

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)

Analytical Report Nr.

AR-22-YL-000145-02

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**SAMPLE PICTURE**

**Analytical Report Nr.**

AR-22-YL-000145-02

**Sample code Nr.**

560-2021-00013263

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**CONCLUSION:**

TEST PROPERTY	PASS	FAIL	REMARKS
● <b>Bacterial Filtration Efficiency (BFE)</b> <b>EN 14683:2019+AC:2019 Annex B</b>			
A- Mask	X		
● <b>Microbial cleanliness (bioburden)</b> <b>EN ISO 11737-1:2018</b>			
A- Mask	X		
<b>Breathability (Differential Pressure)</b> <b>EN 14683:2019+AC:2019 Annex C</b>			
A- Mask	X		
<b>Resistance against penetration by synthetic blood</b> <b>ISO 22609:2004</b>			
A- Mask	X		

**Remark:** Test has been performed as per application request

Analytical Report Nr.

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560-2021-00013263

Date

12/01/2022

## COMPONENT LIST:

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

Analytical Report Nr.

AR-22-YL-000145-02

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560-2021-00013263

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

## • 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

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

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/cm²

-

<60 Pa/cm² ✓ PASS

Complete test data reported at Annex.

Eurofins Textile Testing Spain, S.L.U.

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03203 Elche  
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Activities not covered by ENAC accreditation are marked with ♦ ○ ● □ ■ \*

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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.

Analytical Report Nr.

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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)  
03097/S099

Report electronically validated by

**Maria Jesus Martinez Puig**

Chemical Lab manager

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**EXPLANATORY NOTE**

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- ◆ 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

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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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**End Of Report****Eurofins Textile Testing Spain, S.L.U.**

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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](mailto: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](http://www.spectro.in) || Email: [care@spectro.in](mailto:care@spectro.in)

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

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# TEST REPORT

Page 2 of 3

Report No. N211220002/N211220002-10

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  $21 \pm 5$  °C and a relative humidity of  $85 \pm 5$  %.

#### 8. Inoculum Size

Staphylococcus aureus ATCC 6538 ( $5 \times 10^5$  cfu/ml)

#### 9. Medium Used

Tryptic soya agar

#### 10. Temperature condition

37°C/20 to 52 hours

*Rity Tiwari*

Analyst Signature



Authorised Signatory

# TEST REPORT

## 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

Page: 1 of 1

<b>TEST REPORT</b>	Refer to Analytical Report Number																																																																
<b>SPONSOR</b>	Eurofins Textile & Footwear Testing Spain																																																																
	C/Germán Bernácer 4																																																																
	03203 Elche (Alicante)																																																																
	SPAIN																																																																
<b>TEST METHOD</b>	Microbial cleanliness (Bioburden) – EN 14683:2019/AC 2019 par. 5.2.5 + App D																																																																
<b>TEST ITEM - INFORMATION FROM THE SPONSOR</b>																																																																	
PRODUCT NAME	560-2021-00013263 - MASK																																																																
MATRIX OF THE PRODUCT	Face Mask - Entire Mask																																																																
BATCH	EUAA70-00014888	CODE	Not provided																																																														
<b>EUROFINS COSMETICS &amp; PERSONAL CARE ITALY IDENTIFICATION</b>																																																																	
MATERIAL ITEM ALIQUOT	N721AA4427-1																																																																
PARCEL REGISTRATION N.	IP-N7-2021350-AAE	RECEIVING DATE	16 Dec 2021																																																														
<b>ANALYSIS STARTING DATE</b>	27 Dec 2021	<b>ANALYSIS ENDING DATE</b>	03 Jan 2022																																																														
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<b>RESULTS</b>	<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

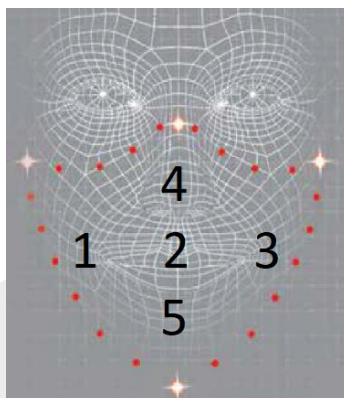
**Tested area of the test sample:** 4,9 cm<sup>2</sup>

**Flow rate during testing:** 8±0,5 l/min

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

**Conditioning:** T<sup>a</sup> 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)						$\Delta P$ (Pa/cm <sup>2</sup> )	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 cm<sup>2</sup>

**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<sup>a</sup> 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	

<b>Conclusion</b>	<b>PASS</b>
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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), (%)	$\geq 95$	$\geq 98$	$\geq 98$
Differential pressure (Pa/cm <sup>2</sup> )	$< 40$	$< 40$	$< 60$
Splash resistance pressure (kPa)	Not required	Not required	$\geq 16$
Microbial cleanliness (CFU/g)	$\leq 30$	$\leq 30$	$\leq 30$