







Test Report SL52025246245601TX Date:June 23,2020 Page 1 of 4

3A MEDICAL PRODUCTS CO.,LTD

GONGYE ROAD #1, YUAN DISTRICT, LUAN CITY, ANHUI PROVINCE, P.R.CHINA

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

Sample Description : (A)Surgical mask

SGS Internal Ref No. : SHHL2004513394MD

Style No. : Mask with earloops 17.5\*9.5

Sample Color : (A)blue

Manufacturer : 3A MEDICAL PRODUCTS CO.,LTD

Country of Origin : China

Lot No./Batch No. : Not provided

Proposed Care Instruction: /

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

Sample Receiving Date : Apr 29, 2020

Testing Period : Apr 29, 2020 - Jun 23, 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 (Account Executive)



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Test Result

# Standard Specification for Performance of Materials Used in Medical Face Masks

(ASTM F2100-19)

## Section 6.1 Bacterial filtration efficiency (BFE)\*

(ASTM F2101-19)

Sample: A

**Conditioning Parameters** Minimum of 4 hours at 21±5°C and 85±5% R.H.

Dimensions of test specimen ~167 mm x ~175 mm

~60 cm<sup>2</sup> Test Area Test Side Inside Flow Rate 28.3 l/min Positive Control Average 2.5 x 103 CFU **Negative Monitor Count** < 1 CFU

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

Remark: Performance Requirement: Level 1≥95%, Level 2≥98%, Level 3≥98%

### Section 6.1 Differential pressure

(EN 14683 :2019+AC :2019 Annex C, Flow rate 8 I/min)

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 cm<sup>2</sup> Flow Rate 8 I/min

1# 2# 3# 4# 5# Differential pressure 4.5 4.6 4.7 4.6 4.5  $\triangle P \text{ (mm H2O/cm}^2)$ 

Remark: Performance Requirement: Level 1<5.0 mmH2O/cm<sup>2</sup>, Level 2<6.0 mmH2O/cm<sup>2</sup>, Level 3<6.0 mmH2O/cm<sup>2</sup>

#### Section 6.1 Sub-micron particulate filtration efficiency(PFE)\*

(ASTM F2299) Sample: A

Area Tested 91.5 cm<sup>2</sup> Test Side Inside Particle Size 0.1 µ m Standard Deviation 0.089

> 1# 2# 3# 4# 5# (PFE), % 99.68 99.78 99.65 99.79 99.58

Remark: Performance Requirement: Level 1≥95%, Level 2≥98%, Level 3≥98%

<sup>\*</sup> Tests denoted with an \* in this test report have been subcontracted to another ISO 17025 Accredited Laboratory.



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#### Section 6.1 Resistance to Penetration by Synthetic Blood

(ASTM F1862/F1862M-2017)

Pressure 120mmHg

Penetration	on inside sur	face					
1#	2#	3#	4#	5#	6#	7#	8#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
9#	10#	11#	12#	13#	14#	15#	16#
Fail	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:			31				
Overall result:			Acceptable				

#### Remark:

- 1) Performance Requirement Level 1 Barrier: 80mmHg, Level 2 Barrier: 120mmHg, Level 3 Barrier: 160mmHg
- 2) Distance of the medical face mask target area surface to the tip of cannula is 30.5cm.
- 3) Condition and Test temperature (21±5)° C, relative humidity (85±5)%
- 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

#### Section 6.2 Flammability

(16 CFR Part 1610 - 2008)

Sample: AFabric Surface: SmoothTest Specimen Direction: Length

	As Received			
	Burn Code			
(1)	IBE			
(2)	IBE			
(3)	IBE			
(4)	IBE			
(5)	IBE			

Flammability Classification: Class 1

Requirement: Class 1 for Level 1/ Level 2/ Level 3

**Conclusion: Pass** 

**Remarks** 

Class 1 Normal Flammability

Class 1 textiles exhibit normal flammability and are acceptable for use in clothing.

#### **Burn Code Description:**

IBE = Ignited, but extinguished



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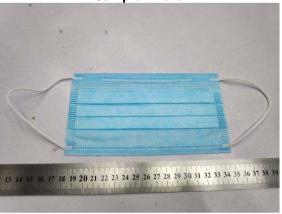
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The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

\*\*\*End of Report\*\*\*



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