

Analytical Report Nr.

AR-21-YL-000550-01

Sample code Nr.

560-2021-00000251

Date

20/01/2021

ANALYTICAL REPORT**Client Information**

Mondmaskerfabriek B.V.
Driepoortenweg 35
BP Arnhem the NETHERLANDS

jaap@mondmaskerfabriek.nl

For the attention of Jaap Stelwagen

Sample Information

Order Code: EUAA70-00010048
Reception Date: 12-Jan-2021
Analysis Starting Date: 12-Jan-2021
Analysis Ending Date: 20-Jan-2021
Sample code Nr. 560-2021-00000251
Sample described as: Masks

Requirements and decision rule

Customer requirements: EN 14683:2019+AC:2019 TYPE IIR
Decision Rule: Shared risk - Simple acceptance.

Information provided by the customer*

Client Reference: M800 E-H 38 gram splash II
Sample Description:
Purchase Order Number:

Batch Not provided

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SAMPLE PICTURE

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CONCLUSION:

TEST PROPERTY	PASS	FAIL	REMARKS
• Bacterial Filtration Efficiency (BFE) EN 14683:2019+AC:2019 Annex B			
A	X		
Breathability (Differential Pressure) EN 14683:2019+AC:2019 Annex C			
A	X		
Resistance against penetration by synthetic blood ISO 22609:2004			
A	X		

Remark: Test has been performed as per application request

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COMPONENT LIST:

COMPONENT ID	COMPONENT NAME	MATERIAL DESCRIPTION	COLOR	REMARKS
CUST 01	A	Mask	Blue	---

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

• Bacterial Filtration Efficiency (BFE)

Analysis Ending Date: 15/01/2021

EN 14683:2019+AC:2019 Annex B

Bacterial Filtration Efficiency (BFE)

99.87 %

- ≥ 98 %

✓ Pass

Complete test report attached as Annex
Test covered by ACCREDIA accreditation scope n° 1827 L

Breathability (Differential Pressure)

Analysis Ending Date: 19/01/2021

EN 14683:2019+AC:2019 Annex C

Differential pressure

54.0 Pa/cm² (± 2.4) Pa/cm²- <60 Pa/cm²

✓ Pass

Complete test data reported at Annex.

Resistance against penetration by synthetic blood

Analysis Ending Date: 20/01/2021

ISO 22609:2004

Number of specimens tested

32

-

N° of specimens failed

0

-

N° of specimens passed

32

- ≥29

✓ Pass

At least 29 of 32 specimens must pass tested at 16KPa

Complete test data reported at Annex.

AQL information according to ISO 22609:2004:

A single sampling plan providing an AQL of 4,0 % requires 32 test specimens.

An AQL of 4.0 % is met for a single sampling plan when 29 or more specimens show pass results.

AQL= Acceptable Quality Limit.

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Signed for and on behalf of Eurofins Textile Testing Spain:
Eurofins Textile Testing Spain, S.L.U.
C/ Carretera de Elche (Alicante)
03078/099

Report electronically validated by

Maria Jesus Martinez Puig

Chemical Lab manager

EXPLANATORY NOTE

- ◆ Test not covered by ENAC accreditation scope
- 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

Eurofins Textile Testing Spain S.L.U is not responsible of the information supplied by the costumer and reported as section "Information provided by the costumer".

Eurofins General Sales Terms and Conditions Applied.

Results obtained refer only to samples, products or material received in Laboratory, as described in section "Sample information" and tested in conditions shown in present report.

Test uncertainties not reported are at customer disposal, for those tests in which it is possible to evaluate the test uncertainty.

The reported expanded uncertainty is based on a standard uncertainty multiplied by a coverage factor $k = 2$, which for a normal distribution provides a level of confidence of approximately 95%.

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If you happen to have any comments, please do it by sending email to textile_spain@eurofins.com and referring to this report number.

End Of Report

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SPAIN

Phone+34 966 299 638**www.eurofins.com/tex**

ENAC is signatory of EA and ILAC Multilateral Agreement for testing
Activities not covered by ENAC accreditation are marked with ◆○●□■

TEST REPORT	Refer to Analytical Report Number																				
SPONSOR	Eurofins Textile & Footwear Testing Spain																				
	C/Germán Bernácer 4																				
	03203 Elche (Alicante)																				
	SPAIN																				
TEST METHOD	Bacterial Filtration Efficiency (BFE) – EN 14683:2019+AC:2019 App B																				
TEST ITEM - INFORMATION FROM THE SPONSOR																					
PRODUCT NAME	560-2021-00000251 - masks																				
MATRIX OF THE PRODUCT	Face Mask																				
BATCH	EUAA70-00010048	CODE	Not provided																		
EUROFINS COSMETICS & PERSONAL CARE ITALY IDENTIFICATION																					
MATERIAL ITEM ALIQUOT	N721AA0116-2																				
PARCEL REGISTRATION N.	IP-N7-2021013-AAG	RECEIVING DATE	13 Jan 2021																		
ANALYSIS STARTING DATE	14 Jan 2021	ANALYSIS ENDING DATE	15 Jan 2021																		
EXPERIMENTAL CONDITIONS	Dimension of the test specimen: 175 mm x 95 mm Size of the area tested: 49 cm ² Flow rate during testing: 28,3 l/min Inner side of the mask to the aerosol challenge.																				
PHOTO OF THE TEST ITEM																					
RESULTS	<table border="1"> <thead> <tr> <th></th> <th>RESULT</th> <th>UNIT</th> </tr> </thead> <tbody> <tr> <td>ALIQUOT 1</td> <td>99,90</td> <td>%</td> </tr> <tr> <td>ALIQUOT 2</td> <td>99,86</td> <td>%</td> </tr> <tr> <td>ALIQUOT 3</td> <td>99,83</td> <td>%</td> </tr> <tr> <td>ALIQUOT 4</td> <td>99,90</td> <td>%</td> </tr> <tr> <td>ALIQUOT 5</td> <td>99,86</td> <td>%</td> </tr> </tbody> </table>				RESULT	UNIT	ALIQUOT 1	99,90	%	ALIQUOT 2	99,86	%	ALIQUOT 3	99,83	%	ALIQUOT 4	99,90	%	ALIQUOT 5	99,86	%
	RESULT	UNIT																			
ALIQUOT 1	99,90	%																			
ALIQUOT 2	99,86	%																			
ALIQUOT 3	99,83	%																			
ALIQUOT 4	99,90	%																			
ALIQUOT 5	99,86	%																			
DETAILED RESULTS	See Addendum N. 1 (1 page)																				

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Cosmetics &
Personal Care



LAB N° 1827 L

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Addendum N.1

Started on: 14/01/2021

Batch: N721AA0116

Sample description: 560-2021-00000251 - masks

Lot Number: EUAA70-00010048

Negative Control Plate Counts

	Stage 1	Stage 2	Stage 3*	Stage 4*	Stage 5*	Stage 6*	Mean
Negative Control (CFU)	0	0	0	0	0	0	0

*number of colonies adjusted with positive-hole correction table

Positive Controls Plate Counts

	Stage 1	Stage 2	Stage 3*	Stage 4*	Stage 5*	Stage 6*	Total CFU
Size of particle (µm)	7,00	4,70	3,30	2,10	1,10	0,65	
Positive Control N.1 (CFU)	135	300	1179	772	221	157	2764
Positive Control N.2 (CFU)	166	317	1219	801	296	194	2993

*number of colonies adjusted with positive-hole correction table

Mean of the total plate counts of the two positive controls (CFU): 2879

Mean Particle Size (MPS)

	MPS
Positive Control N.1 (µm)	2,97
Positive Control N.2 (µm)	2,94
Mean (µm)	2,96

Test specimens Plate Counts

	Stage 1	Stage 2	Stage 3*	Stage 4*	Stage 5*	Stage 6*	Total CFU
N721AA0116-2 - Aliquot 1	0	0	0	0	1	2	3
N721AA0116-2 - Aliquot 2	0	0	0	0	2	2	4
N721AA0116-2 - Aliquot 3	0	0	0	0	2	3	5
N721AA0116-2 - Aliquot 4	0	0	0	0	1	2	3
N721AA0116-2 - Aliquot 5	0	0	0	0	1	3	4

*number of colonies adjusted with positive-hole correction table

Test specimens Bacterial Filtration Efficiency (BFE)

	BFE (%)
N721AA0116-2 - Aliquot 1	99,90
N721AA0116-2 - Aliquot 2	99,86
N721AA0116-2 - Aliquot 3	99,83
N721AA0116-2 - Aliquot 4	99,90
N721AA0116-2 - Aliquot 5	99,86

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METHOD FOR DETERMINATION OF BREATHABILITY (DIFFERENTIAL PRESSURE)

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

Number of test specimens: 5

Number of test per specimen: 5

Sample area tested: Circular, diameter 2,5 cm

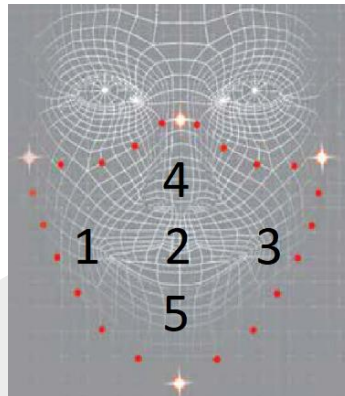
Tested area of the test sample: 4,9 cm²

Flow rate during testing: 8±0,6 l/min

General location of measurement areas: Representative of the overall surface.

Conditioning: T^a between 16,7°C and 26°C. RH between 82,8% and 88% during at least 4 h.

Airflow direction during testing: From the inner layer to the outer layer.



Results

Specimen	Units (Pa)					Mean value (Pa)	ΔP (Pa/cm ²)
	Position 1	Position 2	Position 3	Position 4	Position 5		
1	276	205	264	275	253	255	52,0
2	285	240	255	264	270	263	53,6
3	253	310	296	247	271	275	56,2
4	291	275	292	292	273	285	58,1
5	236	234	257	242	261	246	50,2
						Mean Value	54,0
						Uncertainty	± 2,4

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 RESISTANCE AGAINST PENETRATION BY SYNTHETIC BLOOD

Test Method: ISO 22609:2004; Targeting-plate test method

Number of test specimens: 32

Sample size: Circular, diameter 5,58 cm

Sample area tested: 24,5 cm²

Pressure: 16 kPa (120,0 mm Hg)

Stream velocity of synthetic blood: 550±10 cm/s

Distance of the face mask target area surface from the tip of the cannula: 30,5 cm

Angle of the pneumatic valve with respect to the face mask target area: 90°

Technique used to enhance visual detection of synthetic blood: Hydrophilic cotton

Conditioning: At least 4 hours. T^a between 16,7°C and 26°C. RH between 82,8% and 88%

Environmental test conditions 17,6°C; 85,1% Hr

Pre-treatment: None

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	

Conclusion	PASS
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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