



中国认可  
国际互认  
检测  
TESTING  
CNAS L0599

Test Report

SL52035285642301TX

Date: September 04, 2020

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ANHUI ZHONGNAN AIR DEFENCE WORKS PROTECTIVE CO., LTD  
QIANSHAN COMPREHENSIVE ECONOMIC DEVELOPMENT ZONE, ANHUI PROVINCE, CHINA

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description : (A) Disposable medical mask: plane type, size is 17.5cm\*9.5cm, composed of melt-blown fabric, non-woven fabric, nose bridge strip and earloop. It has 3 layers structure. The inner layer is white non-woven fabric, the middle layer is melt-blown fabric, and the outer layer is blue non-woven fabric

Composition : (A) non-woven melt, Melt-blown fabric

Sample Color : (A) Blue, White

Lot No. : 20200801

Manufacturer : ANHUI ZHONGNAN AIR DEFENCE WORKS PROTECTIVE CO., LTD

Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Aug 12, 2020

Testing Period : Aug 12, 2020 - Sep 04, 2020

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of  
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

*Sara Guo*

Sara Guo (Account Executive)

*Dongjing Liu*

*Helen Xuan*

Dongjing Liu / Hailian Xuan (Authorized Signatory)



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Attention: To check the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: [CN.Doccheck@sgs.com](mailto:CN.Doccheck@sgs.com)

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# EC DECLARATION OF CONFORMITY

With regard to MDD 93/42/EEC as amended by 2007/47/EC for medical devices

Name of the Company : Anhui Zhongnan Air Defence Works Protective Co., Ltd.  
Address : Qianshan Comprehensive Economic Development Zone,  
Anhui Province, China,  
Post code: 246300  
Product Name : Disposable Medical Mask  
Classification and Justification : As per annexure IX of MDD 93/42/EEC, as amended by  
2007/47/EC section 1.1 Rule 1 it's a Class I Medical Device.  
All non-invasive devices are in Class I.  
Model(s) : Plane type: 17.5cm X 9.5cm; 14.5cm X 9.5cm;  
12.5cm X 8.5cm  
Authorized Representative : Europecert  
Name and Address : Alstr. 97, 41063 Mönchengladbach, Germany  
support@europecert.eu

We hereby under our sole responsibility declare, that the product to which this declaration relates, is in conformity with the relevant provisions of standards and other normative document(s) and full fills the essential requirements of 93/42/EEC.

This declaration of conformity is issued under the sole responsibility of Anhui Zhongnan Air Defence Works Protective Co., Ltd. We hereby declare that the medical device specified above meet the provision of the Annex VII of MDD 93/42/EEC as amended by 2007/47/EC for medical devices.

This declaration is based on

- a) EN 14683:2019+AC:2019, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 10993-1:2009/AC:2010, EN ISO 14971:2012, EN ISO 13485:2016  
b) Technical File with issue date: TCF-VC-PE-20200409; 2020.5.08

Manufacturer : Anhui Zhongnan Air Defence Works Protective Co., Ltd.  
Name & Designation : Hongsheng Chen, Quality Manager  
Signature :   
Date : Sep 06, 2020  
Place of Issue : Anhui Qianshan

