EU) 2017/745.

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

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

The above mention declaration of conformity is exclusively under the responsibility of

Comapny: Ningbo Jianxiang Packaging Material Technology Co., Ltd

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NINGBO, 19/08/2020
Place, date


Legally binding signature, Function