



# ¡QUE SEPAN DE LO QUE HABLAS!

MASCARILLAS HIGIÉNCIAS  
TRANSPARENTES REUTILIZABLES

 **inca** FARMA

# MASCARILLA HOMOLOGADA TRANSPARENTE Y REUTILIZABLE



Según norma UNE 0065-2020 y conforme a la norma europea CWA17553:2020  
Laboratorio AMSLAB, certificado 21/007889.

Eficacia de filtración bacteriana (BFE%):  $\geq 98$

Eficacia BFE% a los 15 lavados:  $\geq 94,5$

Respirabilidad. Presión diferencial (Pa/cm<sup>2</sup>):  $< 1$

Respirabilidad (Pa/cm<sup>2</sup>) a los 15 lavados:  $< 1$

## MATERIALES

Una capa de tejido de **100% poliamida con acabado hidrófugo, antibacteriano y antimanchas.**

Vivo de algodón hidrofugado y antibacterias.

Varilla de ajuste nasal.

Arnés sujeción oreja.

**Tejidos y mascarilla fabricados en España.**

## CARACTERÍSTICAS

Transparente y ligera.

Transpirable y repelente de líquidos.

Antibacteriana, no es tóxica y no produce alergias.

No médica, no estéril.

## DURABILIDAD y MANTENIMIENTO

15 lavados.

Tiempo de uso recomendado 4h.

Se recomienda lavar a mano, secar al aire

Y una vez seca planchar (1 punto de plancha a 120º) .

Lavado a máquina a 60º c. No utilizar lejía.

Puede utilizarse secadora a 70ºc.



## TALLAS DISPONIBLES Y COLORES

REF.: 00185. Tamaño adulto - BLANCA

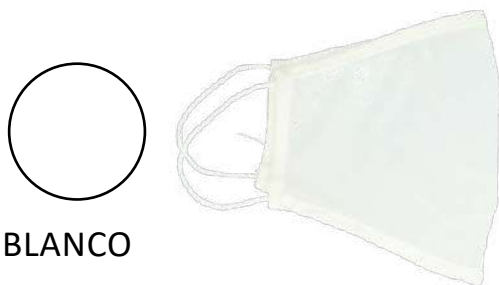
REF.: 00187. Tamaño infantil (7-12 años aprox.) – BLANCA

REF.: 00186. Tamaño adulto - GRIS

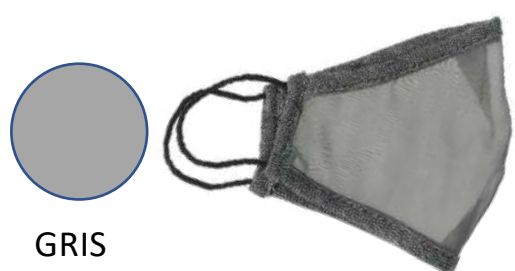
REF.: 00188. Tamaño infantil (7-12 años aprox.) – GRIS

1 ud/blíster

60 uds/ caja



BLANCO



GRIS



**SONREIR  
ES  
SALUD**

**DOCUMENTACIÓN**

Barcelona a 12 de julio 2021

## DECLARACION DE CONFORMIDAD

JOSE ROSAS TABERNER SA con CIF A-08499568 y domicilio en C/Trafalgar 60, 08010 Barcelona

Declara:

Que las mascarillas transparentes higiénicas de los modelos ADULTO, JUNIOR e INFANTIL fabricadas y comercializadas por esta sociedad cumplen con la normativa vigente (conforme a la norma española UNE0065 y conforme a la norma europea CWA 17553:2020).

Que en el ennoblecimiento del tejido se aplican tratamientos hidrofugantes y antibacterianos por baño, utilizando productos libres de ingredientes nocivos o tóxicos.

Que antes de la introducción en el mercado, se han realizado las pruebas y análisis correspondientes en el laboratorio externo AMSLAB, para confirmar el cumplimiento de las normativas vigentes.

Que se ha etiquetado con instrucciones de uso indicando los valores certificados por el laboratorio y el que establece la orden CSM/115/20021, de 11 de febrero del ministerio de Sanidad, Consumo y Bienestar Social.

Así lo hacemos constar a los efectos oportunos.



Mireia Rosàs Castellort  
Dirección

**Job No./Report No:** 21-007889

**Date:** 09/07/2021

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

**Client:** Jose Rosas Taberner, S.A.

**Code:** CL-1669

**Address:** Trafalgar,60 BARCELONA BARCELONA ESPAÑA

**Attn:** Pedro Jose

**e-MAIL:** pedro@castelltort.com

**Tel:** 0034 934683531

**Fax:**

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

Serie (1):		Job no Report No.:	<b>21-007889</b>
Batch No. (1):		Receiving Date:	<b>21/06/2021</b>
Reference No. (1):	<b>REF. 100% POLIAMIDA-MODELO TRANSPARENTE</b>	Test Start Date:	<b>21/06/2021</b>
Composition indicated (1):	<b>100%poliamida</b>	Test End Date:	<b>09/07/2021</b>
		Type:	<b>HIGIENICAL MASKS</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
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
6	S-210621-00203	MAIN FABRIC TRANSPARENT (AFTER 5 WASHING CYCLES AT 60°C)	Pass
ID	ID AMSLab	Description	# Conclusion
7	S-210621-00204	MAIN FABRIC TRANSPARENT (AFTER 15 WASHING CYCLES AT 60°C)	Pass

	CAS	S-210621-00203	S-210621-00204
Change of appearance after washing		No change	Slight change
Number of cycles		5	15
Washing Temperature		60°C	60°C
Method		1	1

**Notes:**

Note 1: Internal method SOP/305 rev. 2: 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)

**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):

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

ID	ID AMSLab	Description	# Conclusion
3	S-210621-00200	MAIN FABRIC TRANSPARENT (ORIGINAL)	Pass

	CAS	S-210621-00200
Test 1: Bacterial Filtration Efficiency		98.0
Test 1: Number of Bacteria		60
Test 2: Bacterial Filtration Efficiency		98.0
Test 2: Number of Bacteria		60
Test 3: Bacterial Filtration Efficiency		98.2
Test 3: Number of Bacteria		55
Test 4: Bacterial Filtration Efficiency		98.2
Test 4: Number of Bacteria		59
Test 5: Bacterial Filtration Efficiency		98.0
Test 5: Number of Bacteria		60

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 cm<sup>2</sup>

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: 21021022

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.

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

ID	ID AMSLab	Description	# Conclusion
10	S-210621-00207	MAIN FABRIC TRANSPARENT (AFTER 5 WASHING CYCLES AT 60°C)	Pass
ID	ID AMSLab	Description	# Conclusion
11	S-210621-00208	MAIN FABRIC TRANSPARENT (AFTER 15 WASHING CYCLES AT 60°C)	Pass

	CAS	S-210621-00207	S-210621-00208
Test 1: Bacterial Filtration Efficiency		96.7	94.7
Test 1: Number of Bacteria		98	160
Test 2: Bacterial Filtration Efficiency		96.8	94.6
Test 2: Number of Bacteria		94	163
Test 3: Bacterial Filtration Efficiency		96.6	94.1
Test 3: Number of Bacteria		102	177
Test 4: Bacterial Filtration Efficiency		96.7	94.4
Test 4: Number of Bacteria		99	168
Test 5: Bacterial Filtration Efficiency		96.6	94.5
Test 5: Number of Bacteria		102	165

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 cm<sup>2</sup>

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: 21021023 for sample for 5 washing cycles and 21021024 for sample for 15 washing cycles

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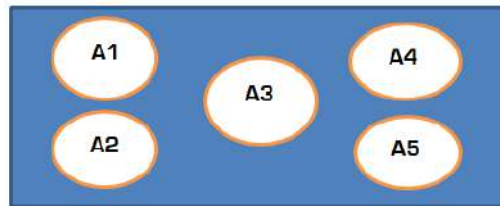
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## # SOP347 - Determination of breathability (Differential Pressure) by UNE-EN 14683 annex C - Original

ID	ID AMSLab	Description	# Conclusion
1	S-210621-00198	MAIN FABRIC 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	<1
2	<1	<1	<1	<1	<1	<1	<1
3	<1	<1	<1	<1	<1	<1	<1
4	<1	<1	<1	<1	<1	<1	<1
5	<1	<1	<1	<1	<1	<1	<1
<b>AVERAGE</b>							<1
<b>UNCERTAINTY (±)</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

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Requirements by specifications:

- Non-reusable Hygienic Mask by UNE 0064-1-2:2020: < 60 Pa/cm<sup>2</sup>
- Reusable Hygienic Mask by UNE 0065:2020: < 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 14683:2019+AC:2019: < 40 Pa/cm<sup>2</sup>
- Surgical Mask type II by UNE-EN 14683:2019+AC:2019: < 40 Pa/cm<sup>2</sup>
- Surgical Mask type IIR by UNE-EN 14683:2019+AC:2019: < 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
4	S-210621-00201	MAIN FABRIC TRANSPARENT (AFTER 5 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/cm <sup>2</sup> )
1	<1	<1	<1	<1	<1	<1	<1
2	<1	<1	<1	<1	<1	<1	<1
3	<1	<1	<1	<1	<1	<1	<1
4	<1	<1	<1	<1	<1	<1	<1
5	<1	<1	<1	<1	<1	<1	<1
AVERAGE							<1
UNCERTAINTY (±)							0.0

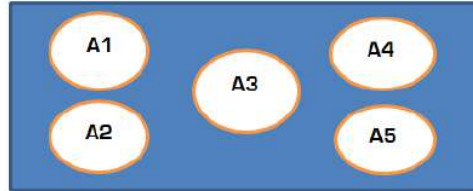
ID	ID AMSLab	Description	# Conclusion
5	S-210621-00202	MAIN FABRIC TRANSPARENT (AFTER 15 WASHING CYCLES AT 60°C)	Pass

BREATHABILITY RESULTS (DIFFERENTIAL PRESSURE)							
TEST PIECE	A1 (Pa)	A2 (Pa)	A3 (Pa)	A4 (Pa)	A5 (Pa)	AVERAGE VALUE (Pa)	P (Pa/cm <sup>2</sup> )
1	<1	<1	<1	<1	<1	<1	<1
2	<1	<1	<1	<1	<1	<1	<1
3	<1	<1	<1	<1	<1	<1	<1
4	<1	<1	<1	<1	<1	<1	<1
5	<1	<1	<1	<1	<1	<1	<1
AVERAGE							<1
UNCERTAINTY (±)							0.0

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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<sup>2</sup>
- 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 0064-1-2:2020: < 60 Pa/cm<sup>2</sup>
- Reusable Hygienic Mask by UNE 0065:2020: < 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 14683:2019+AC:2019: < 40 Pa/cm<sup>2</sup>
- Surgical Mask type II by UNE-EN 14683:2019+AC:2019: < 40 Pa/cm<sup>2</sup>
- Surgical Mask type IIR by UNE-EN 14683:2019+AC:2019: < 60 Pa/cm<sup>2</sup>

Specific Notes:

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

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

ID	ID AMSLab	Description	# Conclusion
2	S-210621-00199	MAIN FABRIC TRANSPARENT (ORIGINAL)	Pass

	CAS	S-210621-00199
(I.C. 95%) - Confidence Interval ±		0.0
Mean Value air permeability (l/m <sup>2</sup> /seg)		>1000.0
Standard deviation		0.0
Value 10 (l/m <sup>2</sup> /seg)		>1000.0
Value 1 (l/m <sup>2</sup> /seg)		>1000.0
Value 2 (l/m <sup>2</sup> /seg)		>1000.0
Value 3 (l/m <sup>2</sup> /seg)		>1000.0
Value 4 (l/m <sup>2</sup> /seg)		>1000.0

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	CAS	S-210621-00199
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 ISO 9237:1996 (equivalent to ISO 9237:1995)

Note 2: Applied pressure: 100 Pa

Note 3: Applied area: 5 cm<sup>2</sup>

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:**

(#: The standards listed below are not included in the ENAC accreditation scope, they are only indicated to inform the applicable requirement)

- 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
8	S-210621-00205	MAIN FABRIC TRANSPARENT (AFTER 5 WASHING CYCLES AT 60°C)	Pass
ID	ID AMSLab	Description	# Conclusion
9	S-210621-00206	MAIN FABRIC TRANSPARENT (AFTER 15 WASHING CYCLES AT 60°C)	Pass

	CAS	S-210621-00205	S-210621-00206
(I.C. 95%) - Confidence Interval ±		0.0	0.0
Mean Value air permeability (l/m2/seg)		>1000.0	>1000.0
Standard deviation		0.0	0.0
Value 10 (l/m2/seg)		>1000.0	>1000.0
Value 1 (l/m2/seg)		>1000.0	>1000.0
Value 2 (l/m2/seg)		>1000.0	>1000.0
Value 3 (l/m2/seg)		>1000.0	>1000.0
Value 4 (l/m2/seg)		>1000.0	>1000.0
Value 5 (l/m2/seg)		>1000.0	>1000.0
Value 6 (l/m2/seg)		>1000.0	>1000.0
Value 7 (l/m2/seg)		>1000.0	>1000.0
Value 8 (l/m2/seg)		>1000.0	>1000.0
Value 9 (l/m2/seg)		>1000.0	>1000.0

-The laboratory is not responsible for the information provided by the client (fields marked with (1)).

-Reported results do not include uncertainties (but are available for the customer).

-Opinions and interpretations expressed herein are outside the scope of accreditation.

-Unless otherwise stated the result shown in this test report refer only the sample/s tested and such sample/s are retained for 30 days only.

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

## Notes:

Note 1: Applied standard UNE-EN ISO 9237:1996 (equivalent to ISO 9237:1995)

Note 2: Applied pressure: 100 Pa

Note 3: Applied area: 5 cm<sup>2</sup>Note 4: Report Unit: l/m<sup>2</sup>/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/m<sup>2</sup>/seg

## Requirements by specifications:

(#: The standards listed below are not included in the ENAC accreditation scope, they are only indicated to inform the applicable requirement)

- European specification CWA 17553:2020: >= 96 l/m<sup>2</sup>/s

## Specific Notes:

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

Issue Date: 09/07/2021

Signed: Manuel Lolo



General Manager

Signed: Pablo Perez



Chemical Lab Manager

Signed: Esteban Ramirez



Physical Lab Manager

Test report reviewed by Esteban Ramírez (Physical Tests) and Lucía Menéndez (Chemical Tests) in the absence of Pablo Pérez

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