¡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%): ≥98
Eficacia BFE% a los 15 lavados: ≥94,5
Respirabilidad. Presión diferencial (Pa/cm2): < 1
Respirabilidad (Pa/cm2) 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.

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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

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SONREIR ES SALUD

DOCUMENTACIÓN

inca FARMA

José Rosàs Taberner, S.A.
Trafalgar, 60 08010 BARCELONA
Tel. (+34) 93 268 36 11 - **Fax.**(+34) 93 268 11 17
www.castelltort.com
CIF.A-08499568

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 Castelltort
Dirección

TEST REPORT

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

Job No./Report No: 21-007889
Date: **09/07/2021**

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:

		Job no Report No.:	**21-007889**
Serie (1):		Receiving Date:	**21/06/2021**
Batch No. (1):		Test Start Date:	**21/06/2021**
Reference No. (1):	**REF. 100% POLIAMIDA-MODELO TRANSPARENTE**	Test End Date:	**09/07/2021**
		Type:	**HIGIENICAL MASKS**
Composition indicated (1):	**100%poliamida**		

#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

-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.
-Test reports without AMSLab seal and authorized signatures are invalid.
-This document can't be reproduced or modified except in full, without prior given approval of the company.
-Any printed copy of this document is copy from the original digital document.

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Tel.: +34 982808074 - Fax.: +34 982803180 analysis@ams-lab.com / www.ams-lab.com

Job No./Report No: 21-007889
Date: **09/07/2021**

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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 60ºC)	Pass

ID	ID AMSLab	Description	# Conclusion
7	S-210621-00204	MAIN FABRIC TRANSPARENT (AFTER 15 WASHING CYCLES AT 60ºC)	Pass

	CAS	S-210621-00203	S-210621-00204
Change of appearance after washing		No change	Slight change
Number of cycles		5	15
Washing Temperature		60ºC	60ºC
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 60º (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.

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

Job No./Report No: 21-007889
Date: **09/07/2021**

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

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 60ºC)	Pass

ID	ID AMSLab	Description	# Conclusion
11	S-210621-00208	MAIN FABRIC TRANSPARENT (AFTER 15 WASHING CYCLES AT 60ºC)	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 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: 21021023 for sample for 5 washing cycles and 21021024 for sample for 15 washing cycles

Job No./Report No: 21-007889
Date: **09/07/2021**

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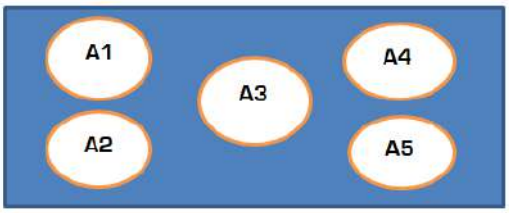
EKOTEKS LABORATUVAR VE GÖZETM HZMETLER A. . Deney Laboratuvar, is accredited by TURKAK under registration number (AB-0583-T) for ISO 17025:2017 as test laboratory.

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)**	ΔP (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
					AVERAGE		<1
					UNCERTAINTY (±)		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) ºC and (85 ± 5) %HR
Note 9: A: sample area tested
Note 10: n.a. = not applicable

Job No./Report No: 21-007889
Date: **09/07/2021**

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

Requirements by specifications:
- Non-reusable Hygienic Mask by UNE 0064-1-2:2020: < 60 Pa/cm2
- Reusable Hygienic Mask by UNE 0065:2020: < 60 Pa/cm2
- European specification CWA 17553:2020: <= 70 Pa/cm2

Other requirements:
- Surgical Mask type I by UNE-EN 14683:2019+AC:2019: < 40 Pa/cm2
- Surgical Mask type II by UNE-EN 14683:2019+AC:2019: < 40 Pa/cm2
- Surgical Mask type IIR by UNE-EN 14683:2019+AC:2019: < 60 Pa/cm2

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 60ºC)	Pass

BREATHABILITY RESULTS (DIFFERENTIAL PRESSURE)							
TEST PIECE	**A1 (Pa)**	**A2 (Pa)**	**A3 (Pa)**	**A4 (Pa)**	**A5 (Pa)**	**AVERAGE VALUE (Pa)**	ΔP (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
					AVERAGE		<1
					UNCERTAINTY (±)		0.0

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

BREATHABILITY RESULTS (DIFFERENTIAL PRESSURE)							
TEST PIECE	**A1 (Pa)**	**A2 (Pa)**	**A3 (Pa)**	**A4 (Pa)**	**A5 (Pa)**	**AVERAGE VALUE (Pa)**	ΔP (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
					AVERAGE		<1
					UNCERTAINTY (±)		0.0

Applied Mass Spectrometry Laboratory, S.L.U.Avda. Benigno Rivera, nº56 27003 Lugo (Spain)
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Date: **09/07/2021**

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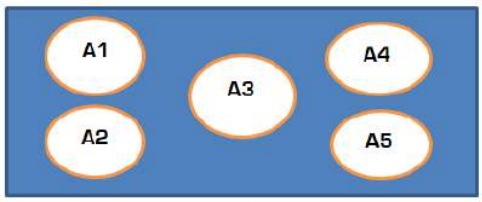

Notes:
Note 1: Applied standard UNE-EN 14683:2019+AC:2019 Annex C for breathability (Differential Pressure)
Note 2: For requirements: Spanish Specification UNE 0064-1, 0064-2, 0065 and European Specification CWA 17553
Note 3: Size of test specimen: 4.9 cm2
Note 4: Tested area of the test specimen: 2.5 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) ºC 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/cm2
- Reusable Hygienic Mask by UNE 0065:2020: < 60 Pa/cm2
- European specification CWA 17553:2020: <= 70 Pa/cm2

Other requirements:
- Surgical Mask type I by UNE-EN 14683:2019+AC:2019: < 40 Pa/cm2
- Surgical Mask type II by UNE-EN 14683:2019+AC:2019: < 40 Pa/cm2
- Surgical Mask type IIR by UNE-EN 14683:2019+AC:2019: < 60 Pa/cm2

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/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

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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 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 ºC 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 60ºC)	Pass

ID	ID AMSLab	Description	# Conclusion
9	S-210621-00206	MAIN FABRIC TRANSPARENT (AFTER 15 WASHING CYCLES AT 60ºC)	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

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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 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 ºC 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

Issue Date: 09/07/2021

Signed: Manuel Lolo	Signed: Pablo Perez	Signed: Esteban Ramirez
General Manager	Chemical Lab Manager	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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