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TESTING
CNAS L0599

Test Report SL52035285167501TX **Date:** August 07, 2020 **Page 1 of 5**
HUBEI HONGRUI PLASTICS CO., LTD
GROUP 6 OF HUANGJING VILLAGE, LONGBAN, XIANTAO CITY, HUBEI, CHINA

THIS REPORT CANCELS AND SUPERSEDES THE TEST REPORT NO. SL52035260496801TX
DATE: July 07, 2020 ISSUED BY SGS (SHANGHAI)
UPDATED SAMPLE INFORMATION

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

Sample Description : (A)Medical Face Mask(Claimed Type IIR)
Style No. : 17.5*9.5cm
Composition : (A)67% non-woven fabric and 33% meltblown
Sample Color : (A)Blue and White
Order No. : 20200601
Lot No./Batch No. : Not provided
Manufacturer : HUBEI HONGRUI PLASTICS CO., LTD
Supplier : HUBEI HONGRUI PLASTICS CO., LTD
Sample Receiving Date : Jun 15, 2020
Testing Period : Jun 15, 2020 - Jul 07, 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).
Test Performed : Selected test(s) as requested by applicant

Comment:

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods	(A)
Clause 5.2 Performance Requirement	
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
Clause 5.2.6 Biocompatibility	EXCLUDED

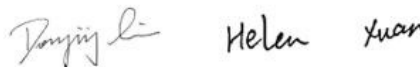

Remark: M=Meet EN 14683:2019+AC:2019 Performance Requirement (Type IIR)



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



Sara Guo (Account Executive)

Dongjing Liu / Hailian Xuan (Authorized Signatory)



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Test Result

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

Clause 5.2 Performance Requirement

Clause 5.2.2 Bacterial filtration efficiency (BFE)

(EN 14683:2019+AC:2019 Annex B)

Sample: A

Conditioning Parameters : Minimum of 4 hours at 21±5°C and 85±5% R.H.
 Dimensions of test specimen : ~174 mm x 156 mm
 Test Area : ~60 cm²
 Test Side : Inside
 Flow Rate : 28.3 l/min
 Positive Control Average : 2734 CFU
 Negative Monitor Count : < 1 CFU

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

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

Clause 5.2.3 Breathability

(EN 14683 :2019+AC:2019 Annex C)

Sample: A

Test number and location : 5 random areas for each specimen (face mask)
 Conditioning Parameters : Minimum of 4 hours at 21±5°C and 85±5% R.H.
 Test Area : 4.9 cm²
 Flow Rate : 8 l/min

	1#	2#	3#	4#	5#
Differential pressure ΔP (Pa/cm ²)	35	35	36	35	31

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



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	Fail	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:			31				
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)° 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

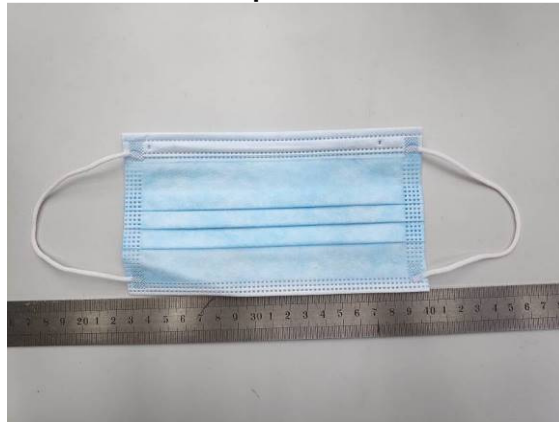
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample Number	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1#	2.81	3	1.07
2#	2.87	3	1.05
3#	2.85	<3	<1.05
4#	2.89	12	4.15
5#	2.93	<3	<1.02

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



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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