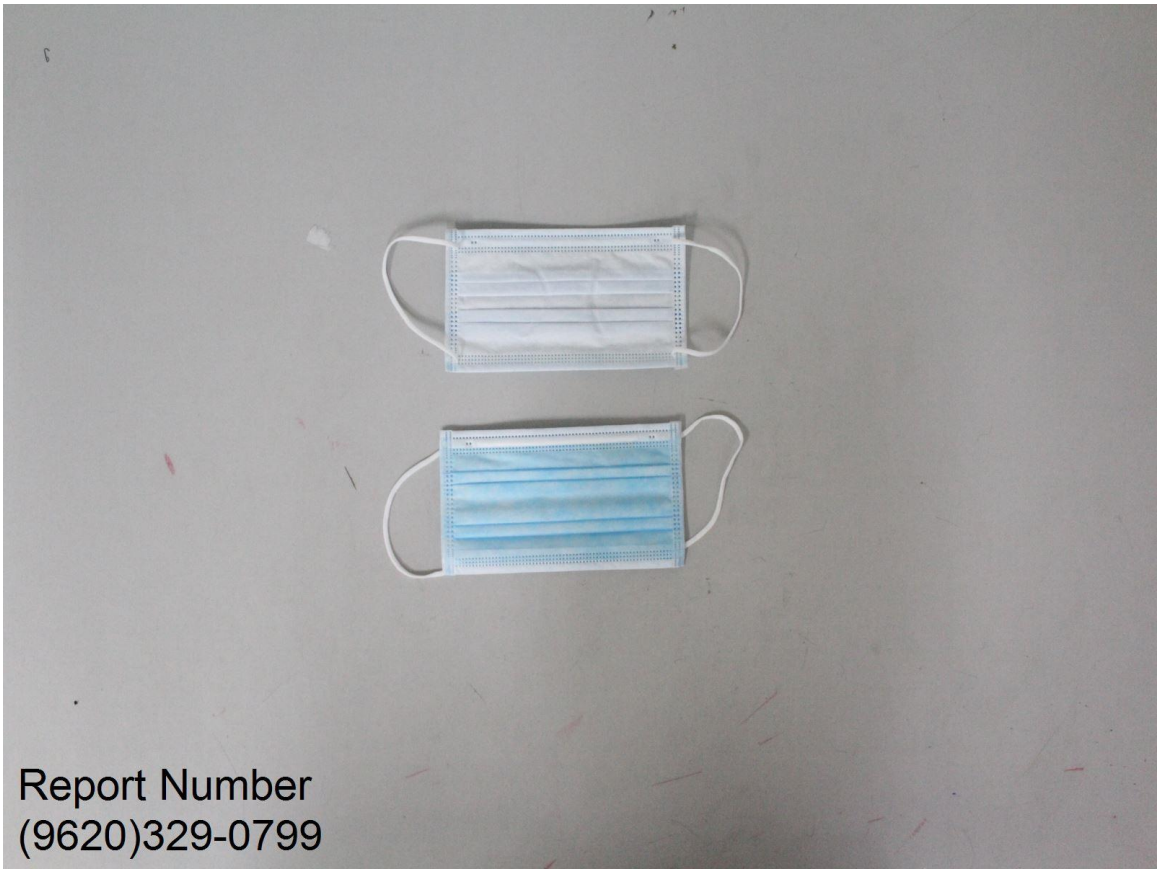
TEST REPORT

Technical Report: (9620)329-0799 (REVISED)



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TEST REPORT

KIM SORA COMPANY LIMITED
STREE NO. 3, HOA KHANH INDUSTRIAL, HOA KHANH BAC WARD, LIEN CHIEU DISTRICT, DA NANG CITY, VIETNAM

ATTN : NGUYEN VAN BAO

LAB NO.:	(9620)329-0799 (REVISED)
FORM NO.:	/
DATE IN:	Nov 25, 2020
MODIFIED DATE:	/
DATE OUT:	Dec 30, 2020
REVISED DATE:	Jan 07, 2021
BUYER:	/
NO. OF WORKING DAYS:	30
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OVERALL RATING	**PASS**

Vendor:	KIM SORA COMPANY LIMITED	**Agent:**	/
Fabric Supplier/Mill:	/	**Factory/Manufacturer:**	/
P.O. No.:	/	**Style No.:**	KIM SORA
Sample Description:	4 PLY MEDICAL MASK (FINSHING: NO TREATMENT)		
Color:	BLUE	**Country of Destination:**	US, EU
Claimed Fabric Weight:	25 GRAM	**Claimed Fabric Count:**	4 PLY

Product Category	MASK COVER
Test Requested	FDA PACKAGE (LEVEL 3)
Previous Report No.	/

Submitted Fiber Content	/
Actual Fiber Content	/
Suggested Fiber Content	/
Submitted Care Instruction(s)	/
Client Expected Care Instruction	/
Suggested Care Instruction(s)	/

C/N

TEST PROPERTY	COMMENTS
FLAMMABILITY OF CLOTHING TEXTILES	PASS
DIFFERENTIAL PRESSURE	PASS
BARRIER TEST – PARTICLE FILTRATION EFFICIENCY (PFE %)	PASS
BACTERIAL FILTRATION EFFICIENCY (BFE) TEST	PASS
SPLASH RESISTANCE	PASS

REMARK:
1. Test was subcontracted to NELSON LABS (A Sotera Health Company).
2. This report was revised on January 7, 2021 for changing to level 3.

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BUREAU VERITAS CPS VIETNAM LTD.

MANDY TRUONG
LAB MANAGER - SOFTLINES

TEST RESULTS

TEST PROPERTY			**REQUIREMENTS**
FLAMMABILITY OF CLOTHING TEXTILES(16 CFR 1610)			
FABRIC SURFACE	PLAIN FIBER SURFACE		
DIRECTION TO BE TESTED	FACE LENGTHWISE		
AS RECEIVED		TIME OF FLAME SPREAD	BURNING CODE
	1	/	IBE
	2	/	IBE
	3	/	IBE
	4	/	IBE
	5	/	IBE
	AVG		
CLASSIFICATION	PASS CLASS 1, NORMAL FLAMMABILITY OF COMMERCIAL STANDARD 16 CFR 1610, FORMERLY 191-53 OF UNITED STATES FLAMMABILITY FABRIC ACT. THE TESTING CONDUCTED AS RECEIVED ONLY. GARMENTS "DAMAGED" BY REFURBISHING		CLASS 1

DNI	DID NOT IGNITE.
IBE	IGNITED, BUT EXTINGUISHED.
SF uc	SURFACE FLASH, UNDER THE STOP THREAD, BUT DOES NOT BREAK THE STOP THREAD.
SF pw	SURFACE FLASH, PART WAY. NO TIME SHOWN BECAUSE THE SURFACE FLASH DID NOT REACH THE STOP THREAD.
SF poi	SURFACE FLASH, AT THE POINT OF IMPINGEMENT ONLY. (EQUIVALENT TO “DID NOT IGNITE” FOR PLAIN SURFACES.)
0.0 sec.	ACTUAL BURN TIME MEASURED AND RECORDED BY THE TIMING DEVICE.
0.0 SF only	TIME IN SECONDS, SURFACE FLASH ONLY. NO DAMAGE TO THE BASE FABRIC.
0.0 SFBB	TIME IN SECONDS, SURFACE FLASH BASE BURN STARTING AT PLACES OTHER THAN THE POINT OF IMPINGEMENT AS A RESULT OF SURFACE FLASH.
0.0 SFBB poi	TIME IN SECONDS, SURFACE FLASH BASE BURN STARTING AT THE POINT OF IMPINGEMENT. THIS RESULT DOES NOT QUALIFY AS A BASE BURN UNDER THE CURRENT INTERPRETATION OF PART OF 16 CFR PART 1610.
0.0 SFBB poi*	TIME IN SECONDS, SURFACE FLASH BASE BURN POSSIBLY STARTING AT THE POINT OF IMPINGEMENT. THE ASTERISK (*) IS ACCOMPANIED BY THE FOLLOWING STATEMENT: “UNABLE TO MAKE ABSOLUTE DETERMINATION AS TO SOURCE OF BASE BURNS.” THIS STATEMENT IS ADDED TO THE RESULT OF ANY SPECIMEN IF THERE IS A QUESTION AS TO ORIGIN OF THE BASE BURN.

TEST RESULTS

TEST PROPERTY	**REQUIREMENTS**

DIFFERENTIAL PRESSURE (BS EN 14683: 2019 ANNEX C, FLOW RATE 8 L PER MIN)

(mmH_2O/cm^2)

1.	3.13
2.	3.62
3.	3.38
4.	3.61
5.	3.16

Requirement
Level 3: < 6.0 mmH_2O/cm^2

TEST RESULTS

BARRIER TEST – PARTICLE FILTRATION EFFICIENCY (PFE %)

(ASTM F2299)

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.

A one-minute count was performed, with the test article in the system. A one-minute control count was performed, without a test article in the system, before and after each test article. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the number of particles penetrating the test article compared to the average of the control values. During testing and controls, the air flow rate is maintained at 1 cubic foot per minute (CFM) ± 5%.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	21.5°C, 22% relative humidity (RH) at 2036; 21.4°C, 22% RH at 2120
Average Filtration Efficiency:	99.72%
Standard Deviation:	0.050

Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	48	14,094	99.66
2	35	14,231	99.75
3	40	13,259	99.70
4	36	12,603	99.71
5	28	13,290	99.79

Requirement

Level 3: PFE: ≥ 98%

TEST RESULTS

BACTERIAL FILTRATION EFFICIENCY (BFE)

Requirement
Level 3≥98

1.1 Reference Standards Item ASTM 2101
Test Method used : ASTM F 2101
1.2 Environmental conditions: (21 ± 5 °C, RH 85 ± 5 %)
1.3 Strain, medium and regent information: Staphylococcus aureus (ATCC 6538)
Solid culture media used Soybean casein digest agar
1.4 Test parameters:
Air flow rate 28.3 L/min
Mean particle diameter of bacterial aerosol (3.0 +/- 0.3) µm

Determination Of Bacterial Suspension Concentration									
Plate 1 (CFU)		**Plate 2 (CFU)**		**Dilution level**			**Concentration (CFU/mL)**		
50		**52**		**-4**			**5.1 x 10^5**		
Groups		**Plate 1**	**Plate2**	**Plate3**	**Plate4**	**Plate 5**	**Plate 6**	**Total**	**BFE**
Negative Control	**r**	1	0	0	0	0	0		**/**
	p	1	0	0	0	0	0	**1**	
Positive Control 1	**r**	14	20	23	71	12	5		**/**
	p	14	20	24	78	12	5	**153**	
Positive Control 2	**r**	17	23	29	84	15	6		**/**
	p	17	24	30	95	15	6	**187**	
Sample 1	**r**	1	2	2	9	1	0		**99.12**
	p	1	2	2	9	1	0	**15**	
Sample 2	**r**	2	2	3	10	2	1		**98.82**
	p	2	2	3	10	2	1	**20**	
Sample 3	**r**	2	3	4	12	2	1		**98.59**
	p	2	3	4	12	2	1	**24**	
Sample 4	**r**	3	4	5	14	2	1		**98.29**
	p	3	4	5	14	2	1	**29**	
Sample 5	**r**	2	3	3	10	2	1		**98.76**
	p	2	3	3	10	2	1	**21**	
Average of positive control			1700						

TEST RESULTS

SPLASH RESISTANCE

3.1 Reference Standards Item :ASTM F 2100
Test method used : ASTM F1862
3.2 Environmental conditions : 24 ºC , 52%RH

3.3 Test parameters:

Pressure (mmHg)	Velocitiy (cm/s)	Time (s)
160	635	0.57

3.4Sample After Tested image

Face side Back side

Picture_160 mmHg Sample after tested

3.5 Test Result
The samples were tested under pressure of 160 mmHg no synthetic blood penetration on the medial side

END OF THE REPORT

C/N