

abbacino

FARMA *inca*

Mascarillas higiénicas
homologadas reutilizables
UNISEX

UNE 0065

CWA 17553



MATERIAL NEOPLUS

FARMA *inca*

ESPECIFICACIONES TÉCNICAS



COMPOSICIÓN:

Tejido doble tela 350 gr/m2. 1ª capa: 92% PES + 8% EA. 2ª capa: 100% PES

CERTIFICADO NORMA UNE 0065/20

CERTIFICADO NORMA CWA 17553



PROTECCIÓN:

Tejido Hidrofugado ambas caras. Tratamiento Antibacteriano APPLIFRESH BC. Agente microbiano permanente estático. Tecnología C6 Blood Barrier.



GRAN TRANSPIRABILIDAD.



CONFORT, MANTIENE LA TEMPERATURA CORPORAL.



NORMATIVA:

Durabilidad de los tratamientos: 30 Lavados a 60°

NORMA UNE 0065/20 Respirabilidad (PA/cm2) < 60 UNE-

EN14683:2019+AC2019 Eficacia Filtración (BFE%) >= 90

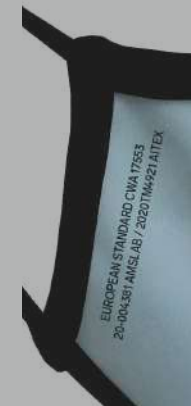
UNE-EN14683:2019+AC2019

NORMA CWA 17553. 60 lavados con una eficacia de 89,4% (Es muy estable)

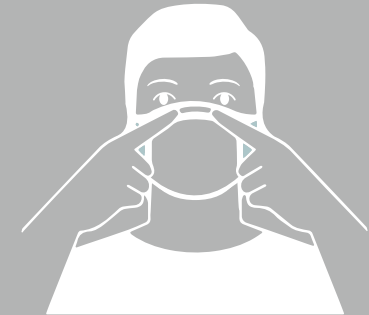


Nuevo tejido que aporta más suavidad en la parte interior.

Opción de añadir ajuste nasal y normativa en la parte exterior.



AJUSTE NASAL



Sistema patentado - Número de solicitud: U202031043

“ADVERTENCIA: Este dispositivo no es un producto sanitario en el sentido de la Directiva 93/42 o del Reglamento UE/2017/745, ni un EPI en el sentido del Reglamento UE/2016/425”

Por motivos de higiene: Las mascarillas deberán de ser devueltas respetando su envoltorio original.



Mascarillas higiénicas
REUTILIZABLES
ADULTO



REF. 01015



REF. 01016



REF. 01017



REF. 01018



REF. 01019



Mascarillas higiénicas
REUTILIZABLES
INFANTIL



REF. 01020



REF. 01021



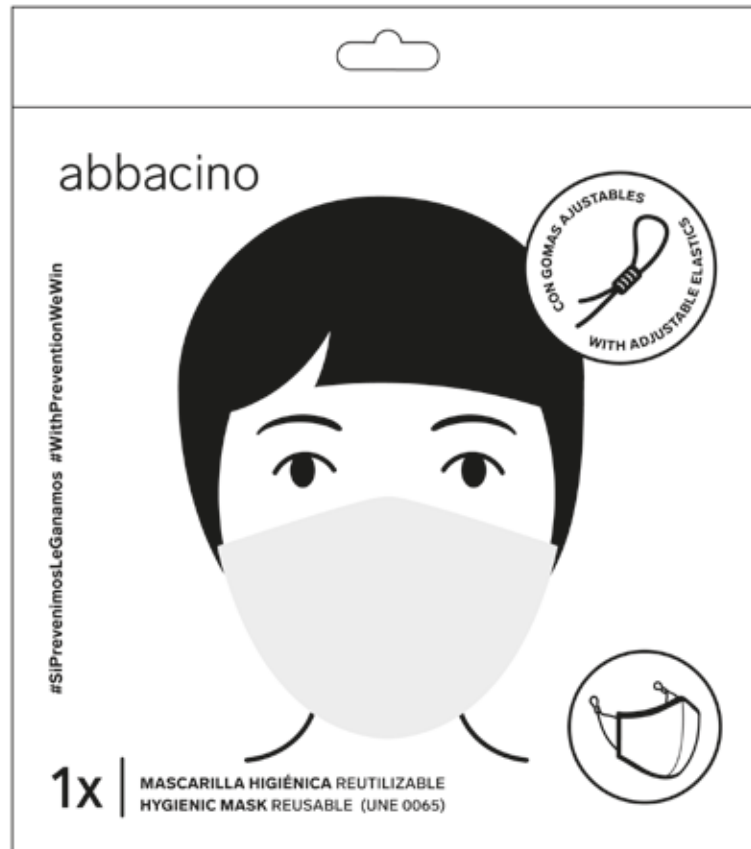
REF. 01022



REF. 01023



REF. 01024



Petra a 14/10/2021

DECLARACION DE CONFORMIDAD

Antoni Vadell Truyols con DNI.18220825H en calidad de administrador de la empresa SEYMA IMPORTACIO SL con NIF. B07713324 y domicilio en C.Bellavista,23 -007520- PETRA-ILLES BALEARS

Declara:

Que las mascarillas higiénicas de los modelos ADULTO e INFANTIL , 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 AQUIMISA , 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.



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Job No./Report No: 21-002859

Date: 08/03/2021

SOP305 - Change of appearance after washing (Garments and fabrics)

ID	ID AMSLab	Description	Conclusion
6	S-210212-00176	MASK BLACK (AFTER 5 WASHING CYCLES AT 60°C)	Pass
ID	ID AMSLab	Description	Conclusion
7	S-210212-00177	MASK BLACK (AFTER 30 WASHING CYCLES AT 60°C)	Pass
ID	ID AMSLab	Description	Conclusion
8	S-210212-00178	MASK BLACK (AFTER 60 WASHING CYCLES AT 60°C)	Pass

	CAS	S-210212-00176	S-210212-00177	S-210212-00178
Change of appearance after washing		No change	Slight change	Slight change
Number of cycles		5	30	60
Washing Temperature		60°C	60°C	60°C

Notes:

Note 1: Washing and drying process applied based on UNE-EN ISO 6330:2012

Note 2:

- Detergent: 20 gr of Commercial detergent / - Drying procedure: Air dry without tumble dry.
- n.a.: not applicable
- Requirement: No obvious change/colour/shape/appearance/seams/embroidery/trimmings/applications

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

- No change in appearance after washing and drying process
- Slight change in appearance after washing and drying process
- Moderate change in appearance after washing and drying process
- Severe change in appearance after washing and drying process

SOP 342- Bacterial Filtration Efficiency (BFE)

ID	ID AMSLab	Description	Conclusion
2	S-210212-00172	MASK BLACK (ORIGINAL)	Pass

	CAS	S-210212-00172
Test 1: Bacterial Filtration Efficiency		95.8
Test 1: Number of Bacteria		126
Test 2: Bacterial Filtration Efficiency		95.8
Test 2: Number of Bacteria		127
Test 3: Bacterial Filtration Efficiency		95.6
Test 3: Number of Bacteria		131
Test 4: Bacterial Filtration Efficiency		95.6
Test 4: Number of Bacteria		133
Test 5: Bacterial Filtration Efficiency		95.8
Test 5: Number of Bacteria		125

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Job No./Report No: 21-002859

Date: 08/03/2021

Notes:

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 for medical mask tests (EN 14683). Results in subcontracted report number: 21006465

SOP 342- Bacterial Filtration Efficiency (BFE) - After Washing

ID	ID AMSLab	Description	Conclusion
9	S-210212-00179	MASK BLACK (AFTER 5 WASHING CYCLES AT 60°C)	Pass
ID	ID AMSLab	Description	Conclusion
10	S-210212-00180	MASK BLACK (AFTER 30 WASHING CYCLES AT 60°C)	Pass
ID	ID AMSLab	Description	Conclusion
11	S-210212-00181	MASK BLACK (AFTER 60 WASHING CYCLES AT 60°C)	See Results

	CAS	S-210212-00179	S-210212-00180	S-210212-00181
Test 1: Bacterial Filtration Efficiency		92.6	90.8	89.4
Test 1: Number of Bacteria		221	276	319
Test 2: Bacterial Filtration Efficiency		92.2	90.5	89.1
Test 2: Number of Bacteria		234	284	328
Test 3: Bacterial Filtration Efficiency		92.4	90.4	89.1
Test 3: Number of Bacteria		228	289	328
Test 4: Bacterial Filtration Efficiency		92.3	90.0	89.3
Test 4: Number of Bacteria		232	300	321
Test 5: Bacterial Filtration Efficiency		92.4	90.0	89.1

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Date: 08/03/2021

	CAS	S-210212-00179	S-210212-00180	S-210212-00181
Test 5: Number of Bacteria		227	300	327

Notes:

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 for medical mask tests (EN 14683). Results in subcontracted report number: 21006466 for samples for 5 washing cycles, 21006467 for samples for 30 washing cycles and 21006468 for samples for 60 washing cycles.

SOP106 - Determination of breathability (Differential Pressure) - Original

ID	ID AMSLab	Description	Conclusion
1	S-210212-00171	MASK BLACK (ORIGINAL)	Pass

	CAS	S-210212-00171
Average Differential pressure (Pa/cm ²)		40
Value 1 Differential pressure (Pa/cm ²)		41
Value 2 Differential pressure (Pa/cm ²)		40
Value 3 Differential pressure (Pa/cm ²)		40
Value 4 Differential pressure (Pa/cm ²)		39
Value 5 Differential pressure (Pa/cm ²)		38

-The laboratory is not responsible for the information received by the client (grey shaded fields)

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Date: 08/03/2021

Notes:

- Note 1: Applied standard UNE-EN 14683:2019 and Spanish Specification UNE 0064-1, 0064-2, 0065 and European Specification CWA 17553
- Note 2: Size of test specimen: 4.9 cm²
- Note 3: Tested area of the test specimen: 2.5 cm
- Note 4: Flow of air: (8 ± 0.2) l/min
- Note 5: Velocity of 272 l/m²/s or 272 mm/s
- 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: 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

SOP106 - Determination of breathability (Differential Pressure) - After Washing

ID	ID AMSLab	Description	Conclusion
3	S-210212-00173	MASK BLACK (AFTER 5 WASHING CYCLES AT 60°C)	Pass
ID	ID AMSLab	Description	Conclusion
4	S-210212-00174	MASK BLACK (AFTER 30 WASHING CYCLES AT 60°C)	Pass
ID	ID AMSLab	Description	Conclusion
5	S-210212-00175	MASK BLACK (AFTER 60 WASHING CYCLES AT 60°C)	Pass

	CAS	S-210212-00173	S-210212-00174	S-210212-00175
Average Differential pressure (Pa/cm ²)		44	47	48
Value 1 Differential pressure (Pa/cm ²)		43	47	47
Value 2 Differential pressure (Pa/cm ²)		44	47	49
Value 3 Differential pressure (Pa/cm ²)		45	48	49
Value 4 Differential pressure (Pa/cm ²)		45	48	48
Value 5 Differential pressure (Pa/cm ²)		44	47	47

Notes:

- Note 1: Applied standard UNE-EN 14683:2019 and Spanish Specification UNE 0064-1, 0064-2, 0065 and European Specification CWA 17553
- Note 2: Size of test specimen: 4.9 cm²
- Note 3: Tested area of the test specimen: 2.5 cm
- Note 4: Flow of air: (8 ± 0.2) l/min
- Note 5: Velocity of 272 l/m²/s or 272 mm/s
- 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: n.a. = not applicable

Requirements by specifications:

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Job No./Report No: 21-002859**Date: 08/03/2021**

- 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

Issue Date: 08/03/2021

Signed: Manuel Lolo


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General Manager

Signed: Pablo Perez


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Chemical Lab Manager

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Physical Lab Manager

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