

Analytical Report Nr.

AR-20-YL-003223-01

Sample code Nr.

560-2020-00002921

Date

09/06/2020

ANALYTICAL REPORT

Client Information

3i Corporation Ltd
114 King Fuk Street, Wong Tai Sin - San Po Kong
hong kong HONG KONG
+852 2345 5398
albert@masklab.hk

For the attention of Albert Chen

Sample Information

Order Code: EUAA70-00006543
Reception Date: 11-May-2020
Analysis Starting Date: 11-May-2020
Analysis Ending Date: 9-Jun-2020
Sample described as: 76 masks

Information provided by the customer:

Client Reference: NM201
Sample Description:
Customer requirements: EN 14683:2019+AC:2019
Purchase Order Number:

Batch Not provided

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SAMPLE PICTURE

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CONCLUSION:

TEST PROPERTY	PASS	FAIL	REMARKS
Differential pressure EN 14683:2019+AC:2019 Annex C			
RAW PRODUCT	X		TYPE IIR
Splash resistance pressure ISO 22609:2004			
RAW PRODUCT	X		TYPE IIR
Flammability 16 CFR 1610:2019			
RAW PRODUCT			NOT APPLICABLE
Bacterial filtration efficiency EN 14683 Annex B			
RAW PRODUCT	X		TYPE IIR
Microbial cleanliness (Bioburden) EN 14683 / EN ISO 11737-1			
RAW PRODUCT	X		TYPE IIR

Remark: Test has been performed as per application request

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COMPONENT LIST:

COMPONENT ID	COMPONENT NAME	MATERIAL DESCRIPTION	COLOR	REMARKS
RAW PRODUCT		Mask	Blue	---



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MASKS TESTING	CAS No.	RESULTS	UNC.	LOQ	GUIDELINES
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Analyses on:RAW PRODUCT

◆ **Splash resistance pressure** Analysis Ending Date: 13/05/2020

ISO 22609:2004

Splash resistance pressure	16 kPa	-
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Complete test data reported at Annex.

○ **Bacterial filtration efficiency** Analysis Ending Date: 25/05/2020

EN 14683 Annex B

Bacterial Filtration Efficiency (BFE)	99.39 %	-
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Complete test data reported at Annex.

○ **Microbial cleanliness (Bioburden)** Analysis Ending Date: 09/06/2020

EN 14683 / EN ISO 11737-1

Bioburden	17.8 cfu/g	-
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Complete test data reported at Annex.

◆ **Differential pressure** Analysis Ending Date: 12/05/2020

EN 14683:2019+AC:2019 Annex C

Differential pressure	36.80 Pa/cm ²	-
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Complete test data reported at Annex.

Flammability Analysis Ending Date: 12/05/2020

16 CFR 1610:2019

Type of fabric	Plain surface	-
Pre-treatment	No	-
Fiber content	N/A	-
Weight per unit area	2.06 oz/yards ²	-
Burn time	1 s	-
Result code	IBE	-
Classification	Class 1	-

DNI= Do not Ignite
IBE= Ignited but extinguished

Results classification according to 16 CFR Part 1610:

Plain surface textile fabric:
Class 1: Burn time is 3.5 seconds or more. ACCEPTABLE
Class 2: Class 2 is not applicable to plain surface textile fabrics
Class 3: Burn time is less than 3.5 seconds. NOT ACCEPTABLE

Performance requirement according to ASTM F2100 - 19e1:

Flammability testing according to 16 CFR Part 1610 must be at least Class 1

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Signed for and on behalf of Eurofins Textile Testing Spain:

Report electronically validated by

Axel Ferrando

Physical-Mechanical Lab Manager

EXPLANATORY NOTE

- ◆ Test no accreditation
- Test is subcontracted within Eurofins group and is accredited
- Test is subcontracted within Eurofins group and is not accredited
- Test is subcontracted outside Eurofins group and is accredited
- Test is subcontracted outside Eurofins group and is not accredited

N/A = Not Applicable

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End Of Report

METHOD FOR DETERMINATION OF BRETHABILITY (DIFFERENTIAL PRESSURE)

Test Method: EN 14683: 2019+AC: 2019 Annex C

Reference and batch number: NM201 / Batch number not provided

Number of test specimens: 5

Number of test per specimen: 5

Sample area tested: Circular, diameter 2,5 cm

Tested area of the test sample: 4,9 cm²

Flow rate during testing: 8 l/min

Results

Specimen	Pos 1 (Pa)	Pos 2 (Pa)	Pos 3 (Pa)	Pos 4 (Pa)	Pos 5 (Pa)	Mean value (Pa)	ΔP (Pa/cm ²)
1	180	205	237	169	200	198	40,4
2	180	192	174	168	158	174	35,6
3	161	187	206	180	178	182	37,2
4	164	153	159	176	182	167	34,0
5	151	188	222	186	150	179	36,6
						Mean Value	36,8
						SD (25 values)	4,4

Observation:

For thick and rigid masks the test method may not be suitable as a proper seal cannot be maintained in the sample holder.

DETERMINATION OF PRESSURE OF SPLASH RESISTANCE

Test Method: ISO 22609:2004

Reference and batch number: NM201 / Batch number not provided

Number of test specimens: 32

Sample size: Circular, diameter 5 cm

Sample area tested: 19,6 cm²

Pressure: 16 kPa (120,0 mm Hg)

Conditioning: 23 °C; 85 % Hr

Environmental test conditions 24 °C; 91 % Hr

Specimen	Results	
	Pass	Fail
1	X	
2		X
3	X	
4	X	
5	X	
6	X	
7	X	
8	X	
9	X	
10	X	
11	X	
12	X	
13	X	
14	X	
15	X	
16	X	
17	X	
18	X	
19	X	
20	X	
21	X	
22	X	
23	X	
24	X	
25	X	
26		X
27	X	
28	X	
29	X	
30	X	
31	X	
32	X	

Observation:

An acceptable quality limit of 4% is met for a single sampling when 29 or more of the 32 tested specimens show "pass" results.

IN VITRO DETERMINATION OF BACTERIAL FILTRATION EFFICIENCY (BFE)

Standard: EN 14683: 2019+AC: 2019 Annex B

Reference and batch number: NM201 / Batch number not provided

Number of test specimens: 5

Dimension of the test specimen: 175 mm x 90 mm

Tested area size: 49 cm²

Size of test specimen was facing towards the challenge aerosol: Inner

Flow rate during testing: 28,3 l/min

Negative Control Plate Counts

	STAGE						MEAN
	1	2	3*	4*	5*	6*	
Negative Control (CFU)	0	0	0	0	0	0	0

*Number of colonies adjusted with positive-hole correction table

Positive Controls Plate Counts

	STAGE						TOTAL CFU
	1	2	3*	4*	5*	6*	
Size of particle (µm)	7,00	4,70	3,30	2,10	1,10	0,65	
Positive Control 1 (CFU)	209	331	921	840	664	248	3213
Positive Control 2 (CFU)	267	313	1241	874	654	322	3671

*Number of colonies adjusted with positive-hole correction table

Mean of the total plate counts of the two positive controls (CFU): 3442

Mean Particle Size (MPS)

	MPS
Positive Control 1 (µm)	2,71
Positive Control 2 (µm)	2,78
Mean (µm)	2,75

Test specimens Plate Counts

	STAGE						TOTAL CFU
	1	2	3*	4*	5*	6*	
Specimen 1	0	0	0	1	3	13	17
Specimen 2	0	0	0	1	5	12	18
Specimen 3	0	0	0	1	4	17	22
Specimen 4	0	0	0	0	3	15	18
Specimen 5	0	0	0	0	7	24	31

*Number of colonies adjusted with positive-hole correction table

Bacterial Filtration Efficiency Calculation (BFE)

TEST	BFE (%)
1	99,51
2	99,48
3	99,36
4	99,48
5	99,10
Average	99,39
SD	0,17

Calculation formula: $B = (C-T) / C \times 100$

C = Plate count average of both positive control runs

T = Total plate count of the sample

MICROBIAL CLEANLINESS (BIOBURDEN)

Test Method: EN ISO 11737-1: 2018

Reference and batch number: NM201 / Batch number not provided

Number of test specimens: 5 of the same batch/lot

Results

Test unit	Biological Load Estimation			
	Ger. Aerob. Mesophiles 31°C CFU/g	Anaerobic bacteria CFU/g	Molds and yeasts CFU/g	Total CFU/g
1	20	2	2	24
2	13	2	1	16
3	15	1	4	20
4	10	1	0	11
5	12	2	4	18
			Average	17,8

Observation:

For Microbiology parameters, according to ISO 8199, re-counts between 1 and 3 CFUs represent a detection of the microorganism; and those between 4 and 9 CFUs are an estimated number.

Operating requirements for surgical masks based on EN 14683: 2019+AC: 2019 standard

TEST	TYPE I	TYPE II	TYPE IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm ²)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16
Microbial cleanliness (CFU/g)	≤ 30	≤ 30	≤ 30