Test Report No.: 721653842
Report Date: 24 April 2020

SUBJECT	**Physical & Microbiological Test**
TEST LOCATION	**TÜV SÜD China** TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	[redacted]
CLIENT ADDRESS	[redacted]
TEST PERIOD	08-Apr-2020~22-Apr-2020

Prepared By	**Authorized By**
Bella Xu	Leo Liu
(Bella Xu) Report Drafter	(Leo Liu) Authorized Signatory

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

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TEST REPORT

Sample Description	:	Disposable Face Mask
Sample Quantity	:	50 pieces
Lot Number/Batch Code	:	KTMFM20200322
Specification	:	Adult
Size	:	/
Level of Mask	:	/
Brand Name	:	/

Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Standard	Test Standard Level 1	Judgement
1	Bacterial Filtration EfficiencTest (BFE), %	ASTM F2101-19	⩾ 95	Pass
2	Differential Pressure Test (mmH2O/cm^2)	EN 14683:2019+AC:2019(E) Annex C	< 5.0	Pass
3	Resistance to Penetration by Synthetic Blood Test (minimum pressure in mm Hg for pass result)	ASTM F1862/F1862M-17	80	Pass
4	Flammability Test	16 CFR Part 1610-2012	Class 1	Pass

Note: Pass = Meet customer requirements;
Fail = Fail customer requirements;
# = No comment;
N.D. = Not detected.

Photo of Samples

Results

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency Test	Specimen 1#: 99.6% Specimen 2#: 99.2% Specimen 3#: 99.5% Specimen 4#: 99.4% Specimen 5#: 99.4%
2	Differential Pressure Test	4.7 mmH_2O/cm^2
3	Resistance to Penetration by Synthetic Blood Test	Specimen 1#~32#: None seen
4	Flammability Test	Class 1

Bacterial Filtration Efficiency Test

1. Purpose

For evaluating the bacterial filtration efficiency of masks.

2. Sample description was given by client

Sample description : Disposable Face Mask
Specification : Adult
Lot Number : KTMFM20200322
Sample Receiving Date : 2020-04-08

3. Test Method

ASTM F2101-19.

4. Apparatus and materials

4.1 *Staphylococcus aureus* ATCC 6538.
4.2 Peptone water.
4.3 Tryptic Soy Broth(TSB).
4.4 Tryptic Soy Agar(TSA).
4.5 Bacterial filtration efficiency test apparatus.
4.6 Six-stage viable particle Anderson sampler.
4.7 Flow meters.

5. Test specimen

5.1 As requested by client, take a total of 5 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

6. Procedure

6.1 Preparation of the bacterial challenge: Dilute the cultutre in peptone water to achieve a concentration of approximately 5×10^5 CFU/mL.
6.2 Adjust the flow rate through the Anderson sampler to 28.3 L/min.
6.3 Deliver the challenge to the nebulizer using a syringe pump. Purge tubing and nebulizer of air bubbles.
6.4 Perform a positive control run without a test specime to determine the number of viable aerosol particles being generated. The mean particle size (MPS) of the aerosol will also be calculated from the results of these positive control plates.
  6.4.1 Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer. Immediaterly begin sampling the aerosol using the Anderson sampler.
  6.4.2 Time the challenge suspension to be delivered to the nebulizer for 1 min.
  6.4.3 Time the air pressure and Anderson sampler to run for 2 min.
  6.4.4 At the conclusion of the positive control ran, remove plates from the Anderson sampler.
6.5 Place new agar plates into Anderson sampler and clamp the test specimen into the top of the Anderson sampler, with the inside of the specimen facing towards the bacterial challenge (test area: 77cm²).
6.6 Repeat the challenge procedure for each test specimen.
6.7 Repeat a positive control after completion of the sample set.
6.8 Perform a negative control run by collecting a 2 min sample of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control.
6.9 Incubate agar plates at (37±2)°C for (48±4) h.
6.10 Count each of the six-stage plates of the Anderson sampler.

7. Calculation

Total the count from each of the six plates for the test specimens and positive controls, as specified by the manufacture of Anderson sampler. The filtration efficiency percentages are calculated as follows:

$$BFE=(C-T) / C \times 100$$

T is the total plate count for the test specimen.

C is the mean of the total plate counts for the two positive controls.

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8. Test results*

P Value / Stage Number	Positive Control (A)	Positive Control (B)	Negative Control	Specimen 1#	Specimen 2#	Specimen 3#	Specimen 4#	Specimen 5#
1	55	103	0	0	0	0	0	0
2	78	91	0	0	0	0	0	0
3	156	165	0	0	0	0	0	0
4	423	395	0	0	1	1	1	1
5	1219	1408	0	8	9	10	12	13
6	485	520	0	3	9	1	1	2
Total (*T*), CFU	2416	2682	<1	11	19	12	14	16
Average (C), CFU	$2.5x10^3 = (P_A+P_B) / 2$							
BFE ,%				99.6	99.2	99.5	99.4	99.4
Requirements	Level 1≥ 95							
Remarks	*P* is the value of corresponding corrected particle counts as specified by the manufacturer of the cascade impactor. *T* is the total of *P* value for the test specimen. *C* is the mean of the total of *P* value of the two positive controls.							

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Differential Pressure Test

1.Purpose

The purpose of the test was to measure the differential pressure of masks.

2.Sample description was given by client

Sample description	:	Disposable Face Mask
Specification	:	Adult
Lot Number	:	KTMFM20200322
Sample Receiving Date	:	2020-04-08

3.Test Method

EN 14683:2019+AC:2019(E) Annex C

4. Apparatus and materials

Differential pressure testing instrument

5.Test specimen

5.1 Test specimen are complete masks or shall be cut from masks. Each specimen shall be able to provide 5 different circular test areas of 2.5 cm in diameter.

5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

6. Procedure

6.1 Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump is started and the flow of air adjusted to 8 L/min.

6.2 The pretreated specimen is placed across the orifice (total area 4.9cm², test area diameter 25mm) and clamped into place so as to minimize air leaks.

6.3 Due to the presence of an alignment system the tested area of the specimen should be perfectly in line and across the flow of air.

6.4 The differential pressure is read directly.

6.5 The procedure described in steps 6.1-6.4 is carried out on 5 different areas of the mask and readings averaged.

Results:

Specimen	Test Results* (mmH_2O/cm^2)	Average (mmH_2O/cm^2)	Requirements	Judgement
1#	4.7	4.7	Level 1 < 5.0	Pass
2#	4.6			
3#	4.9			
4#	4.3			
5#	4.9			

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Resistance to Penetration by Synthetic Blood Test

1.Purpose

For evaluation of resistance of masks to penetration by a fixed volume of synthetic blood at a high velocity.

2.Sample description was given by client

Sample description	:	Disposable Face Mask
Specification	:	Adult
Lot Number	:	KTMFM20200322
Sample Receiving Date	:	2020-04-08

3.Test Method

ASTM F1862/F1862M-17

4.Apparatus and materials

4.1 Synthetic blood.
4.2 Tensiometer.
4.3 Synthetic blood penetration test apparatus;
4.4 Targeting plate.
4.5 Air pressure source.
4.6 Ruler.
4.7 Balance.
4.8 Controlled temperature and humidity chamber.

5.Test specimen

5.1 As requested by client, take a total of 32 test specimens.
5.2 Prior to testing, condition all test specimens for a minimum of 4h at (21±5)°C and (85±5) % relative humidity.

6.Procedure

6.1 Prepare the synthetic blood (42±2 mN/m) for the test.
6.2 Determine the density of the synthetic blood.
6.3 Fill the reservoir with new synthetic blood.
6.4 Position the test specimen 30.5 cm (12 in.) from the exit of the canula.
6.5 Set the reservoir pressure to the approximate pressure.
6.6 Place the targeting plate approximately 1 cm away from the mask.
6.7 Set the valve timer to 0.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).

6.8 Set the valve timer to 1.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).

6.9 Calculate the difference in weight of the two spurts. For a test fluid with a density of 1.005, Table 1 gives the target difference in weight plus lower and upper limits for a velocity range within 2% of the target.

Table 1 Target weight differences

Fluid Pressure (mmHg)		Target Velocities (cm/s)	Weight difference for 1 s difference in spurt duration (g)		
(kPa)	(mmHg)		Min.	Target	Max.
10.7	80	450	2.456	2.506	2.556
16.0	120	550	3.002	3.063	3.124
21.3	160	635	3.466	3.537	3.607

6.10 Adjust the reservoir pressure and repeat steps 6.7 to 6.9 until the weight difference is within the target range.

6.11 Record the weight difference for the spurts exiting the nozzle.

6.12 Record the pressure in the reservoir.

6.13 Set the valve time to 0.5 s. Collect and weigh the amount of fluid passing through the targeting hole.

6.14 Set the valve time to 1.5 s. Collect and weigh the amount of fluid passing through the targeting hole.

6.15 The difference in weight between the 0.5 s and 1.5 s spurts through the targeting plate shall be within +2 % ~ -5 % of the difference in weight from the nozzle.

6.16 If the differential weight is less than 95 % of the weight difference exiting the nozzle, check the aim of the stream to make sure it is passing cleanly through the targeting hole.

6.17 If the differential weight is more than 102 % of the weight difference exiting the nozzle, repeat the weight measurements exiting the nozzle (steps 6.7 to 6.11).

6.18 For standard synthetic blood, the timer duration can be estimated using the formula:

t = 0.5 + (2.01 g at 0.5 s) / (g at 1.5 s - g at 0.5 s).

6.19 Record the timer setting to use as the starting point for subsequent testing.

6.20 Mount a test specimen on the specimen holding fixture. If the mask contains pleats, spread the pleats out when mounting the mask onto the fixture to present a single layer of material as the target area.

6.21 Squirt the synthetic blood onto the test specimen for the calculated time. Ensure that the synthetic blood hits the target area of mask.

6.22 Inspect the inside surface for synthetic blood penetration within 10 s of squirting the synthetic blood against the target area.

6.23 Report the results (none / penetration) for each test specimen at the test pressure.

Results:

Specimen	Test Results*	Requirements	Judgement
1#	None Seen	Pass Pressure at 16.0 kPa (120mmHg)	Pass
2#	None Seen		Pass
3#	None Seen		Pass
4#	None Seen		Pass
5#	None Seen		Pass
6#	None Seen		Pass
7#	None Seen		Pass
8#	None Seen		Pass
9#	None Seen		Pass
10#	None Seen		Pass
11#	None Seen		Pass
12#	None Seen		Pass
13#	None Seen		Pass
14#	None Seen		Pass
15#	None Seen		Pass
16#	None Seen		Pass
17#	None Seen		Pass
18#	None Seen		Pass
19#	None Seen		Pass
20#	None Seen		Pass
21#	None Seen		Pass
22#	None Seen		Pass
23#	None Seen		Pass
24#	None Seen		Pass
25#	None Seen		Pass
26#	None Seen		Pass
27#	None Seen		Pass
28#	None Seen		Pass
29#	None Seen		Pass
30#	None Seen		Pass
31#	None Seen		Pass
32#	None Seen		Pass

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Flammability Test

1. Purpose

The purpose of the test was to measure the flammability of masks.

2. Sample description was given by client

Sample description	:	Disposable Face Mask
Specification	:	Adult
Lot Number	:	KTMFM20200322
Sample Receiving Date	:	2020-04-08

3. Test Method

16 CFR Part 1610-2012.

4. Apparatus and materials

4.1. Flammability apparatus.
4.2. Specimen rack with the angle of inclination is 45°.
4.3. Specimen holder.
4.4. Ignition mechanism.
4.5. Stop weight.
4.6. Stop thread supply.
4.7. Timing Device.
4.8. Desiccator.
4.9. Dry cleaning machine.

5. Test specimen

The specimen size is cut as 50 mm by 150 mm (2 in by 6 in).

6. Procedure

6.1. Conduct preliminary trials to determine the quickest burning direction. Test 5 specimens from the quickest burning direction.
6.1.1 Specimen is placed in the holders with the side to be burned face up.
6.1.2 All specimens mounted in the holders and then be dried in the oven for (30±2)min at (105±3)℃. Remove the mounted specimens from the oven and placed in a desiccator until cool but not less than 15min.
6.1.3 Remove one mounted specimen from the desiccator at a time and place it in position on the specimen rack.
6.1.4 String the stop thread through the guides of the specimen holder and the chamber. Hook the stop weight in place close to and just below the stop weight thread guide. Set the timing mechanism to zero. Close the door of the flammability test chamber.
6.1.5 Activate the trigger device. The trigger device controls the impingement of the test flame onto the specimen and starts the timing device. The timing is automatic and stops when the weight is released by the severing of the stop thread.
6.1.6 Record the burn time (reading of the timer) for each specimen, along with visual observation using the test result codes as following:
i) Assign the preliminary classification of Class 1, normal flammability and proceed to step 6.2 when:
(A) There are no burn times; or
(B) There is only one burn time and it is equal to or greater than 3.5s; or
(C) The average burn time of two or more specimens is equal to or greater than 3.5s.
ii) When there is either only one burn time, and it is less than 3.5s; or there is an average burn time of less than 3.5s. Test these five additional specimens from the quickest burning direction. The burn times for the 10 specimens determine whether to:

(A) Stop testing and assign the final classification as Class 3, when there are two or more burn times with an average burn time of less than 3.5 seconds; or
(B) Assign the preliminary classification of Class 1, normal flammability and proceed to step 6.2 when there are two or more burn times with an average burn time of 3.5s or greater.

iii) If there is only one burn time out of the 10 test specimens, the test is inconclusive. The sample cannot be classified.

6.1.7 At the end of each test, turn on the hood fan to exhaust any fumes or smoke, turn of the fan before testing the next specimen.

6.2. According to the burn time, to determine the preliminary classification. If the specimen is Class 1, the specimen needs to be dry cleaned and laundering before testing.

6.2.1 Dry cleaning procedure

Samples are dry cleaned in a commercial dry-cleaning machine, using the following prescribed conditions:

Solvent: Perchloroethylene, commercial grade.
Detergent Class: Cationic.
Cleaning Time: 10~15 minutes.
Extraction Time: 3 minutes.
Drying Temperature: (60~66) °C (140~150) °F.
Drying Time: 18~20 minutes.
Cool Down/Deodorization Time: 5 minutes.

Samples are dry cleaned in a load that is 80% of the machine's capacity.

6.2.2 Laundering procedure.

The samples, after being subjected to the dry-cleaning procedure, are washed and dried one time in accordance with sections 8.2.2, 8.2.3 and 8.3.1(A) of AATCC Test Method 124-2006 "Appearance of Fabrics after Repeated Home Laundering".

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RESULTS:

The Quickest Burning Direction		The outside of face marks.	
The Treatment of Specimens		Be dry cleaned and laundering before testing.	
Specimen	**Burn Time, s**	**Combustion State**	**Average of Burn Time,s**
1#	Non	DNI	Non
2#	Non	DNI	
3#	Non	DNI	
4#	Non	DNI	
5#	Non	DNI	
6#			
7#			
8#			
9#			
10#			
Test Result	Class 1		
Requirements	Class 1		
Remarks	DNI = Did not ignite. IBE = Ignited, but extinguished.		

Note:

1.*denotes this test was carried out by external laboratory assessed as competent.

2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-

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