Test Report

TL-957

Date : 2022-07-04
No. : HC22030416

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 3DMask Ultra.
Country of Origin : Hong Kong

Sample(s) Received Condition(s): In intact original package under ambient temperature

Date Sample(s) Received : 2022-03-16

Aging schedule : 2022-03-16 to 2022-06-21 (97 days)

Date Tested : 2022-06-23 to 2022-07-04

Investigation Requested : Performance Test as per ASTM F2100-20
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

Remark(s) : Sample was tested after conducted Accelerated Aging Test with Test condition as per ASTM F1980-16: Accelerated Aging Temperature (60°) for 97 days to accelerate 3 years.
- see details in Appendix (page 8)

LAU Yuk Kuen, Joey
Authorized Signatory

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Tel: +852 2666 1888 Fax: +852 2664 4353 Email: hkstc@stc.group Website: www.stc.group

Requirement:

Performance Test as per ASTM F2100-20	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 F2100-120	3DMask Ultra
	Level 3
Bacterial Filtration Efficiency(BFE) % – *Staphylococcus aureus* (ATCC 6538)	Pass
Particulate Filtration Efficiency (PFE) %	Pass
Differential Pressure (ΔP)	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.

Test Result(s):

1. Bacterial Filtration Efficiency (BFE) %

Test method: ASTM F2100-20 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)	3DMask Ultra
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 : 2770 CFU
- Negative control average : <1 CFU
- Mean particle size : 3.1µm
- Testing side : Outside of specimen
- Testing area : 49 cm^2
- Precondition : Minimum of 4 hours at (21±5) ºC and (85±5) % relative humidity (RH)

2. Particulate Filtration Efficiency (PFE) %

Test method: ASTM F2100-20 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)	3DMask Ultra			
	Upstream particle count	Downstream particle count	Resistances to Ventilation (Pa)	PFE
1	66980	30	36	>99.9%
2	68350	10	37	>99.9%
3	67900	40	36	>99.9%
4	58100	40	36	>99.9%
5	53470	50	35	>99.9%

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 F2100-20 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.

Sample : 3DMask Ultra

Specimen(s)	Test area (in Pa/cm^2)					Average	
	1	2	3	4	5	Pa/cm^2	mmH_2O/cm^2
1	52.1	49.6	58.7	57.5	58.8	55.3	5.6
2	55.7	52.2	50.0	58.5	50.8	53.4	5.5
3	57.0	55.7	53.4	55.3	52.6	54.8	5.6
4	53.6	53.8	54.8	56.6	55.5	54.9	5.6
5	54.3	45.0	54.6	57.6	51.8	52.7	5.4

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

4. Synthetic Blood Penetration

Test method: ASTM F2100-20 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: 160mmHg

Specimen Number	**3DMask Ultra**
1-19, 21-32	None Seen
20	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 F2100-20 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)	3DMask Ultra	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

Appendix:

Accelerated Aging test:

Test Condition:

Accelerated Aging Temperature: 60ºC

Q10 = 2

Parameters:

Q_{10}	T_{AA}	T_{RT}	AAF	Desired RT	AAT
2	60 ºC	25 ºC	11.3	1095 days	97 days

Note:

Q_{10} : Arrhenius reaction rate function states that a 10ºC increase or decrease in temperature of a homogeneous process results in approximately, a two times or 1/2-time change in the rate of a chemical reaction (Q_{10} =2)

T_{AA} : Selected Accelerated Aging Temperature (ºC);

TRT: Ambient Temperature (ºC)

AAF (Accelerated Aging factor) = $Q_{10}^{[(T_{AA}-T_{RT})/10]}$

Desired RT: Desired Simulated Real Time

AAT: Accelerated Aging Time to simulate a Desired RT

AAT = Desired RT/ AAF

Calculation for accelerated aging time:

Accelerated Aging factor (AAF) = $Q_{10}^{[(T_{AA}-T_{RT})/10]} = 2^{[(60-25/10)]} = 11.3$

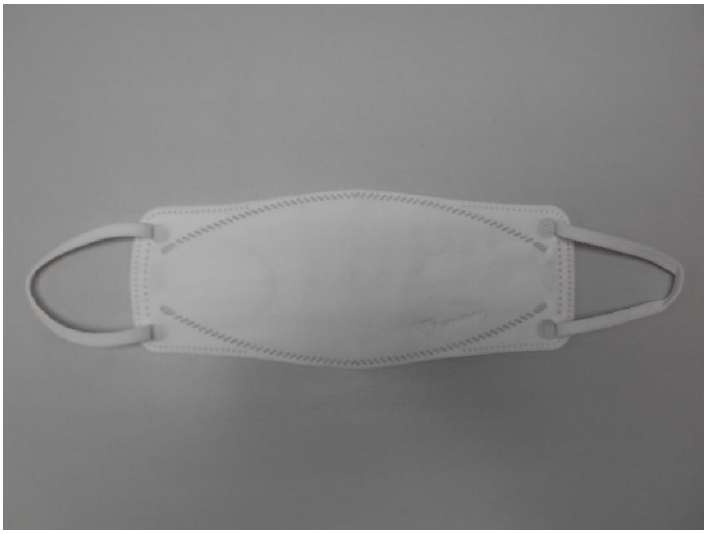
Accelerated Aging Time (AAT) = Desired (RT)/AAF = 1095/11.3 = 97 days

Aging Schedule:

From 2022-03-16 to 2022-06-21

Test Report

Photo(s):



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5. The results in Report apply only to the sample as received and do not apply to the bulk, unless the sampling has been carried out by the Company and is stated as such in the Report.

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10. Clients wishing to use the Report in court proceedings or arbitration shall inform the Company to that effect prior to submitting the sample for testing.

11. Subject to the variable length of retention time for test data and report stored hereinto as to otherwise specifically required by individual accreditation authorities, the Company will only keep the supporting test data and information of this test report for a period of three years. The data and information will be disposed of after the aforementioned retention period has elapsed. Under no circumstances shall we provide any data and information which has been disposed of after the retention period. Under no circumstances shall we be liable for damages of any kind, including (but not limited to) compensatory damages, lost profits, lost data, or any form of special, incidental, indirect, consequential or punitive damages of any kind, whether based on breach of contract of warranty, tort (including negligence), product liability or otherwise, even if we are informed in advance of the possibility of such damages.

12. Issuance records of the Report are available on the internet at www.stc.group. Further enquiry of validity or verification of the Reports should be addressed to the Company.

Test Report

TL-957

Date : 2022-07-04
No. : HC22030417

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 3DMask Ultra.
Country of Origin : Hong Kong

Sample(s) Received Condition(s): In intact original package under ambient temperature

Date Sample(s) Received : 2022-03-16

Aging schedule : 2022-03-16 to 2022-06-21 (97 days)

Date Tested : 2022-06-23 to 2022-07-04

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

Remark(s) : Sample was tested after conducted Accelerated Aging Test with Test condition as per ASTM F1980-16: Accelerated Aging Temperature (60°) for 97 days to accelerate 3 years.
- see details in Appendix (page 7)

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Authorized Signatory

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Requirement

Performance Test as per EN 14683:2019 + AC:2019	**Type I**	**Type II**	**Type IIR**
Bacterial Filtration Efficiency(BFE) % – *Staphylococcus aureus* (ATCC 6538)	≥95%	≥98%	
Breathability (Differential pressure)	<40 Pa/cm^2		<60 Pa/cm^2
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	**3DMask Ultra**
	Type IIR
Bacterial Filtration Efficiency (BFE) % – *Staphylococcus aureus* (ATCC 6538)	Pass
Breathability (Differential pressure)	Pass
Microbial Cleanliness (Bioburden)	Pass
Splash Resistance	Pass

Test Report

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 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 EN 14683:2019 + AC:2019, Annex B

All test method acceptance criteria were met.

Specimen(s)	3DMask Ultra
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 : 2770 CFU
- Negative control average : <1 CFU
- Mean particle size : 3.1µm
- Testing side : Outside of specimen
- Testing area : 49 cm^2
- Precondition : Minimum of 4 hours at (21±5) ºC and (85±5) % relative humidity (RH)

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.

Sample : 3DMask Ultra

Specimen(s)	Test area (in Pa/cm^2)					Average	
	1	2	3	4	5	Pa/cm^2	mmH_2O/cm^2
1	52.1	49.6	58.7	57.5	58.8	55.3	5.6
2	55.7	52.2	50.0	58.5	50.8	53.4	5.5
3	57.0	55.7	53.4	55.3	52.6	54.8	5.6
4	53.6	53.8	54.8	56.6	55.5	54.9	5.6
5	54.3	45.0	54.6	57.6	51.8	52.7	5.4

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

3. Microbial cleanliness (Bioburden)

Test method: EN 14683:2019 + AC:2019, Annex D and EN ISO 11737-1: 2018

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 and EN ISO 11737-1: 2018.

All test method acceptance criteria were met.

Sample : 3DMask Ultra

Specimen(s)	Mask Weight (g)	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	4.31	0	<1
2	4.13	6	1
3	4.18	12	3
4	4.27	0	<1
5	4.25	0	<1
		Mean:	**<1**

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

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±5)ºC and (85±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: ≥120mmHg

Specimen Number	**3DMask Ultra**
1-19, 21-32	None Seen
20	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) ºC and (85±5) % relative humidity (RH)

Appendix:

Accelerated Aging test:

Test Condition:

Accelerated Aging Temperature: 60°C

Q10 = 2

Parameters:

Q_{10}	T_{AA}	T_{RT}	AAF	Desired RT	AAT
2	60 °C	25 °C	11.3	1095 days	97 days

Note:

Q_{10} : Arrhenius reaction rate function states that a 10°C increase or decrease in temperature of a homogeneous process results in approximately, a two times or 1/2-time change in the rate of a chemical reaction (Q_{10} =2)

T_{AA} : Selected Accelerated Aging Temperature (°C);

TRT: Ambient Temperature (°C)

AAF (Accelerated Aging factor) = $Q_{10}^{[(T_{AA} - T_{RT})/10]}$

Desired RT: Desired Simulated Real Time

AAT: Accelerated Aging Time to simulate a Desired RT

AAT = Desired RT/ AAF

Calculation for accelerated aging time:

Accelerated Aging factor (AAF) = $Q_{10}^{[(T_{AA}-T_{RT})/10]} = 2^{[(60-25/10)]} = 11.3$

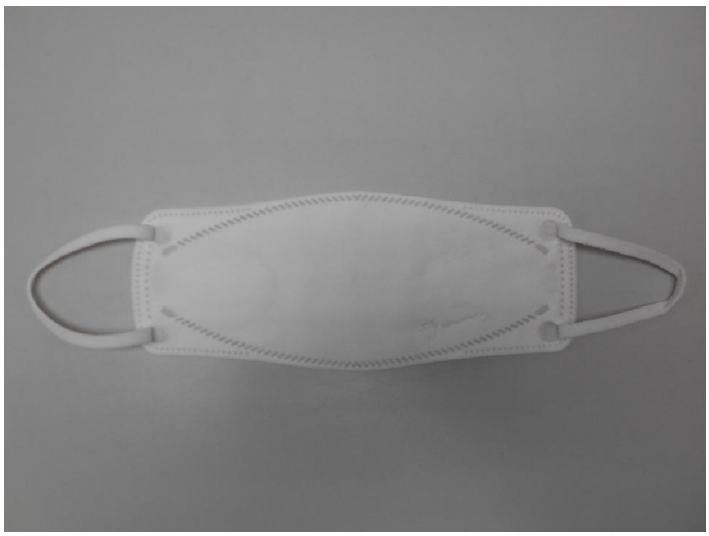
Accelerated Aging Time (AAT) = Desired (RT)/AAF = 1095/11.3 = 97 days

Aging Schedule:

From 2022-03-16 to 2022-06-21

Test Report

Photo(s):



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12. Issuance records of the Report are available on the internet at www.stc.group. Further enquiry of validity or verification of the Reports should be addressed to the Company.