Test Report

TL-957

Date : 2022-07-18
No. : HC22070055

Applicant(Code: 03300112): Powecom Medical Products HK Company Limited
Room 03 & 06 12/F Fabrico Factory Building
78-84 Kwai Chung Road
Kwai Chung NT HK

Description of Sample(s) : One submitted sample said to be 3 ply Mask Nonwoven Surgical Face Mask.
Style No.: N003 ; N003NP ; N003CH
Brand Name : Powecom 保為康

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

Date Sample(s) Received : 2022-06-22 and 2022-07-05

Date Tested : 2022-06-28 to 2022-06-30 and 2022-07-06 to 2022-07-15

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

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

Test Report

Date : 2022-07-18
No. : HC22070055

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 F2100-20	3 ply Mask Nonwoven Surgical Face Mask Style No.: N003 ; N003NP ; N003CH
	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)	**3 ply Mask Nonwoven Surgical Face Mask Style No.: N003 ; N003NP ; N003CH**
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 : 2024 CFU
- Negative control average : <1 CFU
- Mean particle size : 2.7µm
- 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)	3 ply Mask Nonwoven Surgical Face Mask Style No.: N003 ; N003NP ; N003CH			
	Upstream particle count	Downstream particle count	Resistances to Ventilation (Pa)	PFE %
1	67710	50	25	>99.9
2	67640	20	25	>99.9
3	62690	20	25	>99.9
4	55860	100	25	99.8
5	57420	60	24	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 : 3 ply Mask Nonwoven Surgical Face Mask ; Style No.: N003 ; N003NP ; N003CH

Specimen(s)	Test area (in Pa/cm^2)					Average	
	1	2	3	4	5	Pa/cm^2	mmH_2O/cm^2
1	32.0	38.9	36.0	36.5	33.3	35.3	3.6
2	29.8	34.8	41.3	37.4	39.1	36.5	3.7
3	31.1	34.3	35.4	30.5	32.3	32.7	3.3
4	33.5	29.3	35.3	39.9	33.0	34.2	3.5
5	28.9	30.5	31.7	34.8	30.8	31.3	3.2

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)

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	**3 ply Mask Nonwoven Surgical Face Mask Style No.: N003 ; N003NP ; N003CH**
1-12, 14-16, 18-32	None Seen
13, 17	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) ^{o}C and (85±5) % relative humidity (RH)
- Testing condition: 18 - 24 ^{o}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)	**3 ply Mask Nonwoven Surgical Face Mask Style No.: N003 ; N003NP ; N003CH**	**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.	

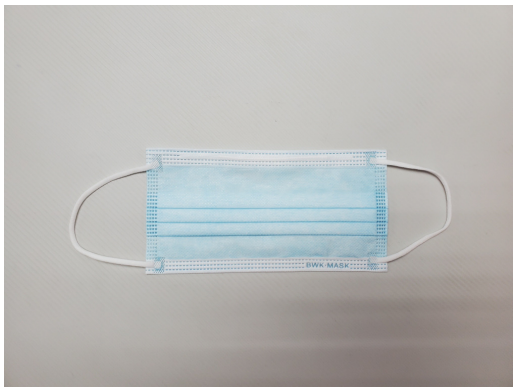
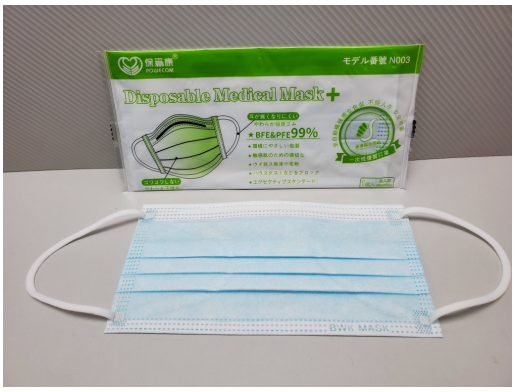
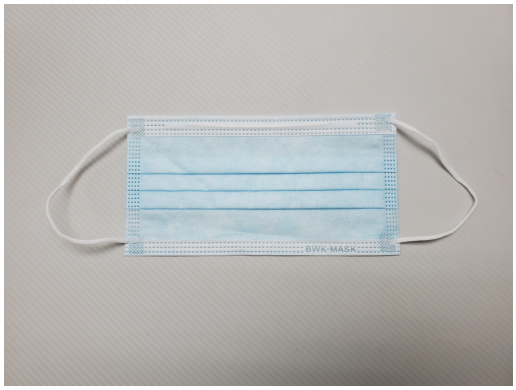
Notes : - Test Side: Outside
- Orientation: Cross

Test Report

Date : 2022-07-18
No. : HC22070055

Photo(s):

3 ply Mask Nonwoven Surgical Face Mask

Style No: N003	
	
Style No: N003NP	Style No: N003CH
	

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

Conditions of Issuance of Test Reports

1. All samples and goods are accepted by The Hong Kong Standards & Testing Centre Limited (the "Company") solely for testing and reporting in accordance with the following terms and conditions. The Company provides its services on the basis that such terms and conditions constitute express agreement between the Company and any person, firm or company requesting its services (the "Clients").

2. Any report issued by the Company as a result of this application for testing service (the "Report") shall be issued in confidence to the Clients and the Report will be strictly treated as such by the Company. It may not be reproduced either in its entirety or in part and it may not be used for advertising or other unauthorized purposes without the written consent of the Company. The Clients to whom the Report is issued may, however, show or send it, or a certified copy thereof prepared by the Company to his customer, supplier or other persons directly concerned. Subject to clause 3, the Company will not, without the consent of the Clients, enter into any discussion or correspondence with any third party concerning the contents of the Report, unless required by the relevant governmental authorities, laws or court orders.

3. The Company shall be at liberty to disclose the testing-related documents and/or files anytime to any third-party accreditation and/or recognition bodies for audit or other related purposes. No liabilities whatsoever shall attach to the Company's act of disclosure.

4. The Company shall not be called or be liable to be called to give evidence or testimony on the Report in a court of law without its prior written consent, unless required by the relevant governmental authorities, laws or court orders.

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.

6. When a statement of conformity to a specification or standard is provided, the ILAC-G8 Guidance document (and/or IEC Guide 115 in the electrotechnical sector) will be adopted as a decision rule for the determination of conformity unless it is inherent in the requested specification or standard, or otherwise specified in the Report.

7. In the event of the improper use the report as determined by the Company, the Company reserves the right to withdraw it, and to adopt any other additional remedies which may be appropriate.

8. Sample submitted for testing are accepted on the understanding that the Report issued cannot form the basis of, or be the instrument for, any legal action against the Company.

9. The Company will not be liable for or accept responsibility for any loss or damage howsoever arising from the use of information contained in any of its Reports or in any communication whatsoever about its said tests or investigations.

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.