

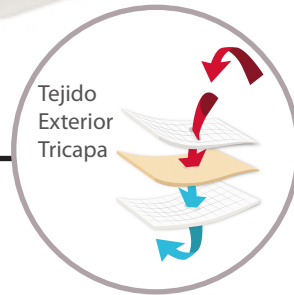
adversia®



EUROSAVOY®

ELEMENTO
PROTECCIÓN

CARA EXTERIOR



Tejido
Exterior
Tricapa

CARA INTERIOR



FICHA TÉCNICA

IDENTIFICACIÓN DEL PRODUCTO

Nombre:	Mascarilla Higiénica Lavable	
Marca:	Eurosavoy	REF 120009
Color:	Blanco 00, Negro 99	
Tallas:	Adulto	
Presentación:	Embolsado individual	

CICLOS E INSTRUCCIONES LAVADOS

LAVADOS	30 CICLOS
TEMPERATURA	60°C
LEJÍA	Blanco (SI), Negro (NO), SUBLIMACIÓN (NO)
PLANCHA	NO



ESPECIFICACIONES TÉCNICAS

Función:	La mascarilla higiénica está destinada a adultos y niños a partir de 3 años sin síntomas que no sean susceptibles de utilizar mascarillas quirúrgicas ni máscaras filtrantes de protección contra partículas, según las medidas establecidas en el documento técnico "Prevención y control de la infección en el manejo de pacientes con COVID-19" publicado por el Ministerio de Sanidad.
Tamaño:	Producto que cubre la boca, nariz y barbilla provisto gomitas para sujeción en las orejas.
Uso:	Producto previsto por el fabricante para ser utilizado en varias ocasiones siempre que se sigan las instrucciones de limpieza del fabricante
Criterios	Eficacia de filtración. (%) ("ensayo BFE") Ensayada a través de ensayo de eficacia de filtración bacteriana (BFE), (%) (apartado 5.2.2 de la Norma UNE-EN 14683:2019+AC:2019) > 95 Respirabilidad (Presión diferencial), (Pa/cm2) (apartado 5.2.3 de la Norma UNE-EN 14683:2019+AC:2019) < 40

NORMALIZACIÓN ESPAÑOLA ESPECIFICACIÓN UNE 0065 DE abril 2020 y en proceso de certificación como mascarilla sanitaria Clase I

"ADVERTENCIA: Este dispositivo no es un producto sanitario en el sentido de la Directiva 93/42 o del Reglamento UE / 2017/745, ni un equipo de protección individual en el sentido del Reglamento UE / 2016/425";

CARACTERÍSTICAS DE LOS TEJIDOS

Descripción:	1º tejido poliéster/poliamida de 126, 2º tejido de spunbod polipropileno de 40
Materia prima:	1º tejido 80% poliéster 20% poliamida, 2º tejido 100% polipropileno
Gramaje:	1º Tejido 126 gr/m ² 2º Tejido 40 gr/m ²
Propiedades físicas:	Transpirables, hidrófugos, actúa como barrera de bacterias y virus. Respetuoso con el medio ambiente

Job No./Report No: 20-004590

Date: 16/06/2020

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

ID	ID AMSLab	Description	Conclusion
2	S-200508-00002	FABRIC BLACK (30 WASHING CYCLES AT 60°C)	See Results

	CAS	S-200508-00002
Change of appearance after washing		Slight change
Number of cycles		30
Washing Temperature		60°C

Notes:

Note 1: Washing and drying process applied based on UNE-EN ISO 6330:2001

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) - After Washing

ID	ID AMSLab	Description	Conclusion
3	S-200508-00003	FABRIC BLACK (AFTER 30 WASHING CYCLES AT 60°C)	See Results

	CAS	S-200508-00003
Test 1: Bacterial Filtration Efficiency		85.0
Test 1: Number of Bacteria		345
Test 2: Bacterial Filtration Efficiency		85.2
Test 2: Number of Bacteria		340
Test 3: Bacterial Filtration Efficiency		84.7
Test 3: Number of Bacteria		351
Test 4: Bacterial Filtration Efficiency		84.5
Test 4: Number of Bacteria		357
Test 5: Bacterial Filtration Efficiency		84.3
Test 5: Number of Bacteria		361

Notes:

Test Method Ref: TS EN 14683:2019 Medical Face Masks, Requirements and Test Methods

Specifications:

UNE 0065: > 90%

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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) : 5x10⁵ cfu/ml

Incubation conditions: 24 hour, 35C ± 2C

Positive control sample average of number of Bacteria (C): 2.3x10³ cfu/ml

(*) Test subcontracted. Results in subcontracted report number: 20015436

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

ID	ID AMSLab	Description	Conclusion
1	S-200508-00001	FABRIC BLACK (AFTER 30 WASHING CYCLES AT 60°C)	See Results

	CAS	S-200508-00001
Average Differential pressure (Pa/cm ²)		10
Value 1 Differential pressure (Pa/cm ²)		10
Value 2 Differential pressure (Pa/cm ²)		10
Value 3 Differential pressure (Pa/cm ²)		9
Value 4 Differential pressure (Pa/cm ²)		10
Value 5 Differential pressure (Pa/cm ²)		10

Notes:

Note 1: Applied standard UNE-EN 14683:2019 and Specification UNE 0064-1, 0064-2 and 0065

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 measurements: 5

Note 8: Conditioned samples: 4 hours at 21 ± 5 °C and 85 ± 5 HR

Note 9: n.a. = not applicable

Requirement by standard:

- Non-reusable Hygienic Mask by UNE 0064-1-2: < 60 Pa/cm²

- Reusable Hygienic Mask by UNE 0065: < 60 Pa/cm²

Specific Notes:

(**) The result is out of specifications

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Job No./Report No: 20-004590

Date: 16/06/2020

Issue Date: 16/06/2020

Signed: Manuel Lolo



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Applied Mass Spectrometry Laboratory S.L.
C.I.F. B - 27.380.914

General Manager

Signed: Pablo Perez



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Applied Mass Spectrometry Laboratory S.L.
C.I.F. B - 27.380.914

Chemical Lab Manager

Signed: Esteban Ramirez



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Applied Mass Spectrometry Laboratory S.L.
C.I.F. B - 27.380.914

Physical Lab Manager

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INFORME DE ENSAYO / TEST REPORT

2020TM1000

FECHA DE RECEPCIÓN / DATE OF RECEPTION

16/04/2020

SOLICITANTE / APPLICANT

FECHA DE ENSAYOS / DATE TESTS

Inicio / Starting: 17/04/2020

Finalización / Ending: 21/04/2020

IDENTIFICACIÓN Y DESCRIPCIÓN DE LAS MUESTRAS / IDENTIFICATION AND DESCRIPTION OF SAMPLES

REFERENCIAS / REFERENCES

Tejido 80% PES / 20% PA Ref. Tec 7191

ENSAYOS REALIZADOS / TESTS CARRIED OUT

- PRETRATAMIENTO / PRE-TREATMENT.
- DETERMINACIÓN IN VITRO DE LA EFICACIA DE LA FILTRACIÓN BACTERIANA (BFE)* / IN VITRO DETERMINATION OF BACTERIAL FILTRATION EFFICIENCY (BFE)*.
- DETERMINACIÓN DE LA RESPIRABILIDAD (PRESIÓN DIFERENCIAL)* / DETERMINATION OF BREATHABILITY (DIFFERENTIAL PRESSURE)*.
- DETERMINACIÓN DE LA PRESIÓN DE RESISTENCIA A LAS SALPICADURAS* / DETERMINATION OF PRESSURE OF SPLASH RESISTANCE*.

Los ensayos marcados con * no están amparados por la acreditación de ENAC
Tests marked with * are not included within the scope of the ENAC accreditation

Rev.1 Esta revisión anula y sustituye a la anterior / This revision cancels and replaces the previous



RESUMEN DE RESULTADOS / RESULTS SUMMARIZE

Realizados sobre la siguiente referencia tras 5 ciclos de lavado a 60°C:
Carried out on the following reference after 5 washing cycles at 60°C:

Tejido 80% PES / 20% PA Ref. Tec 7191

Sobre los requisitos de funcionamiento en base a la norma EN 14683:2019 + AC:2019 de mascarillas quirúrgicas puntos 5.2.2, 5.2.3 y 5.2.4 para los tipos I, II y IIR./ With the performance requirements of EN 14683: 2019 + AC: 2019 standard for surgical masks points 5.2.2, 5.2.3 and 5.2.4 for types I, II and IIR.

Habiéndose obtenido los siguientes resultados: /
Having obtained the following results

Requisitos de funcionamiento / Operating requirements:				RESULTADOS RESULTS (Promedio ± DS) (Average ± SD)	
		Tipo I Type I	Tipo II Type II		Tipo IIR Type IIR
5.2.2.	Eficacia de la filtración bacteriana (BFE) (%) Bacterial Filtration Efficiency (BFE) (%)	≥ 95	≥ 98	≥ 98	94,16 ± 2,45
5.2.3.	Respirabilidad: Presión diferencial (Pa/cm ²) Breathability: Differential pressure (Pa/cm ²)	< 40	< 40	< 60	19 ± 1
5.2.4.	Presión de resistencia a las salpicaduras(kPa) Splash resistance pressure (kPa)	No requerido Not required	No requerido Not required	≥ 16,0	Fallan 2 de 2 a 17 kPa Failure 2 of 2 at 17 kPa

Observaciones / Notes:

- El resto de ensayos de la norma no indicados no han sido evaluados / The rest of the standard tests not indicated have not been evaluated
- DS: Desviación estándar / SD: Standard Deviation.

Job No./Report No: 20-004590

Date: 16/06/2020

Client:

Code: CL-0838

Address:

Attn:

e-MAIL:

Tel:

Fax:

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

Job no Report No.: 20-004590
Receiving Date: 07/05/2020
Test Start Date: 12/05/2020
Test End Date: 29/05/2020
Sample description: RAW MATERIAL

Serie :
 Batch No.:
 Reference No.:
 Composition indicated: **80%PES, 20%PA**

This test report is a modification of issued in the date "29/05/2020". Change: Report without application of specific requirements for international market. Cause: Customer's request.

SUMMARY OF TEST CONCLUSIONS

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

Sample Tested



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