



# Test Report

No.T32120250503SN

Date: May 20, 2021

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SAVEWO LIMITED  
1/F, 266-270 TEXACO ROAD, TSUEN WAN, N.T., HONG KONG

The following samples were submitted and identified by/on behalf of the client as:

SMILE

Case No. : CA321202529029  
Lot No. / Batch Code : NOT PROVIDED  
Sample Description : WHITE MASK WITH PLASTIC FILM  
Style / Item No. : SMILE  
Quantity Submitted : 150 PCS  
Supplier : SAVEWO LIMITED  
Manufacturer : SAVEWO LIMITED  
Country of Origin : HONG KONG  
Sample Receiving Date : APR 21, 2021, APR 27, 2021 AND MAY 14, 2021  
Testing Period : APR 21 TO MAY 20, 2021

Test Requested	Conclusion
ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks	PASS (Level 3)

\*\*\*\*\* FOR FURTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S) \*\*\*\*\*

Signed for and on behalf of  
SGS Hong Kong Ltd.

Au Kam Chi, Gigi  
Technical Manager

Signed for and on behalf of  
SGS Hong Kong Ltd.

Tsang Chuk Hai  
Senior Microbiologist

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**Test Results:**

**ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks**

Scope : This specification covers testing and requirements for materials used in the construction of medical face masks that are used in providing healthcare services such as surgery and patient care. This specification provides for the classification of medical face mask material performance.

Number of Specimen : 150 pcs of complete product

<u>Clause</u>	<u>Test Items/requirement</u>	<u>Test Result Summary</u>
<b>5</b>	<b><u>Classification</u></b>	See Table 1
<b>6</b>	<b><u>Requirements</u></b>	
6.1	The properties of the medical face mask material shall conform to the specifications requirements in Table 1, as tested in accordance with Section 9. ^Bacterial filtration efficiency (ASTM F2101) ^Differential pressure (EN 14683:2019 Annex C) ^Sub-Micron Particulate Filtration (ASTM F2299) Resistance to penetration by synthetic blood (ASTM F1862)	> 98% < 6.0 mm H <sub>2</sub> O/cm <sup>2</sup> > 98% Penetration not seen at 160 mm Hg
6.2	^Flammability 16 CFR Part 1610	Class 1

Note:

- ^ Results of compliance for tests requested is justified according to decision rule based on the non-binary statement with guard band (is equal to the expanded measurement uncertainty with a 95% coverage probability,  $w = U_{95}$ ) as stated in ILAC-G8:09/2019 Clause 4.2.3.  
 "Pass - The measured values were observed in tolerance at the points tested. The specific false accept risk is up to 2.5%."  
 "Fail - One or more measured values were observed out of tolerance at the points tested". The specific false reject risk is up to 2.5%.

Table 1 Medical Face Mask Material Requirements by Performance Level

<b>Characteristics</b>	<b>Level 1 Barrier</b>	<b>Level 2 Barrier</b>	<b>Level 3 Barrier</b>
Bacterial filtration efficiency, %	≥ 95	≥ 98	≥ 98
Differential pressure, mm H <sub>2</sub> O/cm <sup>2</sup>	< 5.0	< 6.0	< 6.0
Sub-micron particulate filtration efficiency at 0.1 micron, %	≥ 95	≥ 98	≥ 98
Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result <sup>#</sup>	80	120	160
Flame spread	Class 1	Class 1	Class 1

<sup>#</sup> - 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.

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**Result 1 Bacterial filtration efficiency ASTM F2101-19**

Test Side : Inside  
 Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.  
 Dimensions of test specimen : 215 mm x 150 mm  
 BFE Test Area : 49 cm<sup>2</sup>  
 BFE Flow Rate : 28.3 l/min  
 Test bacteria : Staphylococcus aureus ATCC 6538  
 Mean Particle Size : 2.8 µm  
 Positive Control Average : 2.6 x 10<sup>3</sup> CFU  
 Negative Monitor Count : < 1 CFU

Test Specimen	Percent BFE (%)
1	99.9
2	99.9
3	99.9
4	99.9
5	99.9

Note: Plate count total for each stage can be provided upon request.

**Result 2 Differential pressure EN14683:2019+AC:2019 Appendix C**

Test Side : Inside  
 Test Location (Target Area) : See below as specified by client  
 Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.  
 Test Area : 4.9 cm<sup>2</sup>  
 Flow Rate : 8 l/min

Test Location	ΔP (mm H <sub>2</sub> O/cm <sup>2</sup> )				
	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5
Top Centre	4.1	4.1	4.0	3.8	4.3
Centre Left	4.4	4.1	3.9	4.2	4.1
Centre Right	4.8	4.2	4.2	4.7	4.8
Bottom Left	4.1	4.1	4.1	4.1	3.9
Bottom	4.0	3.9	4.0	3.9	4.2
Bottom Right	4.0	4.0	4.1	3.8	4.2
Average	4.2	4.1	4.1	4.1	4.3

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Result 3 Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres (ASTM F2299/F2299M-03 (Reapproved 2017))

Test Side : Fabric (Raw Material)  
Pre-Conditioning : Minimum of 4 hours at 21±3°C and 30-50±5% R.H.  
Test Condition : 21±3°C and 50±5% R.H.  
Test Area : 41.61 cm<sup>2</sup>  
Face Velocity : 9.13 cm/s  
Particle Size : 0.1 µm (+/-7.5% CV) Latex Microspheres  
Average Filtration Efficiency : 99.96%  
Standard Deviation : 0.002

Test Specimen	Pressure Drop (inH <sub>2</sub> O)	Downstream Particle Count	Upstream Particle Count	Filtration Efficiency (%)
1	0.336	122	316886	99.96%
2	0.326	123	301698	99.96%
3	0.345	118	287914	99.96%
4	0.340	103	245356	99.96%
5	0.348	96	266469	99.96%

Note: The procedure incorporated a non-neutralized challenge. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks.

Result 4 Resistance to penetration by synthetic blood ASTM F1862/F1862M-17

Test Side : Outside  
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.  
Test Condition : 21±5°C and 85±10% R.H.  
Test Pressure : 160 mmHg  
No of Test Specimen Tested : 32  
No of Test Specimen Passed : 32

Test Specimen #	Synthetic Blood Penetration
1-32	None Seen

Note: Sample was tested in the stage of spreading the pleats out when mounted on the test fixture.

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Result 5 Flammability Test of Clothing Textiles (16 CFR Part 1610 - October 20, 2008 Edition)

Sample : Fabric (Raw Material)  
Fabric Surface : Plain (Face)  
Test Specimen Direction : Length

<b>As Received</b>		
	<u>Flame Spread (sec.)</u>	<u>Burn Code</u>
(1)	--	DNI
(2)	--	DNI
(3)	--	DNI
(4)	--	DNI
(5)	--	DNI
<b>Flammability Classification:</b>		Class 1
<b>Requirement:</b>		Class 1

**Remarks:**

- Class 1 – Normal Flammability**  
 Class 1 textiles exhibit normal flammability and are acceptable for use in clothing.  
 Test Criteria for plain surface textile fabric:  
 (A) There are no burn times; or  
 (B) There is only one burn time and it is equal to or greater than 3.5 seconds; or  
 (C) The average burn time of two or more specimens is equal to or greater than 3.5 seconds.
- Disposable fabrics and garments shall not apply to be refurbished before testing.

**Burn Code Description:**

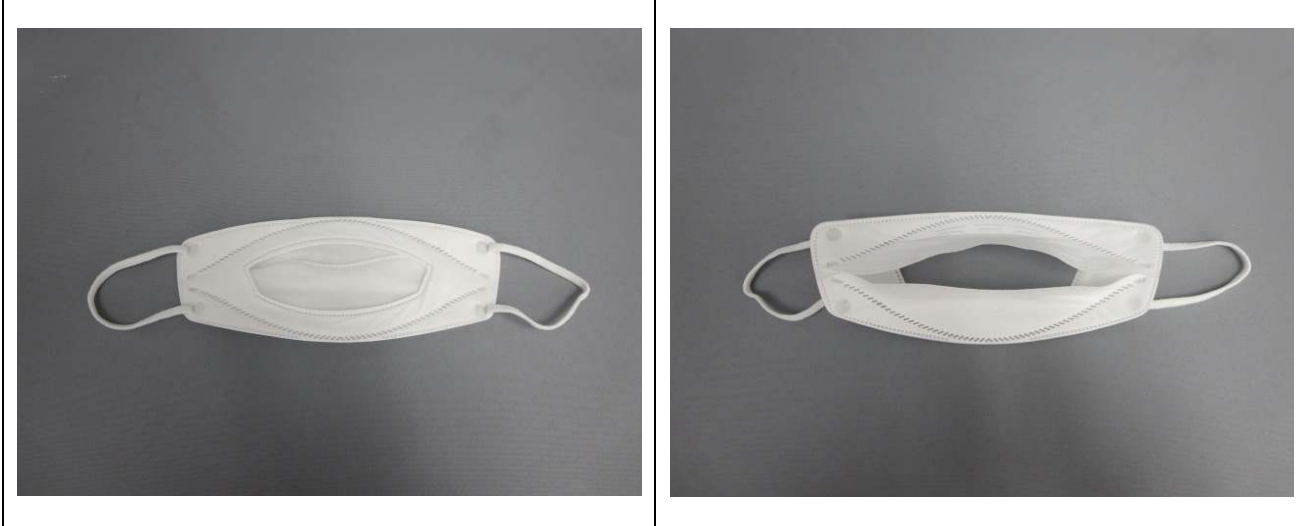
DNI = Did not ignite

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**Sample Photo:**

Sample Picture (As received)



SGS authenticate the photo on original report only

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

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