Test Report

TL-957

Date : 2020-10-20
No. : HC20100315

Applicant(Code:01325765) : 3i Corporation Limited
Unit B 4/F Chiap King Industrial Building
114 King Fuk Street
San Po Kong Kln HK

Description of Sample(s) : One submitted sample said to be masklab KF Series Respirator.
Batch / Lot No.: 2020-09
Country of Origin : Hong Kong

Sample(s) Received Condition(s): In plastic bag under ambient temperature

Date Sample(s) Received : 2020-10-12

Date Tested : 2020-10-12 to 2020-10-20

Investigation Requested : Performance Test as per ASTM F2100-19
1. Bacterial Filtration Efficiency (BFE) %
   – *Staphylococcus aureus* (ATCC 6538)
2. Particulate Filtration Efficiency (PFE) %
3. Differential Pressure
4. Synthetic Blood Penetration
5. Flammability to Class 1

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Requirement:

Performance Test as per ASTM F2100-19	Level 1	Level 2	Level 3
Bacterial Filtration Efficiency (BFE) % – *Staphylococcus aureus* (ATCC 6538)	≥95%	≥98%	
Particulate Filtration Efficiency (PFE) %	≥95%	≥98%	
Differential Pressure (ΔP)	<5.0 mmH_2O/cm^2	<6.0 mmH_2O/cm^2	
Resistance to Penetration by Synthetic Blood	80 mmHg	120 mmHg	160 mmHg
Flame Speed (Flammability to Class 1)	Class 1 (The time of flame spread is 3.5 seconds or more)		

Summary:

Performance Test as per ASTM F2100-19	masklab KF Series Respirator Batch / Lot No.: 2020-09	
	Level 2	Level 3
Bacterial Filtration Efficiency(BFE) % – *Staphylococcus aureus* (ATCC 6538)	Pass	Pass
Particulate Filtration Efficiency (PFE) %	Pass	Pass
Differential Pressure (ΔP)	Pass	Pass
Resistance to Penetration by Synthetic Blood Penetration	Pass	Pass
Flame Speed (Flammability to Class 1)	Pass	Pass

Note: An acceptable quality limit of 4% shall be used for all required testing to establish conformance of medical face masks to a specific performance class.

Test Result(s):

1. Bacterial Filtration Efficiency (BFE) %

Test method: ASTM F2100-19 9.1 & ASTM F2101-19

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 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19.

All test method acceptance criteria were met.

Specimen(s)	**masklab KF Series Respirator Batch / Lot No.: 2020-09**
1	>99.9%
2	99.8%
3	99.8%
4	99.8%
5	>99.9%

Notes : - Challenge bacteria : *Staphylococcus aureus* (ATCC 6538)
- Positive control average : 1703 CFU
- Negative control average : <1 CFU
- Mean particle size : 2.7µm
- Testing side : Outside of specimen
- Testing area : 47 cm^2
- Precondition : Minimum of 4 hours at (21±5) °C and (85±5) % relative humidity (RH)

2. Particulate Filtration Efficiency (PFE) %

Test method: ASTM F2100-19 9.3 & ASTM F2299-17

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.

150 seconds counts were performed, with the test article in the system, 150 seconds 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 F2299-17. All test method acceptance criteria were met.

Specimen(s)	masklab KF Series Respirator Batch / Lot No.: 2020-09			
	Upstream particle count	Downstream particle count	Resistances to Ventilation (Pa)	PFE %
1	70060	850	78	98.8%
2	67870	550	77	99.2%
3	67370	810	73	98.8%
4	69070	840	75	98.8%
5	71160	300	88	99.6%

Notes : - Flow rate : 28.3 Litre/min
- Challenge particles : 0.1 μm PSL
- Testing area : 100 cm^2
- Testing side : Outside of specimen
- Testing condition : 18 - 24 ^oC, 25 -55 % Relative humidity

3. Differential Pressure

Test method: ASTM F2100-19 9.2 & EN 14683:2019 + AC:2019, Annex C

Summary: The Differential Pressure 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. This test complies with EN14683:2019 + AC:2019, Annex C and ASTM F2100-19.

All test method acceptance criteria were met.

Specimen(s)	Test area (in Pa/cm^2)					Average	
	1	2	3	4	5	Pa/cm^2	mmH_2O/cm^2
1	39.9	38.2	42.4	40.4	41.9	40.6	4.1
2	37.6	35.7	40.6	38.4	45.6	39.6	4.0
3	41.2	40.8	41.0	39.2	41.5	40.7	4.2
4	37.1	35.9	40.4	43.3	38.8	39.1	4.0
5	43.9	41.4	47.0	43.7	49.5	45.1	4.6

Notes : - 1 Pa/cm^2 =9.8 mmH_2O/cm^2
- Flow rate: 8 Litre/min
- Precondition : Minimum of 4 hours at (21±5) ºC and (85±5) % relative humidity (RH)

4. Synthetic Blood Penetration

Test method: ASTM F2100-19 9.4 & ASTM F1862-17

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 30.5cm. 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 F1862-17.

Test Pressure: 120mmHg

Specimen Number	**masklab KF Series Respirator Batch / Lot No.: 2020-09**
1-32	None Seen
Requirement: An acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥ 29 of 32 test specimens show passing result (none seen)	

Test Pressure: 160mmHg

Specimen Number	**masklab KF Series Respirator Batch / Lot No.: 2020-09**
1-32	None Seen
Requirement: An acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥ 29 of 32 test specimens show passing result (none seen)	

Notes : - Test Side: Outside
- Precondition : Minimum of 4 hours at (21±5) °C and (85±5) % relative humidity (RH)
- Testing condition: 18 - 24 °C, 25 -55 % Relative humidity

5. Flammability

Test method: ASTM F2100-19 9.5, 16 CFR 1610

Summary: This procedure was performed to evaluate the flammability of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread. The parameter of time is used to separate materials into different classes, thereby assisting in a judgment of fabric suitability for clothing and protective clothing material. The test procedure was performed in accordance with the test method outlined in 16 CFR Part 1610(a) Step 1 – testing in the original state. Step 2 – Refurbishing and testing after refurbishing, was not performed. All test method acceptance criteria were met.

Specimen(s)	**masklab KF Series Respirator** **Batch / Lot No.: 2020-09** **Time of spread of flame (Original state)**	**Class**
1	Did not ignited	1
2	Did not ignited	
3	Did not ignited	
4	Did not ignited	
5	Did not ignited	

Notes : - Test Side: Outside
- Orientation: Cross

Test Report

Date : 2020-10-20
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Photo(s):

******* End of Test Report *******

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