

Eurofins WKS Labservice GmbH  
Industriestr. 1  
49849 Wislum  
DE

Client Account Number: A00814957PVZ  
Eurofins Quote Number: N3OPPH20040702

<b>Eurofins Sample Number LV20AB4831-1</b>	
<b>Original Received Date:</b>	14-Sep-2020
<b>Description:</b>	1 - Mundschutzmaske Typ II R
<b>Lot Number:</b>	602001

Analysis	Specification	Result	Unit
----------	---------------	--------	------

<b>Microbial Cleanliness (Bioburden)</b>			
Aerobic count	----	< 0.91	CFU/g
Aerobic count	----	< 3.00	CFU/sample
Yeasts and Moulds	----	< 0.91	CFU/g
Yeasts and Moulds	----	< 3.00	CFU/sample
Total Bioburden	≤ 30	< 1.82	CFU/g
Total Bioburden	----	< 6.00	CFU/sample

Method: EN 14683:2019/AC 2019 App D  
Analysis Date: 15-Sep-2020 to 22-Sep-2020

<b>Sample Compliance Assessment</b>
LV20AB4831-1 meets the requirement(s) for all listed test(s) where specifications were applied.

<b>Supplemental Information</b>
WKS-ID: 7116/11030

<b>Contracted Company: Eurofins Biolab Srl (Vimodrone)</b>
Via Bruno Buozzi, 2, Vimodrone, MI 20055 Italy InfoFarma@eurofins.com

Questions about this report should be directed to your project manager or the general email listed above.

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**Eurofins Sample Number LV20AB4831-2**

**Original Received Date:** 14-Sep-2020  
**Description:** 2 - Mundschutzmaske Typ II R  
**Lot Number:** 602001

Analysis	Specification	Result	Unit
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**Microbial Cleanliness (Bioburden)**

Aerobic count	----	< 0.91	CFU/g
Aerobic count	----	< 3.00	CFU/sample
Yeasts and Moulds	----	<0.91	CFU/g
Yeasts and Moulds	----	< 3.00	CFU/sample
Total Bioburden	≤ 30	< 1.82	CFU/g
Total Bioburden	----	<6.00	CFU/sample

Method: EN 14683:2019/AC 2019 App D  
Analysis Date: 15-Sep-2020 to 22-Sep-2020

**Sample Compliance Assessment**

LV20AB4831-2 meets the requirement(s) for all listed test(s) where specifications were applied.

**Supplemental Information**

WKS-ID: 7116/11030

**Contracted Company: Eurofins Biolab Srl (Vimodrone)**

Via Bruno Buozzi, 2, Vimodrone, MI 20055 Italy  
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Client Account Number: A00814957PVZ  
Eurofins Quote Number: N3OPPH20040702

**Eurofins Sample Number LV20AB4831-3**

**Original Received Date:** 14-Sep-2020  
**Description:** 3 - Mundschutzmaske Typ II R  
**Lot Number:** 602001

Analysis	Specification	Result	Unit
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**Microbial Cleanliness (Bioburden)**

Aerobic count	----	< 0.91	CFU/g
Aerobic count	----	<3.00	CFU/sample
Yeasts and Moulds	----	< 0.91	CFU/g
Yeasts and Moulds	----	< 3.00	CFU/sample
Total Bioburden	≤ 30	< 1.82	CFU/g
Total Bioburden	----	< 6.00	CFU/sample

Method: EN 14683:2019/AC 2019 App D  
Analysis Date: 15-Sep-2020 to 22-Sep-2020

**Sample Compliance Assessment**

LV20AB4831-3 meets the requirement(s) for all listed test(s) where specifications were applied.

**Supplemental Information**

WKS-ID: 7116/11030

**Contracted Company: Eurofins Biolab Srl (Vimodrone)**

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Client Account Number: A00814957PVZ  
Eurofins Quote Number: N3OPPH20040702

Eurofins Sample Number LV20AB4831-4			
<b>Original Received Date:</b>	14-Sep-2020		
<b>Description:</b>	4 - Mundschutzmaske Typ II R		
<b>Lot Number:</b>	602001		
Analysis	Specification	Result	Unit
<b>Microbial Cleanliness (Bioburden)</b>			
Aerobic count	----	< 0.89	CFU/g
Aerobic count	----	< 3.00	CFU/sample
Yeasts and Moulds	----	< 0.89	CFU/g
Yeasts and Moulds	----	< 3.00	CFU/sample
Total Bioburden	≤ 30	< 1.78	CFU/g
Total Bioburden	----	< 6.00	CFU/sample
Method: EN 14683:2019/AC 2019 App D			
Analysis Date: 15-Sep-2020 to 22-Sep-2020			
<b>Sample Compliance Assessment</b>			
LV20AB4831-4 meets the requirement(s) for all listed test(s) where specifications were applied.			
<b>Supplemental Information</b>			
WKS-ID: 7116/11030			
<b>Contracted Company: Eurofins Biolab Srl (Vimodrone)</b>			
Via Bruno Buozzi, 2, Vimodrone, MI 20055 Italy InfoFarma@eurofins.com			

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Client Account Number: A00814957PVZ  
Eurofins Quote Number: N3OPPH20040702

Eurofins Sample Number LV20AB4831-5	
Original Received Date:	14-Sep-2020
Description:	5 - Mundschutzmaske Typ II R
Lot Number:	602001

Analysis	Specification	Result	Unit
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Microbial Cleanliness (Bioburden)			
Aerobic count	----	< 0.92	CFU/g
Aerobic count	----	< 3.00	CFU/sample
Yeasts and Moulds	----	< 0.92	CFU/g
Yeasts and Moulds	----	< 3.00	CFU/sample
Total Bioburden	≤ 30	< 1.84	CFU/g
Total Bioburden	----	< 6.00	CFU/sample


Method: EN 14683:2019/AC 2019 App D  
Analysis Date: 15-Sep-2020 to 22-Sep-2020

Sample Compliance Assessment
LV20AB4831-5 meets the requirement(s) for all listed test(s) where specifications were applied.

Supplemental Information
WKS-ID: 7116/11030

Contracted Company: Eurofins Biolab Srl (Vimodrone)
Via Bruno Buozzi, 2, Vimodrone, MI 20055 Italy InfoFarma@eurofins.com

Questions about this report should be directed to your project manager or the general email listed above.

<b>TEST REPORT</b>	Refer to Analytical Report Number																				
<b>SPONSOR</b>	Eurofins WKS Labservice GmbH																				
	Industriestr. 1																				
	49849 Wislum																				
	GERMANY																				
<b>TEST METHOD</b>	Bacterial Filtration Efficiency (BFE) – EN 14683:2019+AC:2019 App B																				
<b>TEST ITEM - INFORMATION FROM THE SPONSOR</b>																					
PRODUCT NAME	Mundschutzmaske Typ II R																				
MATRIX OF THE PRODUCT	Face Mask																				
BATCH	602001	CODE	WKS-ID: 7116/11030																		
<b>EUROFINS COSMETICS &amp; PERSONAL CARE ITALY IDENTIFICATION</b>																					
MATERIAL ITEM ALIQUOT	LV20AB4826-1																				
PARCEL REGISTRATION N.	IP-LV-2020258-ADA	RECEIVING DATE	14 Sep 2020																		
<b>ANALYSIS STARTING DATE</b>	15 Sep 2020	<b>ANALYSIS ENDING DATE</b>	17 Sep 2020																		
<b>EXPERIMENTAL CONDITIONS</b>	Dimension of the test specimen: 170 mm x 95 mm Size of the area tested: 49 cm <sup>2</sup> Flow rate during testing: 28,3 l/min Inner side of the mask to the aerosol challenge.																				
<b>PHOTO OF THE TEST ITEM</b>																					
<b>RESULTS</b>	<table border="1"> <thead> <tr> <th></th> <th>RESULT</th> <th>UNIT</th> </tr> </thead> <tbody> <tr> <td>ALIQUOT 1</td> <td>98,40</td> <td>%</td> </tr> <tr> <td>ALIQUOT 2</td> <td>98,72</td> <td>%</td> </tr> <tr> <td>ALIQUOT 3</td> <td>98,83</td> <td>%</td> </tr> <tr> <td>ALIQUOT 4</td> <td>98,87</td> <td>%</td> </tr> <tr> <td>ALIQUOT 5</td> <td>99,09</td> <td>%</td> </tr> </tbody> </table>				RESULT	UNIT	ALIQUOT 1	98,40	%	ALIQUOT 2	98,72	%	ALIQUOT 3	98,83	%	ALIQUOT 4	98,87	%	ALIQUOT 5	99,09	%
	RESULT	UNIT																			
ALIQUOT 1	98,40	%																			
ALIQUOT 2	98,72	%																			
ALIQUOT 3	98,83	%																			
ALIQUOT 4	98,87	%																			
ALIQUOT 5	99,09	%																			
<b>DETAILED RESULTS</b>	See Addendum N. 1 (1 page)																				

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The test results relate only to the tested items. Sampling, except specific indication on test report, is always intended to be made by the Sponsor.  
Information on the test item provided by the Sponsor are under Sponsor responsibility.*



Cosmetics &  
Personal Care



LAB N° 1827 L

Page: 2 of 2

Addendum N.1

Started on: 15/09/2020

Batch: LV20AB4826

Sample description: Mundschutzmaske Typ II R

Lot Number: 602001

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)	137	341	902	559	426	287	2652
Positive Control N.2 (CFU)	171	327	1160	527	475	171	2831

\*number of colonies adjusted with positive-hole correction table

Mean of the total plate counts of the two positive controls (CFU): 2742

Mean Particle Size (MPS)

	MPS
Positive Control N.1 (µm)	2,78
Positive Control N.2 (µm)	2,93
Mean (µm)	2,86

Test specimens Plate Counts

	Stage 1	Stage 2	Stage 3*	Stage 4*	Stage 5*	Stage 6*	Total CFU
LV20AB4826-1 - Aliquot 1	0	0	0	1	19	24	44
LV20AB4826-1 - Aliquot 2	0	0	0	1	12	22	35
LV20AB4826-1 - Aliquot 3	0	0	0	1	6	25	32
LV20AB4826-1 - Aliquot 4	0	0	0	0	9	22	31
LV20AB4826-1 - Aliquot 5	0	0	0	2	8	15	25

\*number of colonies adjusted with positive-hole correction table

Test specimens Bacterial Filtration Efficiency (BFE)

	BFE (%)
LV20AB4826-1 - Aliquot 1	98,40
LV20AB4826-1 - Aliquot 2	98,72
LV20AB4826-1 - Aliquot 3	98,83
LV20AB4826-1 - Aliquot 4	98,87
LV20AB4826-1 - Aliquot 5	99,09

Eurofins Cosmetics & Personal Care Italy Srl – via B.Buozzi 2, Vimodrone (Milano), Italy –

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Analytical Report Nr.

AR-20-YL-005606-01

Sample code Nr.

560-2020-00006099

Date

18/09/2020

**ANALYTICAL REPORT****Client Information**

Eurofins WKS Labservice GmbH

Industriestraße 1

Wilsum GERMANY

0049 5945 89220

labor-wilsum@eurofins-wks.de

For the attention of David Kerperin

**Sample Information****Order Code:** EUAA70-00008165**Reception Date:** 14-Sep-2020**Analysis Starting Date:** 14-Sep-2020**Analysis Ending Date:** 18-Sep-2020**Sample described as:** Masks**Information provided by the customer:****Client Reference:** 7116/11030**Sample Description:** **Customer requirements:** EN 14683:2019+AC:2019 TYPE IIR**Purchase Order Number:****Decision rule**Shared risk - Simple  
acceptance.**Batch**

Not provided



Analytical Report Nr.

AR-20-YL-005606-01

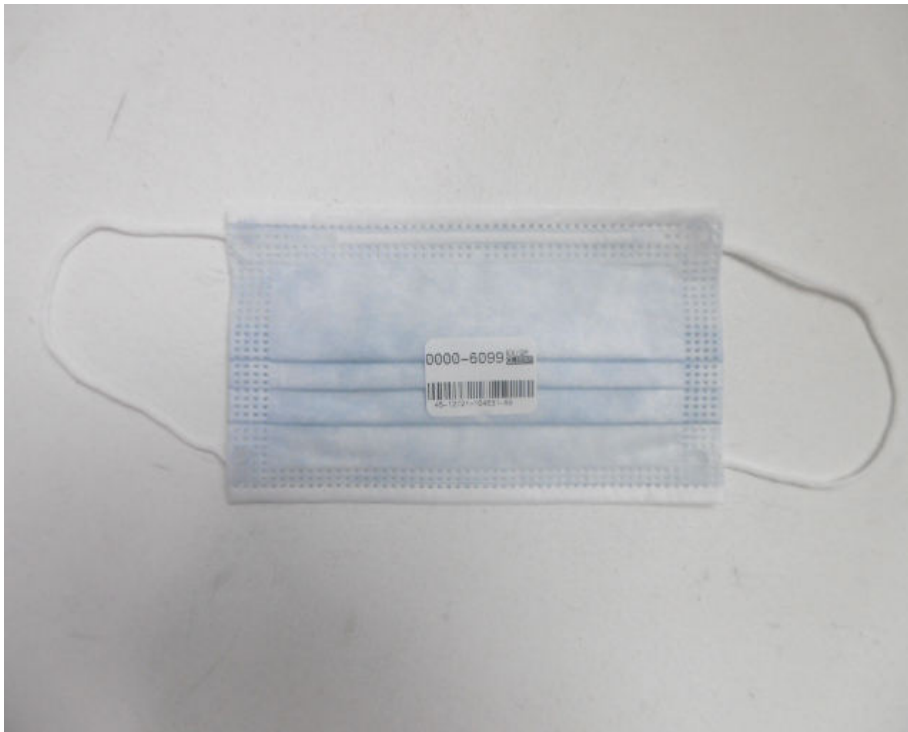
Sample code Nr.

560-2020-00006099

Date

18/09/2020

### SAMPLE PICTURE



**Analytical Report Nr.**

AR-20-YL-005606-01

**Sample code Nr.**

560-2020-00006099

**Date**

18/09/2020

**CONCLUSION:**

TEST PROPERTY	PASS	FAIL	REMARKS
<b>Breathability (Differential Pressure)</b> EN 14683:2019+AC:2019 Annex C			
A - Mask	X		
<b>Resistance against penetration by synthetic blood</b> ISO 22609:2004			
A - Mask	X		

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

Analytical Report Nr.

AR-20-YL-005606-01

Sample code Nr.

560-2020-00006099

Date

18/09/2020

## COMPONENT LIST:

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

Analytical Report Nr.

AR-20-YL-005606-01

Sample code Nr.

560-2020-00006099

Date

18/09/2020

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

### Resistance against penetration by synthetic blood

Analysis Ending Date: 16/09/2020

#### ISO 22609:2004

Result:	31 of 32 pass at 16 KPa	-	29 of 32 samples pass at 16 kPa	✓ Pass
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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.

### Breathability (Differential Pressure)

Analysis Ending Date: 18/09/2020

#### EN 14683:2019+AC:2019 Annex C

Differential pressure	43.9 Pa/cm <sup>2</sup> (± 1.5) Pa/cm <sup>2</sup>	-	<60 Pa/cm <sup>2</sup>	✓ Pass
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Complete test data reported at Annex.

**Analytical Report Nr.**

AR-20-YL-005606-01

**Sample code Nr.**

560-2020-00006099

**Date**

18/09/2020

**Signed for and on behalf of Eurofins Textile Testing Spain:**  
  
Eurofins Textile Testing Spain, S.L.U.  
C/ Germán Bernácer, 4 (Elche)  
E: 0378099

Report electronically validated by

**Maria Jesus Martinez Puig**

Chemical Lab manager

### 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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Eurofins General Sales Terms and Conditions applied.

Results obtained refer only to samples, products or material received in Laboratory, as described in point related to sample description, and tested in conditions shown in present report.

Test uncertainties not reported are at customer disposal.

If you happen to have any comments, please do it by sending email to [textile\\_spain@eurofins.com](mailto:textile_spain@eurofins.com) and referring to this report number.

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**End Of Report**

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

**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)

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. HR% between 82,8 and 88 % Hr

Environmental test conditions 24,1 °C; 78,7 % 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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**METHOD FOR DETERMINATION OF BREATHABILITY (DIFFERENTIAL PRESSURE)**

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

Number of test specimens: 5

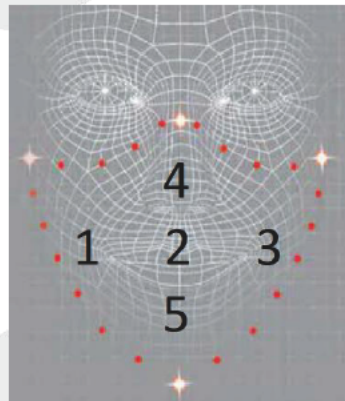
Number of test per specimen: 5

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±0,25 l/min

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



**Results**

Specimen	Units (Pa)					Mean value (Pa)	ΔP (Pa/cm <sup>2</sup> )
	Position 1	Position 2	Position 3	Position 4	Position 5		
1	219	204	229	205	197	211	43,0
2	218	227	224	229	215	223	45,4
3	221	215	203	211	205	211	43,1
4	231	225	245	224	198	225	45,8
5	203	207	206	214	204	207	42,2
						<b>Mean Value</b>	<b>43,9</b>
						<b>Uncertainty</b>	<b>± 1,5</b>

**Observation:**

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