

# TEST REPORT

**Job No./Report No: 21-004736**

**Date: 30/04/2021**

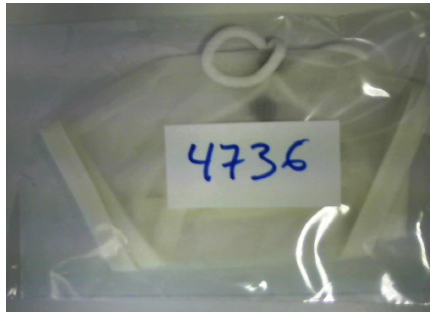
The following sample was (were) submitted and identified by the client as:

Job no Report No.:	<b>21-004736</b>
Receiving Date:	<b>13/04/2021</b>
Test Start Date:	<b>16/04/2021</b>
Test End Date:	<b>30/04/2021</b>
Sample description:	<b>MASK</b>
Series :	
Batch No.:	
Reference No.:	<b>MASCARILLA TRASLUCIDA/CREMA</b>
Composition indicated:	<b>100% polyamide</b>

## SUMMARY OF TEST CONCLUSIONS

SOP description	Conclusions
SOP305 - Method of washing, cleaning and disinfection (Masks and Fabrics for masks)	Pass
SOP 342- Bacterial Filtration Efficiency (BFE) - (Test subcontracted to an accredited laboratory)	Pass
SOP 342- Bacterial Filtration Efficiency (BFE)-After Washing (Test subcontracted to an accredited lab)	Pass
SOP347 - Determination of breathability (Differential Pressure) by UNE-EN 14683 annex C - Original	Pass
SOP347 - Determination of breathability (Differential Pressure) by UNE-EN 14683 annex C - After Washing	Pass

## Sample Tested



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## **SOP305 - Method of washing, cleaning and disinfection (Masks and Fabrics for masks)**

ID	ID AMSLab	Description	Conclusion
3	S-210414-00264	MASK TRANSPARENT (AFTER 30 WASHING CYCLES AT 60°C)	Pass

	CAS	S-210414-00264
Change of appearance after washing		Slight change
Number of cycles		30
Washing Temperature		60°C
Method		1

Notes:

Note 1: Internal method: Washing and drying process applied based on Document from the Ministry of Health published on April 15, 2020 "Cleaning and disinfection of reusable hygienic masks"

Note 2, Washing Applied method:

- Method 1: Washing with normal detergent and water at a temperature of 60°.
- Method 2: 1:50 dilution of bleach with water for 30 minutes.
- Method 3.1: By washing machine with virucidal disinfectant (Sanytol)
- Method 3.2: By hand with virucidal disinfectant (Sanytol)

Note3:

Drying procedure used: Method A: in air

- n.a.: not applicable

Note 3 - Meaning of the grades of change of appearance:

- No change: without changes
- Slight change: there is a slight change in appearance or color.
- Moderate change: there is a moderate change in appearance or apparent defects.
- Severe change: there is a severe change in appearance or apparent serious defects.

Requirement: No change and Slight change will be considered acceptable appearance change. Moderate change and Severe change will be considered unacceptable appearance change.

Notes of change of appearance: \_\_\_\_\_

## **SOP 342- Bacterial Filtration Efficiency (BFE) - (Test subcontracted to an accredited laboratory)**

ID	ID AMSLab	Description	Conclusion
4	S-210416-00058	MASK TRANSPARENT (ORIGINAL)	Pass

	CAS	S-210416-00058
Test 1: Bacterial Filtration Efficiency		95.1
Test 1: Number of Bacteria		146
Test 2: Bacterial Filtration Efficiency		95.3
Test 2: Number of Bacteria		142
Test 3: Bacterial Filtration Efficiency		95.1

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# TEST REPORT

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	CAS	S-210416-00058
Test 3: Number of Bacteria		147
Test 4: Bacterial Filtration Efficiency		95.6
Test 4: Number of Bacteria		133
Test 5: Bacterial Filtration Efficiency		95.3
Test 5: Number of Bacteria		141

Test Method: EN 14683:2019+AC:2019 (TS EN 14683+AC:2019) Annex-B / Medical Face Masks - Requirements and Test Methods

Requirements by specifications:

Spanish specification UNE 0064:2020:  $\geq 95\%$

Spanish specification UNE 0065:2020:  $\geq 90\%$

European specification CWA 17553:2020: Level  $\geq 90\%$  and

European specification CWA 17553:2020: Level  $\geq 70\%$

Other requirements:

- Surgical Mask type I by UNE-EN 14683:  $\geq 95\%$

- Surgical Mask type II by UNE-EN 14683:  $\geq 98\%$

- Surgical Mask type IIR by UNE-EN 14683:  $\geq 98\%$

Report unit Bacterial Filtration Efficiency = %

Report unit Number of Bacteria = cfu/mL

A specimen of the mask material is clamped between a impactor and an aerosol chamber. An aerosol of Staphylococcus aureus is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

Test Flow Rate: 28,3 L/min

Test Flow Time: 2 minute

Sample Sizes: 10x10 cm<sup>2</sup>

Microorganism: Staphylococcus aureus ATCC 6538

Bacterial concentration (cfu/ml): 5x10<sup>5</sup> cfu/ml

Incubation conditions: 24 hour, 35C  $\pm$  2C

Positive control sample average of number of Bacteria (C): 3.0x10<sup>3</sup> cfu/ml

(\* ) Test subcontracted and accredited laboratory (EKOTEKS LABORATUVAR VE GÖZETM HZMETLER A. .) for medical mask for tests (EN 14683). Results in subcontracted report number: 21013541

The Turkish Accreditation Agency (TURKAK) is signatory to the multilateral agreements of the European co-operation for the Accreditation (EA) and of the International Laboratory Accreditation (ILAC) for the Mutual recognition of test reports.

EKOTEKS LABORATUVAR VE GÖZETM HZMETLER A. . Deneý Laboratuvar, is accredited by TURKAK under registration number (AB-0583-T) for ISO 17025:2017 as test laboratory.

## **SOP 342- Bacterial Filtration Efficiency (BFE)-After Washing (Test subcontracted to an accredited lab)**

ID	ID AMSLab	Description	Conclusion
5	S-210416-00059	MASK TRANSPARENT (AFTER 30 WASHING CYCLES AT 60°C)	Pass

	CAS	S-210416-00059
Test 1: Bacterial Filtration Efficiency		95.0
Test 1: Number of Bacteria		150
Test 2: Bacterial Filtration Efficiency		95.1
Test 2: Number of Bacteria		148

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# TEST REPORT

Job No./Report No: 21-004736

Date: 30/04/2021

	CAS	S-210416-00059
Test 3: Bacterial Filtration Efficiency		95.0
Test 3: Number of Bacteria		150
Test 4: Bacterial Filtration Efficiency		95.1
Test 4: Number of Bacteria		147
Test 5: Bacterial Filtration Efficiency		95.1
Test 5: Number of Bacteria		148

Test Method: EN 14683:2019+AC:2019 (TS EN 14683+AC:2019) Annex-B / Medical Face Masks - Requirements and Test Methods

Requirements by specifications:

Spanish specification UNE 0064:2020:  $\geq 95\%$

Spanish specification UNE 0065:2020:  $\geq 90\%$

European specification CWA 17553:2020: Level  $\geq 90\%$  and

European specification CWA 17553:2020: Level  $\geq 70\%$

Other requirements:

- Surgical Mask type I by UNE-EN 14683:  $\geq 95\%$

- Surgical Mask type II by UNE-EN 14683:  $\geq 98\%$

- Surgical Mask type IIR by UNE-EN 14683:  $\geq 98\%$

Report unit Bacterial Filtration Efficiency = %

Report unit Number of Bacteria = cfu/mL

A specimen of the mask material is clamped between a impactor and an aerosol chamber. An aerosol of Staphylococcus aureus is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

Test Flow Rate: 28,3 L/min

Test Flow Time: 2 minute

Sample Sizes: 10x10 cm<sup>2</sup>

Microorganism: Staphylococcus aureus ATCC 6538

Bacterial concentration (cfu/ml): 5x10E5 cfu/ml

Incubation conditions: 24 hour, 35C  $\pm$  2C

Positive control sample average of number of Bacteria (C): 3.0x10E3 cfu/ml

(\*) Test subcontracted and accredited laboratory (EKOTEKS LABORATUVAR VE GÖZETM HZMETLER A. .) for medical mask for tests (EN 14683). Results in subcontracted report number: 21013542

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## **SOP347 - Determination of breathability (Differential Pressure) by UNE-EN 14683 annex C - Original**

ID	ID AMSLab	Description	Conclusion
1	S-210414-00262	MASK TRANSPARENT (ORIGINAL)	Pass

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# TEST REPORT

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BREATHABILITY RESULTS (DIFFERENTIAL PRESSURE)							
TEST PIECE	A1 (Pa)	A2 (Pa)	A3 (Pa)	A4 (Pa)	A5 (Pa)	AVERAGE VALUE (Pa)	P (Pa/cm2)
1	<1	<1	<1	<1	<1	<1.0	<1
2	<1	<1	<1	<1	<1	<1.0	<1
3	<1	<1	<1	<1	<1	<1.0	<1
4	<1	<1	<1	<1	<1	<1.0	<1
5	<1	<1	<1	<1	<1	<1.0	<1
AVERAGE							<1
STANDARD DEVIATION (25 VALUES)							0.0

Notes:

Note 1: Applied standard UNE-EN 14683:2019+AC:2019 Annex C for breathability (Differential Pressure)

Note 2: For requirements: Spanish Specification UNE 0064-1, 0064-2, 0065 and European Specification CWA 17553

Note 3: Size of test specimen: 4.9 cm<sup>2</sup>

Note 4: Tested area of the test specimen: 2.5 cm

Note 5: Flow of air: (8 ± 0.2) l/min

Note 6: Report Unit: Pa and P (Pa/cm<sup>2</sup>)

Note 7: Number of samples tested: 5 / Number of measurements: 5

Note 8: Conditioned samples: 4 hours at (21 ± 5) °C and (85 ± 5) %HR

Note 9: A: sample area tested

Note 10: n.a. = not applicable

Requirements by specifications:

- Non-reusable Hygienic Mask by UNE 0064-1-2: < 60 Pa/cm<sup>2</sup>
- Reusable Hygienic Mask by UNE 0065: < 60 Pa/cm<sup>2</sup>
- European specification CWA 17553:2020: <= 70 Pa/cm<sup>2</sup>

Other requirements:

- Surgical Mask type I by UNE-EN 14683: < 40 Pa/cm<sup>2</sup>
- Surgical Mask type II by UNE-EN 14683: < 40 Pa/cm<sup>2</sup>
- Surgical Mask type IIR by UNE-EN 14683: < 60 Pa/cm<sup>2</sup>

Specific Notes:

(\*\*) The result is out of specifications

## **SOP347 - Determination of breathability (Differential Pressure) by UNE-EN 14683 annex C - After Washing**

ID	ID AMSLab	Description	Conclusion
2	S-210414-00263	MASK TRANSPARENT (AFTER 30 WASHING CYCLES AT 60°C)	Pass

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BREATHABILITY RESULTS (DIFFERENTIAL PRESSURE)							
TEST PIECE	A1 (Pa)	A2 (Pa)	A3 (Pa)	A4 (Pa)	A5 (Pa)	AVERAGE VALUE (Pa)	P (Pa/cm <sup>2</sup> )
1	<1	<1	<1	<1	<1	<1.0	<1
2	<1	<1	<1	<1	<1	<1.0	<1
3	<1	<1	<1	<1	<1	<1.0	<1
4	<1	<1	<1	<1	<1	<1.0	<1
5	<1	<1	<1	<1	<1	<1.0	<1
<b>AVERAGE</b>							<1
<b>STANDARD DEVIATION (25 VALUES)</b>							0.0

Notes:

- Note 1: Applied standard UNE-EN 14683:2019+AC:2019 Annex C for breathability (Differential Pressure)
- Note 2: For requirements: Spanish Specification UNE 0064-1, 0064-2, 0065 and European Specification CWA 17553
- Note 3: Size of test specimen: 4.9 cm<sup>2</sup>
- Note 4: Tested area of the test specimen: 2.5 cm
- Note 5: Flow of air: (8 ± 0.2) l/min
- Note 6: Report Unit: Pa and P (Pa/cm<sup>2</sup>)
- Note 7: Number of samples tested: 5 / Number of measurements: 5
- Note 8: Conditioned samples: 4 hours at (21 ± 5) °C and (85 ± 5) %HR
- Note 9: A: sample area tested
- Note 10: n.a. = not applicable

Requirements by specifications:

- Non-reusable Hygienic Mask by UNE 0064-1-2: < 60 Pa/cm<sup>2</sup>
- Reusable Hygienic Mask by UNE 0065: < 60 Pa/cm<sup>2</sup>
- European specification CWA 17553:2020: <= 70 Pa/cm<sup>2</sup>

Other requirements:

- Surgical Mask type I by UNE-EN 14683: < 40 Pa/cm<sup>2</sup>
- Surgical Mask type II by UNE-EN 14683: < 40 Pa/cm<sup>2</sup>
- Surgical Mask type IIR by UNE-EN 14683: < 60 Pa/cm<sup>2</sup>

Specific Notes:

- (\*\*) The result is out of specifications

Issue Date: 30/04/2021

Signed: Manuel Lolo



General Manager

Signed: Pablo Perez



Chemical Lab Manager

Signed: Esteban Ramirez



Physical Lab Manager

Test report reviewed by Esteban Ramirez (Physical Tests) and Pablo Pérez (Chemical Tests)

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