

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 :

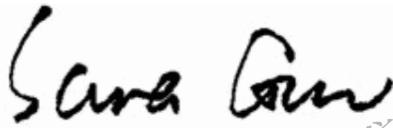
Test Performed : Selected test(s) as requested by applicant

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)

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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 ≥ 95%, Type II ≥ 98%, Type IIR ≥ 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



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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



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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