

Test Report

No.T32120300552SN

Date: Oct 18, 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:

3D BEAR

Case No. : CA321203033029
 Style No. : 3DBEAR
 Lot No. / Batch Code : NOT PROVIDED
 Sample Description : WHITE MASK
 Manufacturer / Supplier : SAVEWO LIMITED
 Country of Origin : HONG KONG
 Sample Receiving Date : SEP 27, 2021
 Testing Period : SEP 27, 2021 – OCT 18, 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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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 : 100 pcs of complete product and raw material

<u>Clause</u>	<u>Test Items/requirement</u>	<u>Test Result Summary</u>
5	Classification	See Table 1
6	Requirements	
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 ₂ O/cm ² > 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

Characteristics	Level 1 Barrier	Level 2 Barrier	Level 3 Barrier
Bacterial filtration efficiency, %	≥ 95	≥ 98	≥ 98
Differential pressure, mm H ₂ O/cm ²	< 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 [#]	80	120	160
Flame spread	Class 1	Class 1	Class 1

- 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 : White Fabric (Raw Material)
 Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
 Dimensions of test specimen : 220 mm x 220 mm
 BFE Test Area : 49 cm²
 BFE Flow Rate : 28.3 l/min
 Test bacteria : Staphylococcus aureus ATCC 6538
 Mean Particle Size : 2.8 µm
 Positive Control Average : 2.3 x 10³ 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
 Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
 Test Area : 4.9 cm²
 Flow Rate : 8 l/min

Test Location	ΔP (mm H ₂ O/cm ²)				
	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5
Top Centre	3.7	4.3	4.4	4.2	4.2
Centre	5.1	4.8	4.6	4.2	4.6
Bottom Centre	4.6	5.3	4.3	4.9	4.9
Centre Left	5.6	4.8	5.2	5.4	5.2
Centre Right	5.6	4.9	5.6	4.8	4.9
Average	4.9	4.8	4.8	4.7	4.8

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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 : White 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 cm²
 Face Velocity : 9.86cm/s
 Particle Size : 0.1 µm (+/-7.5% CV) Latex Microspheres
 Average Filtration Efficiency : 99.88%
 Standard Deviation : 0.02

Test Specimen	Pressure Drop (inH ₂ O)	Downstream Particle Count	Upstream Particle Count	Filtration Efficiency (%)
1	0.297	251	253616	99.90%
2	0.311	292	198368	99.85%
3	0.356	317	245760	99.87%
4	0.312	288	245351	99.88%
5	0.304	284	254231	99.89%

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

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

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

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

Sample Photo:

Sample Picture (As received)



SGS authenticate the photo on original report only

*** End of Report ***

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