Analytical Report Nr. AR-20-YL-004978-02
Sample code Nr. 560-2020-00005232
Date 26/08/2020

ANALYTICAL REPORT

Client Information

Sample Information

Order Code: EUAA70-00007686
Reception Date: 6-Aug-2020
Analysis Starting Date: 6-Aug-2020
Analysis Ending Date: 21-Aug-2020
Sample described as: Masks

Information provided by the customer:

Customer requirements: EN 14683:2019+AC:2019 TYPE IIR
Purchase Order Number: Strongfit Mask Test

Batch Not provided **Decision rule** Not applicable.

(*this report cancels and replaces the previous one, numbered AR-20-YL-004978-01/560-2020-00005232 dated 21/08/2020 which must be destroyed)

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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 - Mask	X		
Brethability (Differential Pressure) EN 14683:2019+AC:2019 Annex C			
A - Mask	X		
Resistance against penetration by synthetic blood ISO 22609:2004			
A - Mask	X		
Microbial cleanliness (Bioburden) EN ISO 11737-1: 2018			
A - Mask	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	Mask	Blue	---

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MASKS TESTING	CAS No.	RESULTS	UNC.	LOQ	GUIDELINES

Analyses on:A - Mask

Resistance against penetration by synthetic blood — Analysis Ending Date: 21/08/2020

ISO 22609:2004

Result:	29 of 32 samples pass at 16 KPa		-	29 of 32 samples pass at 16 KPa	✓ Pass

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.

- **Microbial cleanliness (Bioburden)** — Analysis Ending Date: 21/08/2020

EN ISO 11737-1: 2018

Bioburden	20 cfu/g		-	≤ 30 cfu/g	✓ Pass

Complete test data reported at Annex.

Brethability (Differential Pressure) — Analysis Ending Date: 21/08/2020

EN 14683:2019+AC:2019 Annex C

Differential pressure	56.6 Pa/cm²		-	< 60 Pa/cm²	✓ Pass

Complete test data reported at Annex.

- **Bacterial Filtration Efficiency (BFE)** — Analysis Ending Date: 21/08/2020

EN 14683:2019+AC:2019 Annex B

Bacterial Filtration Efficiency (BFE)	99.97 %		-	≥ 98 %	✓ Pass

Complete test report attached as annex.
Test covered by ACCREDIA accreditation scope nº 1827 L

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MASKS TESTING	CAS No.	RESULTS	UNC.	LOQ	GUIDELINES

Test results of "Microbial cleanliness (Bioburden)" are included at this version due to error at registration

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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 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

End Of Report

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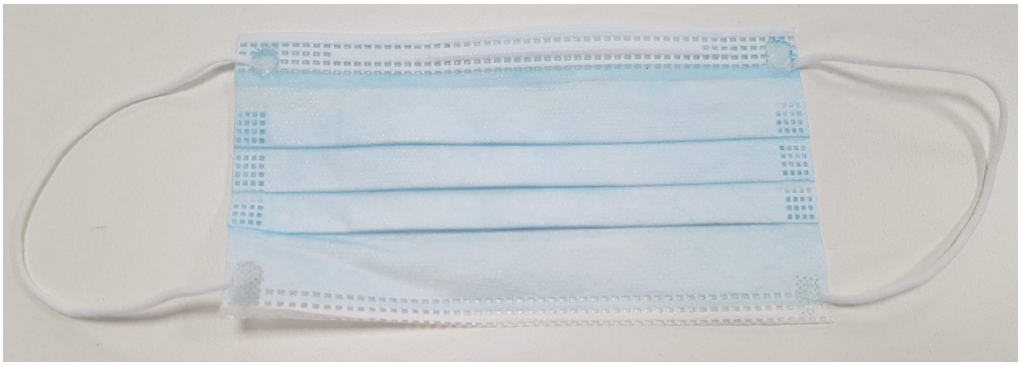
ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO

LAB N° 1827 L

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	560-2020-00005232 - Masks		
MATRIX OF THE PRODUCT	Face Mask		
BATCH	EUAA70-00007686	CODE	Not provided
EUROFINS COSMETICS & PERSONAL CARE ITALY IDENTIFICATION			
MATERIAL ITEM ALIQUOT	LV20AB3065-2		
PARCEL REGISTRATION N.	IP-LV-2020223-ACO	RECEIVING DATE	10 Aug 2020
ANALYSIS STARTING DATE	11 Aug 2020	**ANALYSIS ENDING DATE**	18 Aug 2020
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

	RESULT	UNIT
ALIQUOT 1	99,93	%
ALIQUOT 2	100,00	%
ALIQUOT 3	99,97	%
ALIQUOT 4	99,97	%
ALIQUOT 5	100,00	%

DETAILED RESULTS	See Addendum N. 1 *(1 page)*

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ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO

LAB N° 1827 L

Addendum N.1

Started on: 11/08/2020

Batch: LV20AB3065

Sample description: 560-2020-00005232 - Masks

Lot Number: EUAA70-00007686

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)	176	289	1125	865	304	236	2995
Positive Control N.2 (CFU)	225	305	1093	801	335	211	2970

*number of colonies adjusted with positive-hole correction table

Mean of the total plate counts of the two positive controls (CFU): 2983

Mean Particle Size (MPS)

	MPS
Positive Control N.1 (µm)	2,87
Positive Control N.2 (µm)	2,96
Mean (µm)	2,92

Test specimens Plate Counts

	Stage 1	Stage 2	Stage 3*	Stage 4*	Stage 5*	Stage 6*	Total CFU
LV20AB3065-2 - Aliquot 1	0	0	0	0	0	2	2
LV20AB3065-2 - Aliquot 2	0	0	0	0	0	0	0
LV20AB3065-2 - Aliquot 3	0	0	0	0	0	1	1
LV20AB3065-2 - Aliquot 4	0	0	0	0	0	1	1
LV20AB3065-2 - Aliquot 5	0	0	0	0	0	0	0

*number of colonies adjusted with positive-hole correction table

Test specimens Bacterial Filtration Efficiency (BFE)

	BFE (%)
LV20AB3065-2 - Aliquot 1	99,93
LV20AB3065-2 - Aliquot 2	100,00
LV20AB3065-2 - Aliquot 3	99,97
LV20AB3065-2 - Aliquot 4	99,97
LV20AB3065-2 - Aliquot 5	100,00

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Reviewed and electronically signed for Technical Supervisor Approval by
Giulia Galbusera, Employee
for Eurofins Biolab Srl, on 21-Aug-2020 10:07:01 UTC+02:00

DETERMINATION RESISTANCE AGAINST PENETRATION BY SYNTETIC 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 cm^2

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: 90º

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

Conditioning: At least 4 hours. Tª between 16,7ºC and 26 ºC. HR% between 82,8 and 88 % Hr

Environmental test conditions 23.6 ºC; 83.1 % Hr

Pre-treatment: None

Results		
Specimen	**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**

METHOD FOR DETERMINATION OF BRETHABILITY (DIFFERENTIAL PRESSURE)

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

Number of test specimens: 5

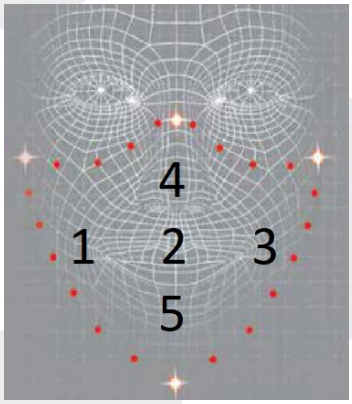
Number of test per specimen: 5

Sample area tested: Circular, diameter 2,5 cm

Tested area of the test sample: 4,9 cm^2

Flow rate during testing: 8±0,25 l/min

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



Results

Specimen	Units (Pa)						ΔP (Pa/cm^2)
	Position 1	Position 2	Position 3	Position 4	Position 5	Mean value (Pa)	
1	257	287	293	294	269	280	57,1
2	319	275	262	227	251	267	54,4
3	267	253	290	297	263	274	55,9
4	274	303	284	285	302	290	59,1
5	305	226	289	288	279	277	56,6
						Mean Value	**56,6**
						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.

MICROBIAL CLEANLINESS (BIOBURDEN)

Test Method: EN ISO 11737-1: 2018

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

Results

	Biological Load Estimation			
	Ger. Aerob. Mesophiles 31ºC	Anaerobic bacteria	Molds and yeasts	Total
Test unit	CFU/g	CFU/g	CFU/g	CFU/g
1	17	2	4	23
2	15	3	2	20
3	16	0	2	18
4	15	1	0	16
5	21	0	2	23
			Average	**20**

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