

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

Sample Description : (A)SINGLE-USE MEDICAL FACE MASK (Claimed Type IIR)  
 Sample Color : (A)Blue  
 Manufacturer :  
 Other Information :  
 Proposed Care Instruction : -  
 Test Performed : Selected test(s) as requested by applicant  
 Sample Receiving Date : Apr 03, 2020  
 Testing Period : Apr 08, 2020 - Apr 27, 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).

**Comment:**

<b>Medical Face Masks-Requirements and Test Methods(EN 14683:2019)</b>	(A)
Clause 5.2.2 Bacterial filtration efficiency (BFE)	M
Clause 5.2.3 Breathability	M
Clause 5.2.4 Splash Resistance	M
Clause 5.2.5 Microbial Cleanliness	M

Remark: M=Meet EN 14683:2019 Type IIR requirement  
 F=Below EN 14683:2019 Type IIR requirement

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

Sara Guo (Account Executive)



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Test Result

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

**Clause 5.2.2 Bacterial filtration efficiency (BFE)\*\*@**

	1#	2#	3#	4#	5#
(BFE), %	>99.9	99.7	99.8	>99.9	>99.9

Remark: Performance Requirement: Type I >95%, Type II >98%, Type IIR >98%

\*\* : The test was carried out by external laboratory assessed as competent

@ : This test method is not in CNAS accredited scope

**Clause 5.2.3 Breathability**

(EN 14683 :2019 Annex C, Flow rate 8 l/min)

	1#	2#	3#	4#	5#
Differential pressure ΔP (Pa/cm <sup>2</sup> )	50.2	49.9	52.6	53.4	52.7

Remark: Performance Requirement: Type I <40 Pa/cm<sup>2</sup>, Type II <40 Pa/cm<sup>2</sup>, Type IIR <60 Pa/cm<sup>2</sup>

**Clause 5.2.4 Splash Resistance**

(ISO 22609 :2004, Pressure 16.0 kPa)

**Penetration on inside surface**

1#	2#	3#	4#	5#	6#	7#	8#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
9#	10#	11#	12#	13#	14#	15#	16#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
17#	18#	19#	20#	21#	22#	23#	24#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
25#	26#	27#	28#	29#	30#	31#	32#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass

Number of Pass: 32  
Overall result: Acceptable

Remark:

- 1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
- 2) Distance of the medical face mask target area surface to the tip of cannula is 300±10mm.
- 3) Condition and Test temperature (21±5)<sup>o</sup> C, relative humidity (85±10)%
- 4) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results

**Clause 5.2.5 Microbial Cleanliness**

(EN 14683: 2019 Annex D)

	1#	2#	3#	4#	5#
CFU/g	3	9	1	1	3

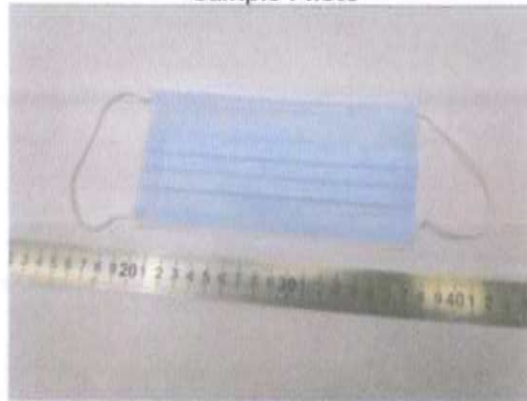
Remark: Performance Requirement: Type I ≤30 CFU/g, Type II ≤30 CFU/g, Type IIR ≤30 CFU/g



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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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