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OASIS MEDICAL TECHNOLOGY LTD FLAT/RM 13-24, 2/F SINO INDUSTRIAL PLAZA,9 KAI CHEUNG ROAD,KOWLOON BAY,Hong Kong

Job No. : HKHC200400001385

The following sample was submitted and identified by the client as Oasis Medicare Surgical Masks

Product Description	:	Oasis Medicare Surgical Masks
Quantity Received	:	2 boxes x 50 pcs/box
Sample Appearance	:	Blue mask
Item No.	:	OM-A01
SGS Sample No.	:	HKHC200400001385-101
Sample Receiving Condition	:	In unopened paper box original package under ambient condition
Manufacturer / Supplier	:	Oasis Medical Technology Ltd
Country of Origin	:	Hong Kong
Sample Receiving Date	:	Apr 20, 2020
Testing Period	:	Apr 20, 2020 – Jun 01, 2020

Test Requested

1. To perform Bacterial Filtration Efficiency Test and Differential Pressure Test on the submitted sample.

- 2. To perform Particle Filtration Efficiency Test on the submitted sample.
- 3. To perform Synthetic blood fluid penetration resistance test on the submitted sample.
- 4. To perform Flammability test on the submitted sample.

Test Methods and Test Results

Please refer to the following page(s).

Signed for and on behalf of SGS Hong Kong Ltd.

HO CHI MING, RICKY SENIOR MANAGER - COSMETICS, PERSONAL CARE & HOUSEHOLD SERVICES Signed for and on behalf of SGS Hong Kong Ltd.

WONG KIN MAN, GILMAN TECHNICAL DEVELOPMENT MANAGER - COSMETICS, PERSONAL CARE & HOUSEHOLD SERVICES



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Test Methods and Test Results

Test Report

1. Bacterial Filtration Efficiency Test

Summary

The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at $1.7 - 3.0 \times 10^3$ colony forming units (CFU) with a mean particle size (MPS) of $3.0 \pm 0.3 \mu$ m. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19.

Test Side	•	White side
BFE Test Area	• •	~40 cm ²
BFE Flow Rate	•••	28.3 Litres per minute (L/min)
Delta P Flow Rate	•••	8 Liters per minute (L/min)
Conditioning Parameters	•••	85 \pm 5% relative humidity (RH) and 21 \pm 5°C for a minimum of 4 hours
Test Article Dimensions	•••	~174 mm x ~168 mm
Positive Control Average	• •	2.3 x 10 ³ CFU
Negative Monitor Count	:	<1 CFU
MPS	•••	3.0 μm

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Results:

Test Article Number	Percent BFE (%)
1	99.5
2	99.8
3	99.4
4	99.5
5	99.6

Test Article Number	Delta P (mm H ₂ O/cm ²)	Delta P (Pa/cm ²)
1	8.4	82.7
2	7.7	75.9
3	8.3	81.4
4	7.7	75.4
5	8.2	80.0

The filtration efficiency percentages were calculated using the following equation:

% BFE =
$$\frac{C-T}{C}$$
 x 100

C = Positive control average

T= Plate count total recovered downstream of the test article

Note:

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- 2. The analysis was performed by a SGS assessed competent subcontractor laboratory.

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2. Particle Filtration Efficiency Test

Test Report

Summary

This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized (atomized), dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

Three one-minute counts were performed, with the test article in the system, and the results averaged. Three one-minute control counts were performed, without a test article in the system, before and after each test article and the counts were averaged. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the average number of particles penetrating the test article compared to the average of the control values.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. All test method acceptance criteria were met.

Test Side	:	Blue side
Area Tested	•••	91.5 cm ²
Particle Size	•••	0.1 μm
Laboratory Conditions	•••	22°C, 23% relative humidity (RH) at 0303; 22°C, 23% RH
		at 0332
Average Filtration Efficiency	•••	98.55%
Standard Deviation	•••	0.711

Results:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	279	13984	98.0
2	103	13961	99.26
3	293	13920	97.9
4	250	14096	98.2
5	89	14282	99.38

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3. Synthetic blood fluid penetration resistance

Test Report

Summary:

This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2019 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of $21\pm5^{\circ}$ C and a relative humidity of $85\pm10^{\circ}$. Instead, testing was performed at ambient conditions within one minute of removal from the environment chamber held at those parameters.

Number of Test articles tested	•••	32
Number of Test articles passed	• •	32
Test Side	:.	Blue side
Pre-conditioning	:	Minimum of 4 hours at $21 \pm 5^{\circ}$ C and $85 \pm 5^{\circ}$ relative humidity (RH)
Test Conditions	:	20.7°C and 22% RH

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when \geq 29 of 32 test articles show passing results.

Test Pressure: 120 mmHg (16.0 kPa)

Test Article Number	Synthetic Blood Penetration
1-32	None Seen

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4. Flammability test

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

Fabric Surface	:	Smooth
Test Specimen Direction	:	Length

	As Received				
	Flame Spread (sec.)	Burn Code			
(1)		IBE			
(2)		IBE			
(3)		IBE			
(4)		IBE			
(5)		IBE			

Flammability Classification : Class 1

Class 1

Remarks :

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

Burn Code Description:

IBE = Ignited, but extinguished

Note:

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PHOTO APPENDIX



*** End of Report ***

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