Test Report

中国认可
国际互认
检测
TESTING
CNAS L0413

TL-957

Date : 2022-01-06
No. : HC21120732

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 PremiumMASK.
Country of Origin : Hong Kong

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

Date Sample(s) Received : 2021-12-23

Date Tested : 2021-12-23 to 2022-01-06

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

The Hong Kong Standards and Testing Centre Limited
10 Dai Wang Street, Tai Po Industrial Estate, Tai Po, N.T., Hong Kong
Tel: +852 2666 1888 Fax: +852 2664 4353 Email: hkstc@stc.group Website: www.stc.group

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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	**PremiumMASK**
	Type IIR
Bacterial Filtration Efficiency (BFE) % – *Staphylococcus aureus* (ATCC 6538)	Pass
Breathability (Differential pressure)	Pass
Microbial Cleanliness (Bioburden)	Pass
Splash Resistance	Pass

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)	PremiumMASK
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 : 2422 CFU
- Negative control average : <1 CFU
- Mean particle size : 3.0 µm
- Testing side : Outside of specimen
- Testing area : 46.5 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 : PremiumMASK

Specimen(s)	Test area (in Pa/cm^2)					Average	
	1	2	3	4	5	Pa/cm^2	mmH_2O/cm^2
1	43.5	42.5	35.6	57.0	39.6	43.6	4.5
2	38.7	42.6	35.4	43.9	44.1	40.9	4.2
3	40.2	42.6	39.9	41.7	52.5	43.4	4.4
4	42.6	41.1	43.1	41.5	63.1	46.3	4.7
5	45.5	45.8	42.0	52.7	56.7	48.5	5.0

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 : PremiumMASK

Specimen(s)	Mask Weight (g)	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	3.78	0	<1
2	3.82	3	<1
3	3.78	2	<1
4	3.75	1	<1
5	3.77	1	<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	**PremiumMASK**
1-3, 5-13, 15-26, 28-32	None Seen
4, 14, 27	Penetrated
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)

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Photo(s):

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

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