

Date : 2021-03-18  
No. : HC21030298

Page 1 of 7

**Applicant(Code:01325900) :** Savewo Limited  
1/F  
266-270 Texaco Road  
Tsuen Wan NT HK

**Description of Sample(s) :** One submitted sample said to be Extreme Pro.  
Model No.: 3D5PX  
Country of Origin : Hong Kong

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

**Date Sample(s) Received :** 2021-03-08

**Date Tested :** 2021-03-10 to 2021-03-17

**Investigation Requested :** Performance Test as per EN 14683:2019 + AC:2019  
1. Bacterial Filtration Efficiency (BFE) %  
– *Staphylococcus aureus* (ATCC 6538)  
2. Differential pressure  
3. Microbial cleanliness (Bioburden)  
4. Splash resistance



LAU Yuk Kuen, Joey  
Authorized Signatory





**STC**  
Test Report

Date : 2021-03-18  
No. : HC21030298

Page 2 of 7

**Requirement:**

Performance Test as per EN 14683:2019 + AC:2019	Type I	Type II	Type IIR
Bacterial Filtration Efficiency(BFE) % – <i>Staphylococcus aureus</i> (ATCC 6538)	≥95%	≥98%	
Breathability (Differential pressure)	<40 Pa/cm <sup>2</sup>		<60 Pa/cm <sup>2</sup>
Microbial Cleanliness (Bioburden)	≤30 cfu/g		
Splash Resistance	Not Required		Pass at ≥16.0kPa (≥120 mmHg)

**Summary:**

Performance Test as per EN 14683:2019 + AC:2019	Extreme Pro Mode No.: 3D5PX
	Type IIR
Bacterial Filtration Efficiency (BFE) % – <i>Staphylococcus aureus</i> (ATCC 6538)	PASS
Breathability (Differential pressure)	PASS
Microbial Cleanliness (Bioburden)	PASS
Splash Resistance	PASS

Date : 2021-03-18  
No. : HC21030298

Page 3 of 7

**Test Result(s):**

**1. Bacterial Filtration Efficiency (BFE) %**

**Test method:** EN 14683:2019 + AC:2019, Annex B

**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 EN 14683:2019 + AC:2019, Annex B

All test method acceptance criteria were met.

Specimen(s)	<b>Extreme Pro Mode No.: 3D5PX</b>
1	>99.9%
2	99.9%
3	99.9%
4	99.9%
5	>99.9%

- Notes :
- Challenge bacteria : *Staphylococcus aureus* (ATCC 6538)
  - Positive control average : 2693 CFU
  - Negative control average : <1 CFU
  - Mean particle size : 3.3 $\mu\text{m}$
  - 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)

Date : 2021-03-18  
No. : HC21030298

Page 4 of 7

## 2. Differential Pressure

**Test method:** 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 EN 14683:2019 + AC:2019, Annex C.

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	35.1	36.7	37.6	44.8	36.8	38.2	3.9
2	35.1	32.8	33.4	38.1	33.6	34.6	3.5
3	33.8	43.8	36.2	33.9	38.4	37.2	3.8
4	35.8	37.2	38.5	41.8	39.7	38.6	3.9
5	35.7	35.7	37.1	39.7	39.5	37.5	3.8

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)

Date : 2021-03-18  
No. : HC21030298

Page 5 of 7

### 3. Microbial cleanliness (Bioburden)

**Test method:** EN 14683:2019 + AC:2019, Annex D

**Summary:** The full mask is aseptically removed from the packaging and placed in a sterile 500ml bottle containing 300ml extraction liquid and shake for 5 min at 250 rpm. 100 ml of the extraction liquid is filtered through a 0.45µm filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) with chloramphenicol for fungi enumeration. The plates are incubated for 3 days at 30°C and 7 days at (20 to 25)°C for TSA and SDA plates respectively. The total bioburden is expressed by addition of the TSA and SDA counts. This test complies with EN14683:2019 + AC:2019, Annex D.

All test method acceptance criteria were met.

Specimen(s)	Mask Weight (g)	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	10.89	12	1
2	11.06	15	1
3	10.95	12	1
4	11.02	18	2
5	11.13	15	1
<b>Mean:</b>			<b>1</b>

Notes : - CFU denotes Colony Forming Unit  
- EN 14683:2019 + AC:2019 requirement: ≤ 30 CFU/g

Date : 2021-03-18  
No. : HC21030298

Page 6 of 7

#### 4. Synthetic Blood Penetration

**Test method:** ISO 22609:2004

**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 ISO 22609:2004 (as referenced in EN14683:2019 + AC:2019) with the following exception: ISO 22609:2004 requires testing to be performed in an environment with a temperature of  $(21\pm 5)^{\circ}\text{C}$  and  $(85\pm 5)\%$  relative humidity (RH). Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

All test method acceptance criteria were met.

**Test Pressure:**  $\geq 120\text{mmHg}$

Specimen Number	Extreme Pro Mode No.: 3D5PX
1-32	None 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

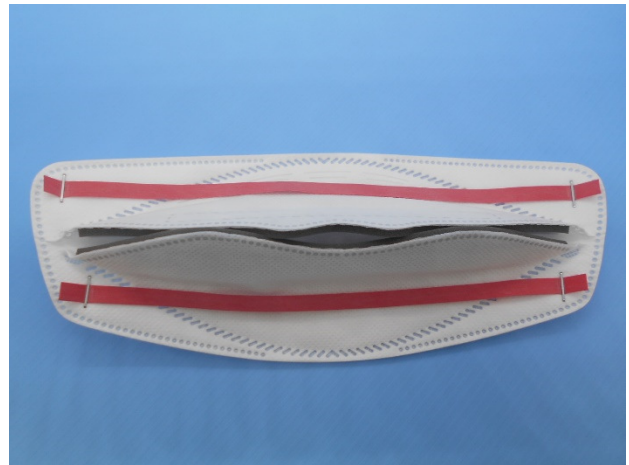
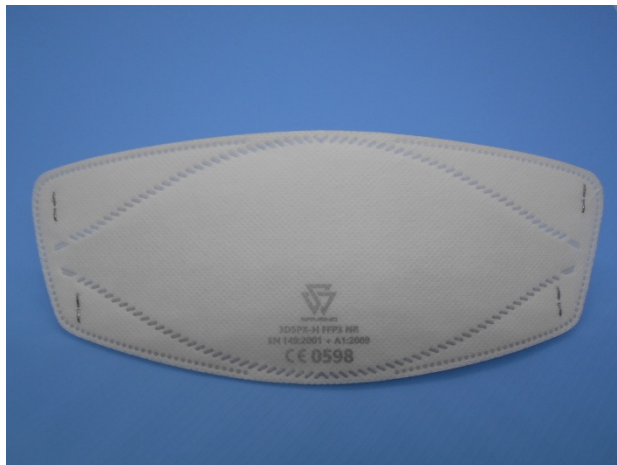
- Precondition : Minimum of 4 hours at  $(21\pm 5)^{\circ}\text{C}$  and  $(85\pm 5)\%$  relative humidity (RH)

**STC**  
**Test Report**

Date : 2021-03-18  
No. : HC21030298

Page 7 of 7

**Photo(s):**



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

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