

Job No./Report No: 21-005429

Date: 12/05/2021

SOP and results with (#) are not included in the ENAC accreditation scope

Client:Xulamask, S.L.

Code: CL-1558

Address:C/ Balançó i Boter 22, 2º Atico 08302 Mataró Barcelona- Cataluña

Attn:Jordi Valls

e-MAIL: jordi@xula.es

Tel:+34 639 34 03 17

Fax:

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

Job no Report No.:	21-005429
Receiving Date:	27/04/2021
Test Start Date:	28/04/2021
Test End Date:	12/05/2021
Sample description:	MASK

Serie :

Batch No.:

Reference No.: **MASCARILLA TRANSPARENTE XULA
BLACK M/PF.MTX.001.3**

Composition indicated: **Unknow**

This test report is a modification of issued in the date "12/05/2021". Change: The original customer's contact person and contact mail (Victor Bartumeus <victor@xula.es>) has been replaced by a new one (Jordi Valls <jordi@xula.es>). Cause: Customer's request.
Change: The original address (C/Josep Alcalde Abril,24,1-2 MATARÓ BARCELONA ESPAÑA) has been replaced by a new one (C/ Balançó i Boter 22, 2º Atico 08302 Mataró Barcelona- Cataluña). Cause: Customer's request.
Change: The original Tel: (0034 653616279) has been replaced by a new one (+34 639 34 03 17). Cause: Customer's request.

#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)	See Results
#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
SOP106 - Determination of Air Permeability by ISO 9237 (for CWA 17553) - Original	Pass
SOP106 - Determination of Air Permeability by ISO 9237 (for CWA 17553) - 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
4	S-210428-00042	MASK TRANSPARENT (AFTER 40 WASHING CYCLES AT 60°C)	Pass

	CAS	S-210428-00042
Change of appearance after washing		Slight change
Number of cycles		40
Washing Temperature		60°C
Method		1

Notes:

Note 1: Internal method SOP/305 rev. 1: 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° (Normal cycle by washing machine)
- 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)

Note 3:

Drying procedure used: Method A: in air

- n.a.: not applicable

Note 4 (Only for methods 1 and 3.1):

- Detergent used: Reference 3
- Type of counterweight used: Type III (100% polyester) / Type II (50% cotton 50% polyester) / Type I (100% cotton)

Note 5 - 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 (If applicable):

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

ID	ID AMSLab	Description	# Conclusion
2	S-210428-00040	MASK TRANSPARENT (ORIGINAL)	Pass

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	CAS	S-210428-00040
Test 1: Bacterial Filtration Efficiency		95.8
Test 1: Number of Bacteria		126
Test 2: Bacterial Filtration Efficiency		95.4
Test 2: Number of Bacteria		138
Test 3: Bacterial Filtration Efficiency		95.4
Test 3: Number of Bacteria		137
Test 4: Bacterial Filtration Efficiency		95.3
Test 4: Number of Bacteria		141
Test 5: Bacterial Filtration Efficiency		95.2
Test 5: Number of Bacteria		144

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: >=95%

Spanish specification UNE 0065:2020: >= 90%

European specification CWA 17553:2020: Level >= 90% and

European specification CWA 17553:2020: Level >= 70%

Other requirements:

- Surgical Mask type I by UNE-EN 14683: >= 95%
- Surgical Mask type II by UNE-EN 14683: >= 98%
- Surgical Mask type IIR by UNE-EN 14683: >= 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 cm²

Microorganism: Staphylococcus aureus ATCC 6538

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

Incubation conditions: 24 hour, 35C ± 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: 21014955

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. . Denedy Laboratuvar, is accredited by TURKAK under registration number (AB-0583-T) for ISO 17025:2017 as test laboratory.

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

ID	ID AMSLab	Description	# Conclusion
5	S-210428-00043	MASK TRANSPARENT (AFTER 40 WASHING CYCLES AT 60°C)	See Results

	CAS	S-210428-00043
Test 1: Bacterial Filtration Efficiency		86.2
Test 1: Number of Bacteria		414
Test 2: Bacterial Filtration Efficiency		86.0
Test 2: Number of Bacteria		419
Test 3: Bacterial Filtration Efficiency		86.1
Test 3: Number of Bacteria		418
Test 4: Bacterial Filtration Efficiency		86.3
Test 4: Number of Bacteria		411
Test 5: Bacterial Filtration Efficiency		86.2
Test 5: Number of Bacteria		414

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 cm²

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: 21014957

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

ID	ID AMSLab	Description	# Conclusion
1	S-210428-00039	MASK TRANSPARENT (ORIGINAL)	Pass

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	<1.0
2	<1	<1	<1	<1	<1	<1.0	<1.0
3	<1	<1	<1	<1	<1	<1.0	<1.0
4	<1	<1	<1	<1	<1	<1.0	<1.0
5	<1	<1	<1	<1	<1	<1.0	<1.0
AVERAGE							<1.0
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 cm²
- 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/cm²)
- 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/cm²
- Reusable Hygienic Mask by UNE 0065: < 60 Pa/cm²
- European specification CWA 17553:2020: <= 70 Pa/cm²

Other requirements:

- Surgical Mask type I by UNE-EN 14683: < 40 Pa/cm²
- Surgical Mask type II by UNE-EN 14683: < 40 Pa/cm²
- Surgical Mask type IIR by UNE-EN 14683: < 60 Pa/cm²

Specific Notes:

- (**) The result is out of specifications

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

ID	ID AMSLab	Description	# Conclusion
3	S-210428-00041	MASK TRANSPARENT (AFTER 40 WASHING CYCLES AT 60°C)	Pass

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	<1.0
2	<1	<1	<1	<1	<1	<1.0	<1.0
3	<1	<1	<1	<1	<1	<1.0	<1.0
4	<1	<1	<1	<1	<1	<1.0	<1.0
5	<1	<1	<1	<1	<1	<1.0	<1.0
AVERAGE							<1.0
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 cm²
- 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/cm²)
- 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/cm²
- Reusable Hygienic Mask by UNE 0065: < 60 Pa/cm²
- European specification CWA 17553:2020: <= 70 Pa/cm²

Other requirements:

- Surgical Mask type I by UNE-EN 14683: < 40 Pa/cm²
- Surgical Mask type II by UNE-EN 14683: < 40 Pa/cm²
- Surgical Mask type IIR by UNE-EN 14683: < 60 Pa/cm²

Specific Notes:

- (**) The result is out of specifications

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SOP106 - Determination of Air Permeability by ISO 9237 (for CWA 17553) - Original

ID	ID AMSLab	Description	# Conclusion
6	S-210428-00044	MASK TRANSPARENT (AFTER 40 WASHING CYCLES AT 60°C)	Pass

	CAS	S-210428-00044
(I.C. 95%) - Confidence Interval ±		0.0
Mean Value air permeability (l/m2/seg)		>1000.0
Standard deviation		0.0
Value 10 (l/m2/seg)		>1000.0
Value 1 (l/m2/seg)		>1000.0
Value 2 (l/m2/seg)		>1000.0
Value 3 (l/m2/seg)		>1000.0
Value 4 (l/m2/seg)		>1000.0
Value 5 (l/m2/seg)		>1000.0
Value 6 (l/m2/seg)		>1000.0
Value 7 (l/m2/seg)		>1000.0
Value 8 (l/m2/seg)		>1000.0
Value 9 (l/m2/seg)		>1000.0

Notes:

Note 1: Applied standard UNE-EN 14683:2019 and European Specification CWA 17553:2020

Note 2: Applied pressure: 100 Pa

Note 3: Applied area: 5 cm²

Note 4: Report Unit: l/m2/seg (= mm/seg)

Note 5: Number of measurements: 10

Note 6: Conditioned samples: 24 hours at 20 ± 2 °C and 65 ± 4 HR

Note 7: n.a. = not applicable

Note 8: Standard deviation units and I.C. 95% units: l/m2/seg

Requirements by specifications:

- European specification CWA 17553:2020: >= 96 l/m2/s

Specific Notes:

(**) The result is out of specifications

SOP106 - Determination of Air Permeability by ISO 9237 (for CWA 17553) - After washing

ID	ID AMSLab	Description	# Conclusion
7	S-210428-00045	MASK TRANSPARENT (AFTER 40 WASHING CYCLES AT 60°C)	Pass

	CAS	S-210428-00045
(I.C. 95%) - Confidence Interval ±		0.0
Mean Value air permeability (l/m2/seg)		>1000.0
Standard deviation		0.0
Value 10 (l/m2/seg)		>1000.0
Value 1 (l/m2/seg)		>1000.0
Value 2 (l/m2/seg)		>1000.0

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	CAS	S-210428-00045
Value 3 (l/m2/seg)		>1000.0
Value 4 (l/m2/seg)		>1000.0
Value 5 (l/m2/seg)		>1000.0
Value 6 (l/m2/seg)		>1000.0
Value 7 (l/m2/seg)		>1000.0
Value 8 (l/m2/seg)		>1000.0
Value 9 (l/m2/seg)		>1000.0

Notes:

Note 1: Applied standard UNE-EN 14683:2019 and European Specification CWA 17553:2020

Note 2: Applied pressure: 100 Pa

Note 3: Applied area: 5 cm²

Note 4: Report Unit: l/m²/seg (= mm/seg)

Note 5: Number of measurements: 10

Note 6: Conditioned samples: 24 hours at 20 ± 2 °C and 65 ± 4 HR

Note 7: n.a. = not applicable

Note 8: Standard deviation units and I.C. 95% units: l/m²/seg

Requirements by specifications:

- European specification CWA 17553:2020: >= 96 l/m²/s

Specific Notes:

(**) The result is out of specifications

Issue Date: 12/05/2021

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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