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FARMAinca

Mascarillas higiénicas
homologadas reutilizables
**UNISEX**

**UNE 0065**

**CWA 17553**

MATERIAL NEOPLUS

# 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

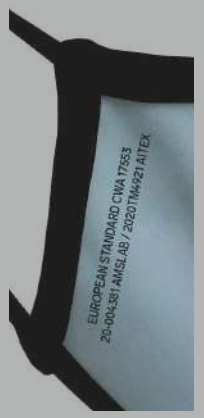
PROTECCIÓN:
Tejido Hidrofugado ambas caras. Tratamiento Antibacteriano APPLIFRESH BC. Agente microbiano permanente estático.
Tecnología C6 Blood Barrier.

GRAN TRANSPIRABILIDAD.

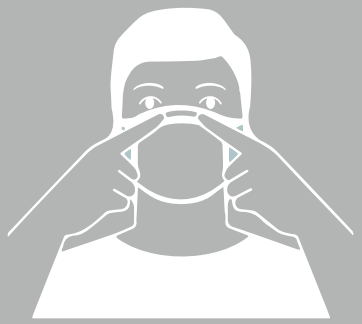
CONFORT, MANTIENE LA TEMPERATURA CORPORAL.

NORMATIVA:
Durabilidad de los tratamientos: 30 Lavados a 60º
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.

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# Mascarillas higiénicas REUTILIZABLES **ADULTO**

MASCARILLA ADULTO UNISEX

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REF. 01015

REF. 01016

REF. 01017

REF. 01018

REF. 01019

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# Mascarillas higiénicas REUTILIZABLES **INFANTIL**

MASCARILLA INFANTIL

FARMAinca

REF. 01020

REF. 01021

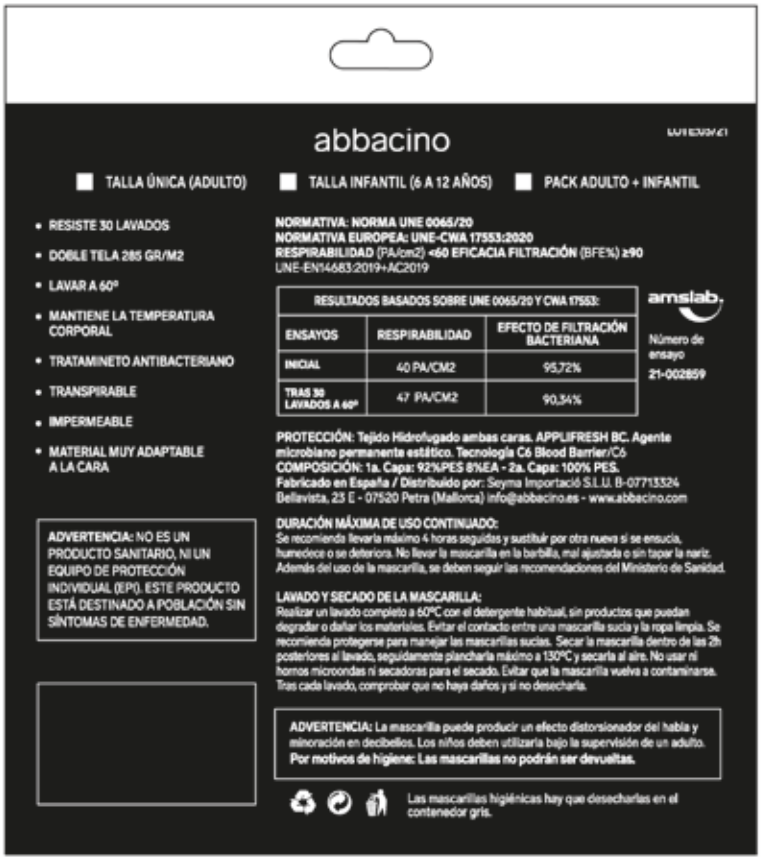
REF. 01022

REF. 01023

REF. 01024

# PACKAGING

FARMAinca

# EXPOSITOR DE MOSTRADOR

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REF. 01025

↔30 ↕27 ↗10,5 CM


REF. 01026

↔30 ↕27 ↗10,5 CM

Por la compra de un expositor
de mascarillas completo (25 unidades)
te **REGALAMOS** 25 fundas de mascarilla.

REF. 000107
REF. 000108
REF. 000109
REF. 000110

**Regalo valorado en 25€**

abbacino

INCA PRODUCT SL

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.

SEYMA IMPORTACIO S.L.U.

C.I.F: B - 07 713 324
Bellavista, 27
07520 - PETRA (Illes Balears)
Tel. 971 56 10 33
Fax 971 83 00 51

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# TEST REPORT

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

**Client:** Seyma Importación, S.L. **Code:** CL-1367
**Address:** C/Bellavista,27 PETRA ILLES BALEARS ESPAÑA
**Attn:** Sebastian Vadell **e-MAIL:** svadell@abbacino.es
**Tel:** 0034 971561033 **Fax:**

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

| | |
|---|---|
| Serie : | |
| Batch No.: | |
| Reference No.: | **MASCARILLA HIGIÉNICA REUTILIZABLE/ART. 7024 NEO-PLUS/SUBLIMADO A UNA CARA** |
| Composition indicated: | **1ª CAPA: ART.5168 Hidrófugo y antibacteriano + HOT MELT + 2ª CAPA. art. 5154 / LOTE: 2D7528//D7555** |

| | |
|---|---|
| Job no Report No.: | **21-001658** |
| Receiving Date: | **12/02/2021** |
| Test Start Date: | **12/02/2021** |
| Test End Date: | **25/02/2021** |
| Sample description: | **MASK** |

This test report is a modification of issued in the date "25/02/2021". Changes: Product batch is added (LOTE: 2D7528//D7555) and the photograph is modified so that the logo can be view correctly . Cause: Customer´s request.

This test report is a copy of results of the report "21-001658"

## SUMMARY OF TEST CONCLUSIONS

| SOP description | Conclusions |
|---|---|
| SOP305 - Change of appearance after washing (Garments and fabrics) | Pass |
| SOP 342- Bacterial Filtration Efficiency (BFE) | Pass |
| SOP 342- Bacterial Filtration Efficiency (BFE) - After Washing | See Results |
| SOP106 - Determination of breathability (Differential Pressure) - Original | Pass |
| SOP106 - Determination of breathability (Differential Pressure) - After Washing | Pass |

## Sample Tested


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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 60ºC) | Pass |
| **ID** | **ID AMSLab** | **Description** | **Conclusion** |
| 7 | S-210212-00177 | MASK BLACK (AFTER 30 WASHING CYCLES AT 60ºC) | Pass |
| **ID** | **ID AMSLab** | **Description** | **Conclusion** |
| 8 | S-210212-00178 | MASK BLACK (AFTER 60 WASHING CYCLES AT 60ºC) | 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 | | 60ºC | 60ºC | 60ºC |

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 (ORIGNAL) | 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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**Tel.: +34 982808074 - Fax.: +34 982803180 analysis@ams-lab.com / www.ams-lab.com**

## 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: >=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 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 60ºC) | Pass |
| **ID** | **ID AMSLab** | **Description** | **Conclusion** |
| 10 | S-210212-00180 | MASK BLACK (AFTER 30 WASHING CYCLES AT 60ºC) | Pass |
| **ID** | **ID AMSLab** | **Description** | **Conclusion** |
| 11 | S-210212-00181 | MASK BLACK (AFTER 60 WASHING CYCLES AT 60ºC) | 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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| | 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: >=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 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 (ORIGNAL) | Pass |

| | CAS | S-210212-00171 |
|---|---|---|
| Average Differential pressure (Pa/cm2) | | 40 |
| Value 1 Differential pressure (Pa/cm2) | | 41 |
| Value 2 Differential pressure (Pa/cm2) | | 40 |
| Value 3 Differential pressure (Pa/cm2) | | 40 |
| Value 4 Differential pressure (Pa/cm2) | | 39 |
| Value 5 Differential pressure (Pa/cm2) | | 38 |

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**Job No./Report No: 21-002859**
**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 ºC 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 60ºC) | Pass |
| **ID** | **ID AMSLab** | **Description** | **Conclusion** |
| 4 | S-210212-00174 | MASK BLACK (AFTER 30 WASHING CYCLES AT 60ºC) | Pass |
| **ID** | **ID AMSLab** | **Description** | **Conclusion** |
| 5 | S-210212-00175 | MASK BLACK (AFTER 60 WASHING CYCLES AT 60ºC) | Pass |

| | CAS | S-210212-00173 | S-210212-00174 | S-210212-00175 |
|---|---|---|---|---|
| Average Differential pressure (Pa/cm2) | | 44 | 47 | 48 |
| Value 1 Differential pressure (Pa/cm2) | | 43 | 47 | 47 |
| Value 2 Differential pressure (Pa/cm2) | | 44 | 47 | 49 |
| Value 3 Differential pressure (Pa/cm2) | | 45 | 48 | 49 |
| Value 4 Differential pressure (Pa/cm2) | | 45 | 48 | 48 |
| Value 5 Differential pressure (Pa/cm2) | | 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 ºC and 85 ± 5 HR
Note 9: n.a. = not applicable

Requirements by specifications:

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- 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 | Signed: Pablo Perez | Signed: Esteban Ramirez |
|---|---|---|
|  |  |  |
| General Manager | Chemical Lab Manager | Physical Lab Manager |

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