

Analytical Report Nr.

AR-22-YL-000145-02

Sample code Nr.

560-2021-00013263

Date

12/01/2022

ANALYTICAL REPORT**Client Information**

BALTIC MASKS, UAB
Savanoriu ave. 178F
Vilnius LITHUANIA
+37065388888
evgenij.s@balticmasks.com
For the attention of Evgenij Škulėpa

Sample Information

Order Code: EUAA70-00014888
Reception Date: 15-Dec-2021
Analysis Starting Date: 15-Dec-2021
Analysis Ending Date: 10-Jan-2022
Sample code Nr. 560-2021-00013263
Sample described as: Masks

Requirements and decision rule

Customer requirements: EN 14683:2019+AC:2019 TYPE IIR
Decision Rule: Shared risk - Simple acceptance. Probability of False Acceptance <50%

Information provided by the customer(2)

Client Reference: BM-026
Sample Description:
Purchase Order Number:

Batch Not provided

((1) this report cancels and replaces the previous one, numbered AR-22-YL-000145-01/560-2021-00013263 dated 10/01/2022 which must be destroyed)

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SAMPLE PICTURE



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CONCLUSION:

TEST PROPERTY	PASS	FAIL	REMARKS
<ul style="list-style-type: none"> ● Bacterial Filtration Efficiency (BFE) EN 14683:2019+AC:2019 Annex B 			
A- Mask	X		
<ul style="list-style-type: none"> ● Microbial cleanliness (bioburden) EN ISO 11737-1:2018 			
A- Mask	X		
<ul style="list-style-type: none"> ● Breathability (Differential Pressure) EN 14683:2019+AC:2019 Annex C 			
A- Mask	X		
<ul style="list-style-type: none"> ● Resistance against penetration by synthetic blood ISO 22609:2004 			
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	Nonwoven	White	---

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MASKS TESTING	CAS No.	RESULTS	UNC.	LOQ	GUIDELINES
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• **Bacterial Filtration Efficiency (BFE)**

EN 14683:2019+AC:2019 Annex B

Analyses on:A- Mask

Analysis Ending Date: 27/12/2021

Bacterial Filtration Efficiency (BFE)	>98 %	-	≥ 98 %	✓ PASS
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Complete test data reported at Annex.
Testing covered by NABL accreditation n°TC-5492.

• **Microbial cleanliness (bioburden)**

EN ISO 11737-1:2018

Analyses on:A- Mask

Analysis Ending Date: 10/01/2022

Bioburden	<30 cfu/g	-	≤ 30 cfu/g	✓ PASS
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Complete test data reported at Annex.
Test covered by ACCREDIA accreditation scope n° 1827 L

Breathability (Differential Pressure)

EN 14683:2019+AC:2019 Annex C

Analyses on:A- Mask

Analysis Ending Date: 22/12/2021

Differential pressure	<60 Pa/cm ²	-	<60 Pa/cm ²	✓ PASS
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Complete test data reported at Annex.

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MASKS TESTING	CAS No.	RESULTS	UNC.	LOQ	GUIDELINES
---------------	---------	---------	------	-----	------------

Resistance against penetration by synthetic blood

ISO 22609:2004

Analyses on:A- Mask

Analysis Ending Date: 28/12/2021

Number of specimens tested	32	-			
Number of specimens failed	0	-			
Number 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/ Germán Bernácer, 4 (Elche)
03003 Elche (Alicante)
B-978099

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

(2)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**Eurofins Textile Testing Spain, S.L.U.**

Calle Germán Bernácer, 4

03203 Elche

SPAIN

Phone+3496629938**www.eurofins.com/tex**

ENAC is signatory of EA and ILAC Multilateral Agreement for testing

Activities not covered by ENAC accreditation are marked with ◆ ○ ● □ ■ *

CIN:U74220DL1998PTC092698

TEST REPORT

Test Report Issued To:

EUROFINS TEXTILE TESTING SPAIN SL

C/ GERMAN BERNACER, 9,31, 03203,
ELCHE (ALICANTE), ELCHE ALICANTE, SPAIN

Test Report No: N211220002/N211220002-10

Date of Issue: 27-Dec-2021



Sample Booking/Receipt Date: 20-Dec-2021

Date of Start of Testing: 20-Dec-2021

Date of Completion of Test: 25-Dec-2021

Customer Relationship Number 60680

Sample Description :

MASK 560-2021-00013263



Customer Reference No

EUA70-00014888

Kind Attention

MELODIE RUIZ

E-Mail:

resultsintercotexspain@eurofins.com

Contact No:

+34 966 299 638

Sample Condition : Good

Sample Quantity (Approx) : 10

Sample Size (Approx) : NA - mm

SAMPLE NOT DRAWN BY OUR LABORATORY. THE RESULTS RELATE ONLY TO THE ITEMS TESTED

Report Issued By

Authenticity of report can be verified by mail at verification@spectrolab.in

This is a Digitally Signed Report and hence doesn't require Physical Signature.

Spectro Analytical Labs Private Limited, E-41, Okhla Indl. Area, Phase-II, New Delhi-110020(India)

Phone :+91-11-40522000, 41611000 || Web: www.spectro.in|| Email: care@spectro.in

ISO 9001:2015, ISO 14001:2015 & ISO 45001:2018 Certified Laboratory

Please refer to our Website <http://www.spectro.in/spectro-policies.html> for Terms & Condition

Discipline: - Biological
Group: - Miscellaneous

TEST REPORT FOR DETERMINATION OF:

Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus

1. Name of Product
Mask

2. Test Method
BS EN 14683:2019/Annex B: Medical Face masks - Requirements and test methods

3. Scope
To perform bacterial filtration efficiency test on surgical mask as per procedure given BSEN 14683:2019, by using biological aerosol of Staphylococcus aureus.

4. Testing Laboratory
Name: Spectro Analytical Labs Pvt Limited
Address: E-41, Okhla Phase-2
New Delhi
Pin Code: 110020
Ph: 011-40522000

5. Date of Test
Test Date:- 20.12.2021

6. Specimen Verification
6.1. Specimen Definition
The testing laboratory was not involved in the selection of the test specimen.

7. Conditioning
Each test specimens were placed for 5 h at a temperature of 21±5 °C and a relative humidity of 85±5 %.

8. Inoculum Size
Staphylococcus aureus ATCC 6538 (5x10⁵ cfu/ml)

9. Medium Used
Tryptic soya agar

10. Temperature condition
37°C/20 to 52 hours

Ritzy Tiwari

Analyst Signature



Authorised Signatory

11. Observations, Requirements & Result

Sr. no.	Test Parameters	Result	Limits as per BS EN 14683:2019/ANNEX B	Test Method
1	Bacterial Filtration Efficiency of Specimen (%)	98.9	Level 1= \geq 95 Level 2= \geq 98 Level 3= \geq 98	BS EN 14683:2019
		99.2		
		99.1		
		99.3		
		99.0		
	Average of BFE results (%)	99.1		
2	Area of test Specimen	Face side	Face side	BS EN 14683:2019
3	Flow rate of aerosol	28.3	28.3 L/Minute	BS EN 14683:2019
4	Mean particle size of Challenge aerosol of Staphylococcus aureus, micron	2.95	3 \pm 0.3	BS EN 14683:2019
5	Average Plate count of Positive control of Staphylococcus aureus in count, per test	1873	1700-3000	BS EN 14683:2019
6	Average Plate count of Negative control	Negative	Negative	BS EN 14683:2019

Remarks: The sample showed average 99.1 % Bacterial filtration efficiency against Staphylococcus aureus ATCC 6538 according to BS EN 14683:2019 test method.

-- End of Test Report --

Rity Tiwari

Analyst Signature



Authorised Signatory

Cosmetics &
Personal Care

LAB N° 1827 L

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TEST REPORT	Refer to Analytical Report Number																																																																	
SPONSOR	Eurofins Textile & Footwear Testing Spain																																																																	
	C/Germán Bernácer 4																																																																	
	03203 Elche (Alicante)																																																																	
	SPAIN																																																																	
TEST METHOD	Microbial cleanliness (Bioburden) – EN 14683:2019/AC 2019 par. 5.2.5 + App D																																																																	
TEST ITEM - INFORMATION FROM THE SPONSOR																																																																		
PRODUCT NAME	560-2021-00013263 - MASK																																																																	
MATRIX OF THE PRODUCT	Face Mask - Entire Mask																																																																	
BATCH	EUAA70-00014888	CODE	Not provided																																																															
EUROFINS COSMETICS & PERSONAL CARE ITALY IDENTIFICATION																																																																		
MATERIAL ITEM ALIQUOT	N721AA4427-1																																																																	
PARCEL REGISTRATION N.	IP-N7-2021350-AAE	RECEIVING DATE	16 Dec 2021																																																															
ANALYSIS STARTING DATE	27 Dec 2021	ANALYSIS ENDING DATE	03 Jan 2022																																																															
PHOTO OF THE TEST ITEM																																																																		
RESULTS	<table border="1"> <thead> <tr> <th>RESULTS</th> <th>SPECIFICATION</th> <th>AEROBIC COUNT</th> <th>MYCOTIC COUNT</th> <th>TOTAL BIOBURDEN</th> <th>UNIT</th> </tr> </thead> <tbody> <tr> <td rowspan="2">ALIQUOT 1</td> <td>/</td> <td>33.00</td> <td>3.00</td> <td>36.00</td> <td>CFU/sample</td> </tr> <tr> <td>≤ 30</td> <td>9.51</td> <td>0.86</td> <td>10.37</td> <td>CFU/g</td> </tr> <tr> <td rowspan="2">ALIQUOT 2</td> <td>/</td> <td>27.00</td> <td>3.00</td> <td>30.00</td> <td>CFU/sample</td> </tr> <tr> <td>≤ 30</td> <td>8.39</td> <td>0.93</td> <td>9.32</td> <td>CFU/g</td> </tr> <tr> <td rowspan="2">ALIQUOT 3</td> <td>/</td> <td>6.00</td> <td>3.00</td> <td>9.00</td> <td>CFU/sample</td> </tr> <tr> <td>≤ 30</td> <td>1.74</td> <td>0.87</td> <td>2.61</td> <td>CFU/g</td> </tr> <tr> <td rowspan="2">ALIQUOT 4</td> <td>/</td> <td>15.00</td> <td>3.00</td> <td>18.00</td> <td>CFU/sample</td> </tr> <tr> <td>≤ 30</td> <td>4.34</td> <td>0.87</td> <td>5.21</td> <td>CFU/g</td> </tr> <tr> <td rowspan="2">ALIQUOT 5</td> <td>/</td> <td>12.00</td> <td>3.00</td> <td>15.00</td> <td>CFU/sample</td> </tr> <tr> <td>≤ 30</td> <td>3.70</td> <td>0.93</td> <td>4.63</td> <td>CFU/g</td> </tr> </tbody> </table>					RESULTS	SPECIFICATION	AEROBIC COUNT	MYCOTIC COUNT	TOTAL BIOBURDEN	UNIT	ALIQUOT 1	/	33.00	3.00	36.00	CFU/sample	≤ 30	9.51	0.86	10.37	CFU/g	ALIQUOT 2	/	27.00	3.00	30.00	CFU/sample	≤ 30	8.39	0.93	9.32	CFU/g	ALIQUOT 3	/	6.00	3.00	9.00	CFU/sample	≤ 30	1.74	0.87	2.61	CFU/g	ALIQUOT 4	/	15.00	3.00	18.00	CFU/sample	≤ 30	4.34	0.87	5.21	CFU/g	ALIQUOT 5	/	12.00	3.00	15.00	CFU/sample	≤ 30	3.70	0.93	4.63	CFU/g
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Reviewed and electronically signed for Technical Supervisor Approval by
Martina Casini, Laboratory Manager
for Eurofins Cosmetic & Personal Care Italy Srl, on 04-Jan-2022 18:51:32 UTC+01:00

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

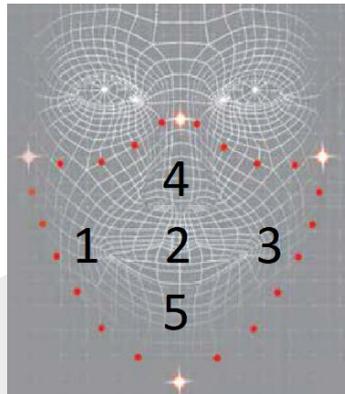
Tested area of the test sample: 4,9 cm²

Flow rate during testing: 8±0,5 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)						ΔP (Pa/cm ²)	Uncertainty
	Position 1	Position 2	Position 3	Position 4	Position 5	Mean value (Pa)		
1	202	209	199	198	212	204	41,6	± 1,6
2	203	208	204	197	204	203	41,5	± 1,3
3	206	204	211	205	206	206	42,1	± 1,2
4	203	207	199	198	204	202	41,3	± 1,2
5	198	206	198	205	203	202	41,2	± 1,2

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 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 cm²

Pressure: 16 kPa (120,0 mm Hg)

Synthetic blood volume: 2 ml

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 19,7°C; 79,9% 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