

Test Report

SL52025258108601TX

Date: June 11, 2020

Page 1 of 3

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

Sample Description : Face Mask

Style No. : Medical face mask (non-sterile)
Composition : non-woven fabric, melt-blown fabric
Sample Color : blue
Manufacturer :

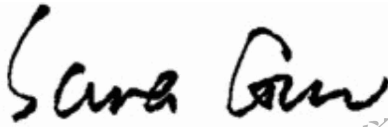
Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : May 19, 2020

Testing Period : May 20, 2020 - Jun 11, 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



Sara Guo (Account Executive)



Dongjing Liu (Authorized Signatory)



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

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

3rd Building, No. 889, Yishan Road, Xuhui District Shanghai, China 200233
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233

t (86-21) 61402666 f (86-21) 64958763
t (86-21) 61402666 f (86-21) 64958763

www.sgsgroup.com.cn
e sgs.china@sgs.com

Test Result

Medical Face Masks-Requirements and Test Methods
(EN 14683:2019+AC:2019)

Clause 5.2.2 Bacterial filtration efficiency (BFE)
(EN 14683:2019+AC:2019 Annex B)

	1#	2#	3#	4#	5#
(BFE), %	99.9	99.8	99.8	99.9	99.9

Remark: Performance Requirement: Type I $\geq 95\%$, Type II $\geq 98\%$, Type IIR $\geq 98\%$

* This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by external laboratory accredited by CMA (China Metrology Accreditation).

Clause 5.2.3 Breathability
(EN 14683:2019+AC:2019 Annex C, Flow rate 8 l/min)

	1#	2#	3#	4#	5#
Differential pressure ΔP (Pa/cm ²)	36	26	28	27	26

Remark: Performance Requirement: Type I < 40 Pa/cm², Type II < 40 Pa/cm², Type IIR < 60 Pa/cm²

Clause 5.2.5 Microbial Cleanliness
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

	1#	2#	3#	4#	5#
CFU/g	23	25	25	19	24

Remark: Performance Requirement: Type I ≤ 30 CFU/g, Type II ≤ 30 CFU/g, Type IIR ≤ 30 CFU/g

Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/Terms-and-Conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/Terms-and-Conditions/Terms-e-Documents.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

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

3rd Building, No.889, Yishan Road, Xuhui District Shanghai, China 200233
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233

t (86-21) 61402666 f (86-21) 64958763
t (86-21) 61402666 f (86-21) 64958763

www.sgsgroup.com.cn
e sgs.china@sgs.com



Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

EC Declaration of Conformity

Regarding Medical Device Directive(93/42/EEC)

including Directive 2007/47/EC

Manufacturer:

Name:

Address:

EC Representative

Name:

Address:

Product

Name: Disposable Medical Face Mask

Model: CJ-01

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 14683:2019

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

The CE Mark:



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

Company:

Address:

April 22nd 2020

Date

General Manager,

Legally binding signature, Function