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**Applicant(Code:01326301) :** JP-PROTECTION ApS  
Skifervej 2, DK-4990 Sakskøbing, Denmark

**Description of Sample(s) :** One submitted sample said to be Medical Face Mask.  
Country of Origin : Denmark

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

**Date Sample(s) Received :** 2021-06-25

**Date Tested :** 2021-06-28 to 2021-07-09

**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



LAU Yuk Kuen, Joey  
Authorized Signatory





## Test Report

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### Requirement:

Performance Test as per ASTM F2100-19	Level 1	Level 2	Level 3
Bacterial Filtration Efficiency (BFE) % – <i>Staphylococcus aureus</i> (ATCC 6538)	≥95%	≥98%	
Particulate Filtration Efficiency (PFE) %	≥95%	≥98%	
Differential Pressure ( $\Delta P$ )	<5.0 mmH <sub>2</sub> O/cm <sup>2</sup>	<6.0 mmH <sub>2</sub> O/cm <sup>2</sup>	
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	Medical Face Mask
	Level 2
Bacterial Filtration Efficiency(BFE) % – <i>Staphylococcus aureus</i> (ATCC 6538)	Pass
Particulate Filtration Efficiency (PFE) %	Pass
Differential Pressure ( $\Delta P$ )	Pass
Resistance to Penetration by Synthetic Blood Penetration	Pass
Flame Speed (Flammability to Class 1)	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.*

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**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  $1.7 - 3.0 \times 10^3$  colony forming units (CFU) with a mean particle size (MPS) of  $3.0 \pm 0.3\mu\text{m}$ . 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)	Medical Face Mask
1	99.9%
2	>99.9%
3	>99.9%
4	99.7%
5	99.9%

Notes : - Challenge bacteria : *Staphylococcus aureus* (ATCC 6538)  
 - Positive control average : 2502CFU  
 - Negative control average : <1 CFU  
 - Mean particle size : 3.1 $\mu\text{m}$   
 - Testing side : Outside of specimen  
 - Testing area : 49 cm<sup>2</sup>  
 - Precondition : Minimum of 4 hours at (21 $\pm$ 5) °C and (85 $\pm$ 5) % relative humidity (RH)

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**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.

The upstream and downstream particle counts at each position were sampled and recorded. The filtration efficiency was calculated using the average number of particles penetrating the test article (downstream particle count) compared to the average of the upstream particle count.

The procedure employed the basic particle filtration method described in ASTM F2299-17. All test method acceptance criteria were met.

Specimen(s)	Medical Face Mask			
	Upstream particle count	Downstream particle count	Resistances to Ventilation (Pa)	PFE %
1	113500	40	29	>99.9
2	113420	0	31	>99.9
3	114420	30	30	>99.9
4	114160	10	30	>99.9
5	113060	10	31	>99.9

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

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### 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 <sup>2</sup> )					Average	
	1	2	3	4	5	Pa/cm <sup>2</sup>	mmH <sub>2</sub> O/cm <sup>2</sup>
1	42.7	41.3	34.4	46.8	33.2	39.7	4.0
2	41.3	41.8	39.0	40.2	38.6	40.2	4.1
3	39.0	38.3	38.4	39.0	44.0	39.7	4.1
4	44.0	39.7	41.7	43.4	36.8	41.1	4.2
5	36.9	40.8	38.0	38.5	43.2	39.5	4.0

Notes : - 1 mmH<sub>2</sub>O/cm<sup>2</sup> = 9.8 Pa/cm<sup>2</sup>  
 - Flow rate: 8 Litre/min  
 - Precondition : Minimum of 4 hours at (21±5) °C and (85±5) % relative humidity (RH)

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#### 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	Medical Face Mask
1-10, 12-32	None Seen
11	Seen
<p><b>Requirement:</b> An acceptable quality limit of 4.0% is met for a normal single sampling plan when <math>\geq 29</math> of 32 test specimens show passing result (none seen)</p>	

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

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**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)	Medical Face Mask	Class
	Time of spread of flame (Original state)	
1	Did not ignite	1
2	Did not ignite	
3	Did not ignite	
4	Did not ignite	
5	Did not ignite	

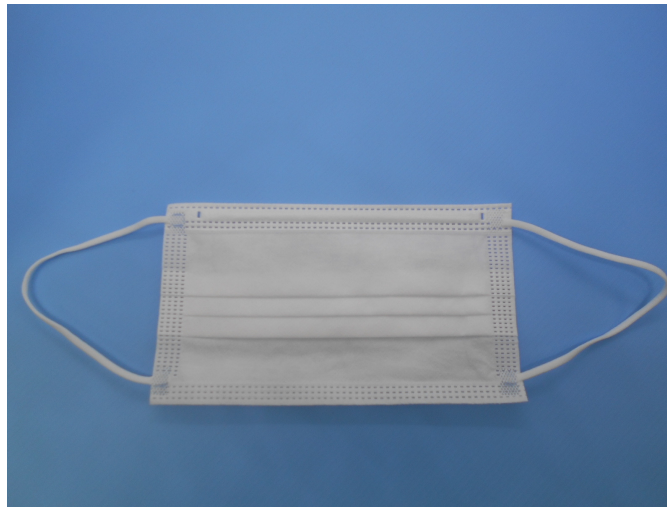
Notes : - Test Side: Outside  
- Orientation: Cross

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**Photo(s):**



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



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