eurofins | Product Testing

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TEST REPORT

8 January 2021

1 Sample Information

Sample name	Test / Risen Medical / Batch no. 20201028
Sample reception	08/12/2020
Sample no.	392-2020-00561201
Analysis period	11/12/2020 - 08/01/2021

2 Picture of Sample

3 Results

Please see enclosure with detailed results.

4 Conclusion

The sample **complies** with the requirements in EN 14683 for a Type IIR surgical mask.

Eurofins Product Testing A/S

Pernille Krintel
Analytical Service Manager

Jeanette K. Pedersen
Analytical Service Manager

5 Brief Evaluation of the Results

Type of analysis	Result	Standard
Bacterial Filtration Efficiency (BFE), (%)	99.81	EN 14683:2019, Annex B
Differential Pressure, (Pa/cm^2)	47.1	EN 14683:2019 + AC:2019, Annex C
Splash Resistance Pressure, (kPa)	> 16	ISO 22609:2004
Microbial Cleanliness (cfu/g)	< 30	EN 14683 / EN ISO 11737-1

Operational requirements for surgical masks based on EN 14683:2019 + AC:2019

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

*: Not accredited
<: Less than
>: Greater than
LOD: Limit of detection
¤: Internal test method
n.d: Not detected
n.m: Not measurable
LOQ: Limit of quantification
Um(%): The expanded uncertainty Um(%) equals 2 x RSD%. For further information please visit www.eurofins.dk/uncertainty
The results are only valid for the tested sample(s).

Analytical Report Nr.	AR-21-YL-000131-01
Sample code Nr.	560-2020-00009768
Date	07/01/2021

ANALYTICAL REPORT

Client Information

Eurofins Product Testing Denmark A/S
Smedeskovvej 38
Galten DENMARK DENMARK

dk_usr_results_pt@eurofins.dk
For the attention of Interco results

Sample Information

Order Code:	EUAA70-00009731
Reception Date:	14-Dec-2020
Analysis Starting Date:	14-Dec-2020
Analysis Ending Date:	7-Jan-2021
Sample code Nr.	560-2020-00009768
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:	392-2020-00561201
Sample Description:	Ansigtsmasker Type IIR - True Nordic health
Purchase Order Number:	

Batch	20201028

Analytical Report Nr.	AR-21-YL-000131-01
Sample code Nr.	560-2020-00009768
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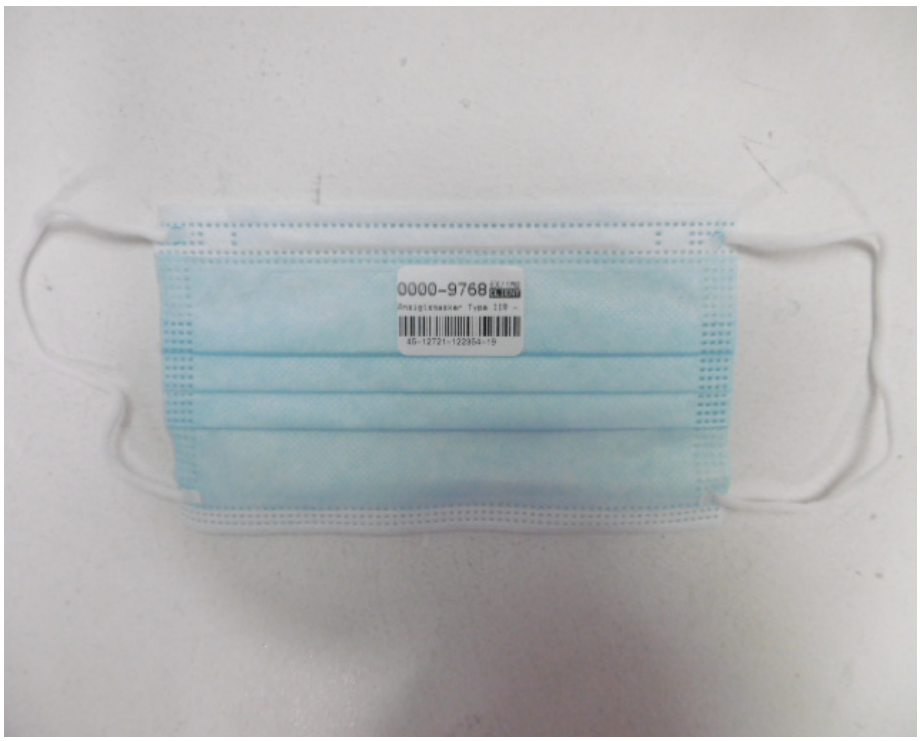
SAMPLE PICTURE



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CONCLUSION:

TEST PROPERTY	PASS	FAIL	REMARKS
• **Bacterial Filtration Efficiency (BFE)** EN 14683:2019+AC:2019 Annex B			
A-Mask	X		
• **Microbial cleanliness (bioburden)** EN ISO 11737-1:2018			
A-Mask	X		
Breathability (Differential Pressure) EN 14683:2019+AC:2019 Annex C			
A-Mask	X		
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	Mask	Blue	---

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Date 07/01/2021

MASKS TESTING	CAS No.	RESULTS	UNC.	LOQ	GUIDELINES

Analyses on:A-Mask

- **Bacterial Filtration Efficiency (BFE)** — Analysis Ending Date: 23/12/2020

EN 14683:2019+AC:2019 Annex B

Bacterial Filtration Efficiency (BFE)		99.81 %		-	≥ 98 % ✔ Pass

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

Breathability (Differential Pressure) — Analysis Ending Date: 18/12/2020

EN 14683:2019+AC:2019 Annex C

Differential pressure		47.1 Pa/cm²	(± 1.4) Pa/cm²	-	<60 Pa/cm² ✔ Pass

Complete test data reported at Annex.

Resistance against penetration by synthetic blood — Analysis Ending Date: 07/01/2021

ISO 22609:2004

Number of specimens tested		32		-	
Nº of specimens failed		3		-	
Nº of specimens passed		29		-	≥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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Sample code Nr. 560-2020-00009768
Date 07/01/2021

MASKS TESTING	CAS No.	RESULTS	UNC.	LOQ	GUIDELINES
• **Microbial cleanliness (bioburden)**					Analysis Ending Date: 28/12/2020
EN ISO 11737-1:2018					
Bioburden		<30 cfu/g		-	≤ 30 cfu/g ✔ Pass

Complete test data reported at Annex.
Test covered by ACCREDIA accreditation scope nº 1827 L

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Signed for and on behalf of Eurofins Textile Testing Spain:

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

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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

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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	Microbial cleanliness (Bioburden) – EN 14683:2019/AC 2019 par. 5.2.5 + App D		
TEST ITEM - INFORMATION FROM THE SPONSOR			
PRODUCT NAME	560-2020-00009768 - masks		
MATRIX OF THE PRODUCT	Face Mask		
BATCH	EUAA70-00009731	CODE	Not provided
EUROFINS COSMETICS & PERSONAL CARE ITALY IDENTIFICATION			
MATERIAL ITEM ALIQUOT	N720AA1118-1		
PARCEL REGISTRATION N.	IP-N7-2020350-AAF	RECEIVING DATE	15 Dec 2020
ANALYSIS STARTING DATE	21 Dec 2020	**ANALYSIS ENDING DATE**	28 Dec 2020

RESULTS

TOTAL BIOBURDEN	SPECIFICATION	RESULT	UNIT
ALIQUOT 1	/	6.00	CFU/sample
	≤ 30	1.92	CFU/g
ALIQUOT 2	/	<6.00	CFU/sample
	≤ 30	<1.96	CFU/g
ALIQUOT 3	/	<6.00	CFU/sample
	≤ 30	<1.84	CFU/g
ALIQUOT 4	/	<6.00	CFU/sample
	≤ 30	<1.94	CFU/g
ALIQUOT 5	/	<6.00	CFU/sample
	≤ 30	<1.88	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 28-Dec-2020 16:30:54 UTC+01:00

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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	560-2020-00009768		
MATRIX OF THE PRODUCT	Face Mask		
BATCH	EUAA70-00009731	CODE	Not provided
EUROFINS COSMETICS & PERSONAL CARE ITALY IDENTIFICATION			
MATERIAL ITEM ALIQUOT	N720AA1119-1		
PARCEL REGISTRATION N.	IP-N7-2020350-AAF	RECEIVING DATE	15 Dec 2020
ANALYSIS STARTING DATE	21 Dec 2020	**ANALYSIS ENDING DATE**	22 Dec 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	99,78	%
ALIQUOT 2	99,82	%
ALIQUOT 3	99,86	%
ALIQUOT 4	99,78	%
ALIQUOT 5	99,82	%

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

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LAB N° 1827 L

Addendum N.1

Started on: 21/12/2020

Batch: N720AA1119

Sample description: 560-2020-00009768

Lot Number: EUAA70-00009731

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)	146	188	1078	670	406	279	2767
Positive Control N.2 (CFU)	153	312	1036	543	423	313	2780

*number of colonies adjusted with positive-hole correction table

Mean of the total plate counts of the two positive controls (CFU): 2774

Mean Particle Size (MPS)

	MPS
Positive Control N.1 (µm)	2,71
Positive Control N.2 (µm)	2,79
Mean (µm)	2,75

Test specimens Plate Counts

	Stage 1	Stage 2	Stage 3*	Stage 4*	Stage 5*	Stage 6*	Total CFU
N720AA1119-1 - Aliquot 1	0	0	0	0	3	3	6
N720AA1119-1 - Aliquot 2	0	0	0	0	1	4	5
N720AA1119-1 - Aliquot 3	0	0	0	0	2	2	4
N720AA1119-1 - Aliquot 4	0	0	0	0	1	5	6
N720AA1119-1 - Aliquot 5	0	0	0	0	1	4	5

*number of colonies adjusted with positive-hole correction table

Test specimens Bacterial Filtration Efficiency (BFE)

	BFE (%)
N720AA1119-1 - Aliquot 1	99,78
N720AA1119-1 - Aliquot 2	99,82
N720AA1119-1 - Aliquot 3	99,86
N720AA1119-1 - Aliquot 4	99,78
N720AA1119-1 - Aliquot 5	99,82

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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 22-Dec-2020 15:52:03 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

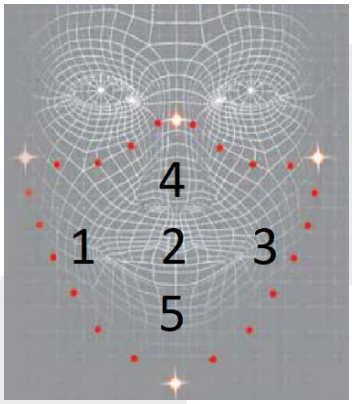
Tested area of the test sample: 4,9 cm^2

Flow rate during testing: 8±0,6 l/min

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

Conditioning: Tª between 16,7ºC and 26ºC. 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)
	Position 1	Position 2	Position 3	Position 4	Position 5	Mean value (Pa)	
1	244	222	249	225	231	234	47,8
2	230	222	224	219	225	224	45,7
3	235	220	238	224	249	233	47,6
4	251	224	223	228	224	230	46,9
5	242	221	234	225	237	232	47,3
						Mean Value	**47,1**
						Uncertainty	**± 1,4**

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 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 26ºC. RH between 82,8% and 88%

Environmental test conditions 17,5ºC; 78,8% 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**

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