

MASCARILLA FFP2 APOSÁN 10U

Código 034396

Fabricante

Descriptiva

Laboratorios XACARA S.L.

Mascarilla de filtrado de partículas FFP2 NR, PFE $\geq 94\%$, color blanco, caja de 10 unidades.



Ficha de producto marca “aposan”

Descripción general del producto

Laboratorios **XACARA S.L.**

Oficinas: C/ Impresores, 20. 28660 Boadilla del Monte (Madrid)

Planta: C/ Mario Roso de Luna, 29. Nave 5. 28022 Madrid

EL EPI **LXME02**, ha sido fabricado con los requisitos generales de salud y seguridad especificados en el Reglamento (UE) 2016/425, en particular, las especificaciones contenidas en las normas EN 149: 2001 + A1: 2009, publicada por el Comité Europeo de Normalización, como EPI de Categoría III. Requisitos, pruebas, marcado de conformidad según el certificado el certificado **CE0099** de **AENOR INTERNACIONAL S.A.U**; Calle Génova, 6. 28004 Madrid (España).

Esta media máscara filtrante está fabricada para protección respiratoria contra partículas, excepto partículas para situaciones de escape. Según lo solicitado por las recomendaciones de la Organización Mundial de la Salud, para este uso específico, el factor de protección nominal proporcionado por esta media máscara filtrante es el mismo que el factor de protección nominal FFP2 definido en EN149: 2001 + A1: 2009

- La mascarilla filtrante tipo EPI están diseñadas para proteger a los usuarios contra contaminantes ambientales y cumple con los requisitos específicos para evitar la inhalación de estos, (no protege de vapores ni gases).
- Contienen un filtro de micropartículas gracias al cual protege de fuera hacia dentro en distintos grados, así pues, además de proteger contra las partículas de mayor tamaño que impactan en su superficie externa, están diseñadas para actuar como un filtro de los aerosoles de menor tamaño.

Aviso de alergia.

El EPI se fabrica con material no tejido, cuya composición es de:

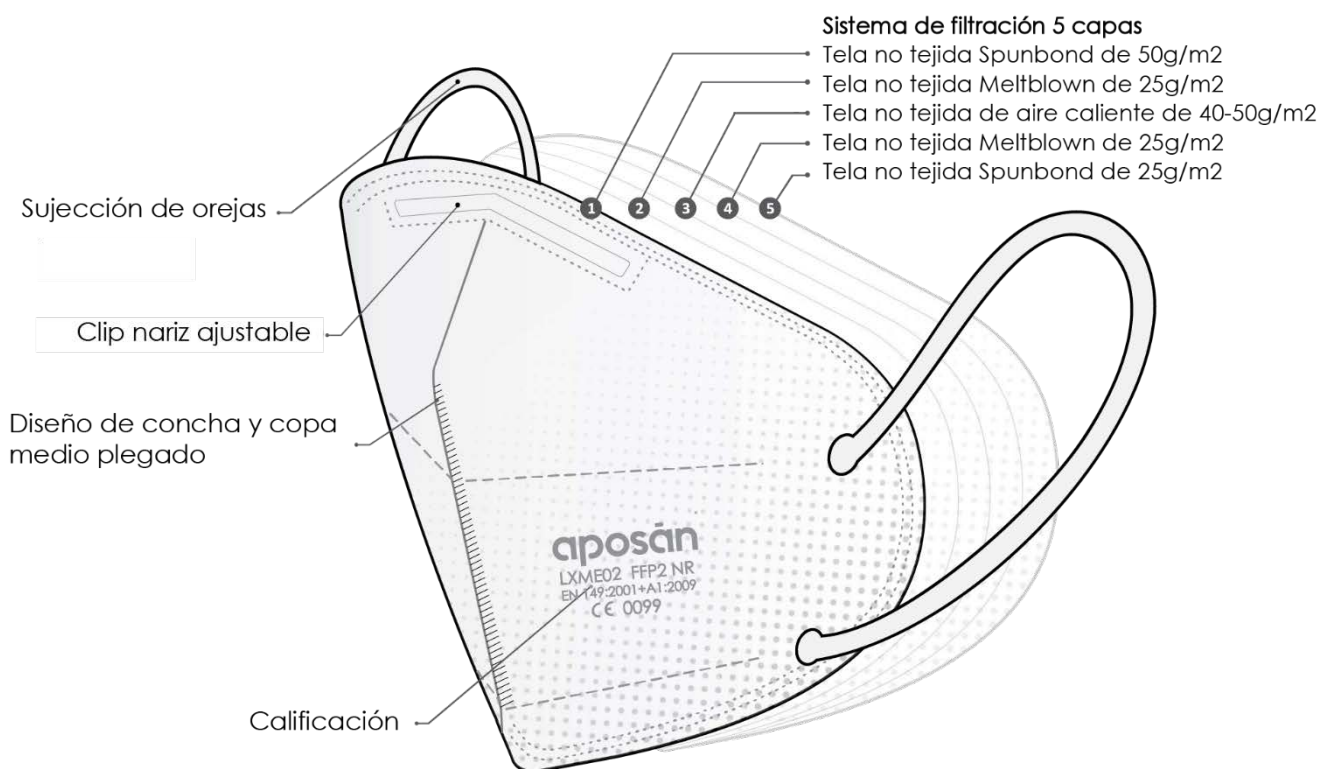
- 42% Tela no tejida
- 29% Tela fundida por soplado
- 29% Algodón de aire caliente

Descripción de los materiales de fabricación

Está compuesto por 5 **capas**, ordenadas de fuera a dentro como se indica a continuación.

- 260 mm 50 GSM. Tela no tejida Spunbond Non-woven fabrics.
- 260 mm 25 GSM. Tela no tejida MeltBlown.
- 260 mm 50 GSM. Tela no tejida Hot Air Cotton.
- 260 mm 25 GSM. Tela no tejida MeltBlown.
- 260 mm 25 GSM. Tela no tejida Spunbond Non-woven fabrics.
- El lazo de sujeción de las orejas de 5 mm plano.
- El puente de la nariz de alambre doble de 5 mm de ancho.

Es esquema de las capas que componen la mascarilla se describe a continuación.



La impronta en la mascarilla se imprime siguiendo la siguiente especificación:

apósán

LXME02 FFP2 NR
 EN 149: 2001+A1:2009
 CE 0099

Recomendaciones de uso

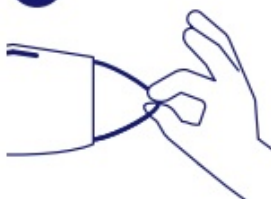
La mascarilla filtrante se sujeta en las orejas mediante las gomas elásticas insertadas en la misma. Para mayor sujeción se recomienda poner ajustadores de gomas. Ajuste la media máscara filtrante siguiendo las siguientes instrucciones:

1



Lávate las manos durante 40-60 segundos antes de manipularla.

2



Toca solo las gomas de la mascarilla.

3



Póntela sobre nariz y boca, asegurándote de que no quedan grandes espacios entre tu cara y la mascarilla.

4



Pasa las bandas elásticas por detrás de tus orejas.

5



Pellizca la pinza nasal para ajustarla bien a la nariz.

6



Evita tocar la parte exterior de la mascarilla. Si lo haces, lávate las manos antes y después.

7



Antes de quitarte la mascarilla, lávate las manos.

8

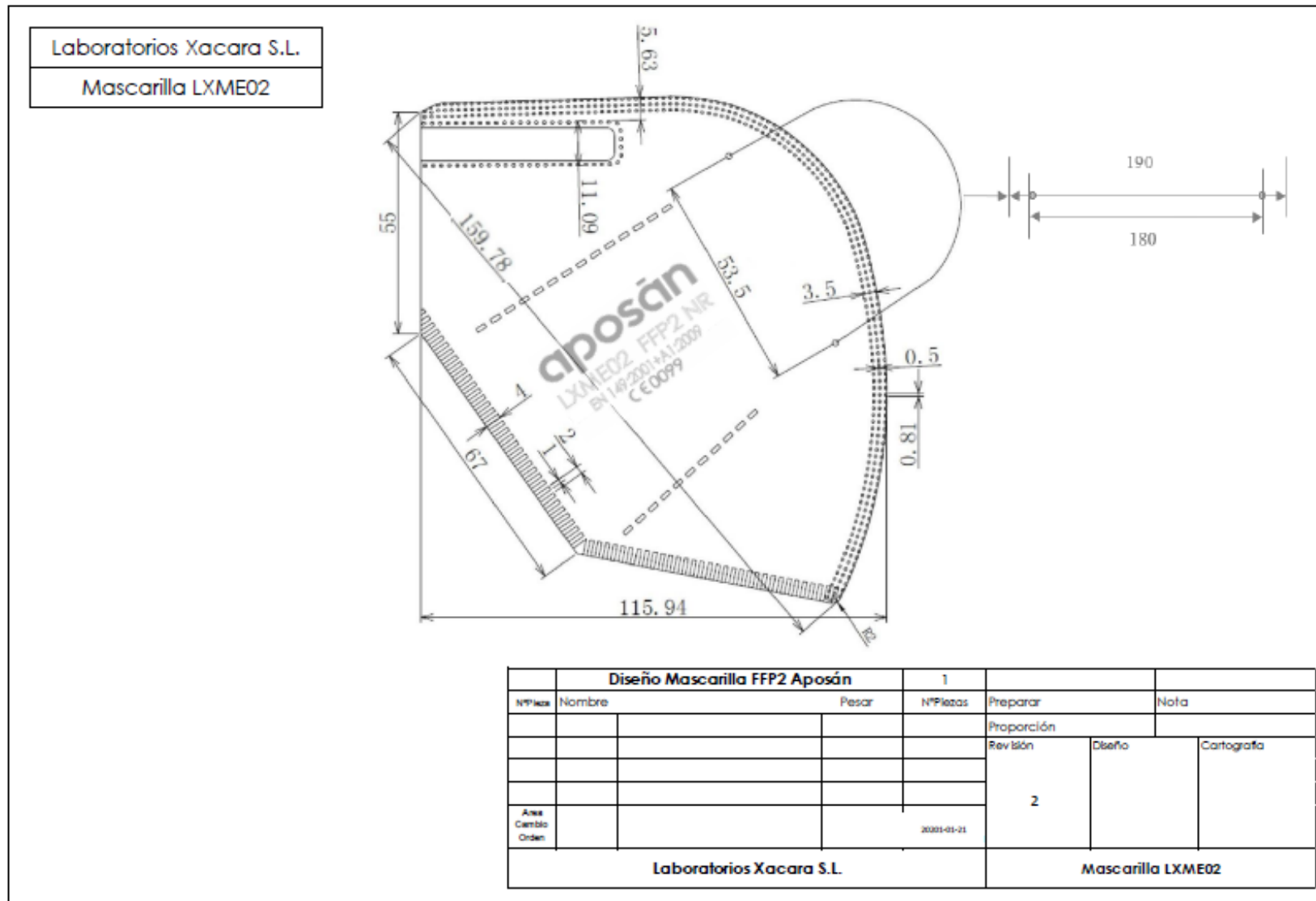


Retírala tocando sólo las bandas elásticas.

9



Para desecharla, introdúcela en una bolsa de plástico. Deposítala cerrada en la basura y lávate las manos.



Advertencia: un solo uso

Las mascarillas EPI tienen como finalidad filtrar el aire inhalado evitando la entrada de partículas contaminantes en nuestro organismo.

El usuario debe conocer el uso y manejo de la máscara.

- Es poco probable que se cumplan los requisitos de fugas si el vello facial pasa por debajo del sello facial.
- Máscara no válida en condiciones de baja calidad del aire o zonas poco ventiladas.
- Estas mascarillas no aportan oxígeno.
- Máscara no válida en atmósferas explosivas.
- Este producto no es resistente a las llamas y no debe usarse en áreas con llamas abiertas.
- No utilizar zonas de riesgo de explosión.
- Este EPI no debe usarse contra riesgos distintos a los descritos anteriormente.
- Por cuestiones de comodidad e higiene, se recomienda no usar la mascarilla durante más de 8H. En caso de que se humedezca o deteriore por el uso, se recomienda sustituirla por otra.
- Producto EPI, NO SANITARIO.
- No estéril.
- No reutilizar. "NR", la media máscara del filtro de partículas no debe utilizarse para más de un turno de trabajo.

Almacenamiento

Mantenga la pieza alejada de la exposición innecesaria a la luz solar, en lugares secos y protegida contra agentes agresivos.

Caducidad

Dos años desde la fecha de fabricación, bajo las condiciones de almacenamiento específicas.

Nº de lote y fecha de producción

Indicado en la bolsa individual.

Ver en pegatina/ impresión de la caja.

Descripción	Caja mascarilla Filtrantes FFP2 10 UDS	ACABADOS: CMYK + 2 pantones  Pantone 192 C  Pantone Cool Grey 7C
Dimensiones	197 x 125 x 65 mm	
Nº Tintas	CMYK + 2 pantones	
Fecha	150221-V12	
Aprobación	☒ Diseño ☒ Calidad ☒ Dirección	



 Pantone 192 C

 Pantone Cool Grey 7C

120,55mm

160,35 mm

MASCARILLAS FILTRANTES FFP2 NR*

MÁSCARAS AUTOFILTRANTES FFP2 NR*

* NO REUTILIZABLE / NÃO REUTILIZÁVEL

aposañ
BOTIQUÍN

1. Lávese las manos durante 40-60s antes de manipularla. Lave las manos por 40-60s antes de manipular a máscara.

2. Toque solo las gomas de la mascarilla. Toque apenas los elásticos de la máscara.

3. Póngasela sobre nariz y boca, asegurándose de que no queden grandes espacios entre su cara y la mascarilla. Coloque-a sobre o seu nariz e boca, assegurando-se de que não fica um grande espaço entre o seu rosto e a máscara.

4. Pase las bandas elásticas por detrás de sus orejas. Pase as tiras elásticas por detrás das suas orelhas.

5. Pellique la pinza nasal para ajustarla bien a la nariz y realice la prueba de ajuste de fuga**. Aperte a pinça nasal para ajustar bem ao nariz e realize a prova de ajuste de fuga**.

6. Evite tocar la parte exterior de la mascarilla. Si lo hace, lávese las manos antes y después. Evite tocar na parte da máscara. Se fizer isso, lave as suas mãos antes e depois.

7. Antes de quitarse las mascarillas, lávese las manos. Antes de tirar a sua máscara, lave as mãos.

8. Retírela tocando solo los elásticos. Despejela corrala en la basura y lívese las manos. Remova-a tocando apenas nas tiras elásticas.

9. Para descartarla, introdúzcala en una bolsa de plástico. Deposítela corrala en a basura y lívese las manos. Para a descartar, insira-a num saco de plástico. Deposite-o fechado no lixo e lave as mãos.

⚠️ ADVERTENCIA: UN SOLO USO. Las mascarillas EPI tienen como finalidad filtrar el aire inhalado evitando la entrada de partículas contaminantes en nuestro organismo. El usuario debe conocer el uso y manejo de la máscara. Es poco probable que se cumplan los requisitos de fugas si el vello facial pasa por debajo del sello facial. Máscara no válida en condiciones de baja calidad del aire o zonas poco ventiladas. Estas mascarillas no aportan oxígeno. Máscara no válida en atmósferas explosivas. Este producto no es resistente a las llamas y no debe usarse en áreas con llamas abiertas. No utilizar en zonas de riesgo de explosión. Este EPI no debe usarse contra riesgos distintos a los descritos anteriormente. Por cuestiones de comodidad e higiene, se recomienda no usar la mascarilla durante más de 8h. En caso de que se humedezca o deteriore por el uso, se recomienda sustituirla por otra. Producto EPI. No esteril. No reutilizar. "NR", la media máscara del filtro de partículas no debe utilizarse para mas de un turno de trabajo. **ALMACENAMIENTO:** Mantenga la pieza alejada de la exposición innecesaria a la luz solar, en lugares secos y protegida contra agentes agresivos.

⚠️ AVISO: PARA USO ÚNICO. O objetivo das máscaras EPI é filtrar o ar inalado evitando a entrada de partículas contaminantes no nosso corpo. O usuário deve conhecer o uso e manuseio da máscara. É pouco provável que os requisitos de fugas sejam cumpridos se os pelos faciais passarem sob a máscara facial. Máscara inválida em condições de baixa qualidade de ar ou zonas pouco ventiladas. Estas máscaras não fornecem oxigênio. Este produto não é resistente a chamas e não deve ser usado em áreas com chamas abertas. Não utilizar em áreas com risco de explosão. Este EPI não deve ser usado contra outros riscos além dos descritos acima. Por razões de conforto e higiene, recomendamos não usar a máscara por mais de 8 horas. Ceso fique húmida ou se deteriorar com o uso, é recomendável substituí-la por outra. Produto EPI. Não esteril. "NR", a meia máscara do filtro de partículas não deve ser usada por mais de um turno de trabalho. **ARMazenamento:** Mantenha a peça afastada da exposição desnecessária ao sol, em locais secos e protegidos de agentes agressivos.

RECOMENDACIONES DE USO: La mascarilla filtrante se sujeta en las orejas mediante las gomas elásticas insertadas en la misma. Usar bajo las recomendaciones del fabricante, siguiendo las instrucciones del etiquetado. ** Haga una prueba de ajuste-fuga para comprobar que se ha puesto la mascarilla de forma correcta. Cubra la mascarilla con las dos manos y exhale con fuerza. Si detecta fugas a través de los bordes, modifique la posición de la mascarilla sobre la cara, reajuste el clip nasal o ajuste la tensión de las cintas de sujeción. Repita el proceso hasta que no detecte ninguna fuga. **AVISO DE ALERGIA:** 42% Tela no tejida, 29% Tela fundida por soplado, 29% Algodón de aire caliente.

RECOMENDAÇÕES DE USO: A máscara filtrante é presa nas orelhas pelos elásticos, inseridos na mesma. Usar de acordo com as recomendações do fabricante, seguindo as instruções da embalagem. ** Faça um teste de ajuste de fuga para verificar se colocou a máscara corretamente. Cubra a máscara com as duas mãos e expire com força. Se detectar fuga pelas bordas, reposicione a máscara no rosto, reajuste o clipe para o nariz ou ajuste a tensão no arnês. Repita o processo até que nenhuma fuga seja encontrada. **AVISO DE ALERGIA:** 42% Tecido não tecido, 29% Tecido fundido, 29% Algodão ar quente.

Laboratórios XACARA S.L.
Dirección fiscal: C/ Ingleses, 20,
28660 Boadilla del Monte (Madrid)
Fabrica: C/ Mario Roso de Luna,
23, Nave 5, 28022 Madrid
Distribuido por: Grupo Colares
Distribuido em Portugal: Distilene, Lda.

**DECLARACIÓN DE CONFORMIDAD /
DECLARAÇÃO DE CONFORMIDADE**

Credencial
Dos años desde la fecha de fabricación, bajo las condiciones de almacenamiento especificadas. Dois anos desde a data de fabrico sob as condições de armazenamento especificadas.

Nº de lote y fecha de producción
Indicado en la bolsa individual. Ver en pegatina / impressão de la caja. Indicado na bolsa individual. Ver na etiqueta / impressão na caixa.
Referencia / Referência: LXMED2

Organismo Notificado: Requisitos, pruebas, marcado de conformidad según AENOR INTERNACIONAL S.A.J.
Calle Génova, 6. 28004 Madrid (España)

EPI Equipo de protección individual
EPI Equipamentos de proteção individual



Certificado de Examen UE de Tipo EU Type-Examination Certificate

A18/000350

AENOR, como organismo notificado (nº 0099) para el Reglamento (UE) 2016/425, ha emitido este certificado a favor de
In compliance with Regulation (EU) 2016/425, the notified body AENOR (nº 0099) has issued this certificate to

LABORATORIOS XACARA, S.L.

Domicilio social / Registered office CALLE IMPRESORES, 20 28660 BOADILLA DEL MONTE (Madrid - España)
para el producto / for the product Dispositivos de protección respiratoria. Medias máscaras filtrantes de protección contra partículas. / Respiratory protection devices. Half filter masks to protect against particles.

conforme con el Reglamento in compliance with Regulation Reglamento UE 2016/425 de Equipos de Protección Individual (Regulation EU 2016/425 on Personal Protective Equipment)

Norma armonizada / Harmonized standard EN 149:2001+A1:2009

Más información en el anexo / See annex for more information.

Centro de producción / Production site CALLE MARIO ROSO DE LUNA, 29 NAVE 5 28022 MADRID (España)

Esquema de evaluación Assessment scheme Anexo V (Examen UE de Tipo – Módulo B) del Reglamento (UE) 2016/425. El tipo del EPI cumple los requisitos esenciales de salud y seguridad aplicables. Este certificado se utilizará únicamente en relación con uno de los procedimientos de evaluación de la conformidad a que se hace referencia en el artículo 19, letra c) del Reglamento (UE) 2016/425.

Annex V (EU Type-examination – Module B) of Regulation (EU) 2016/425. The PPE type complies with the applicable essential health and safety requirements. This certificate shall only be used in conjunction with one of the conformity assessment procedures referred to in point (c) of Article 19 of Regulation (EU) 2016/425.

Fecha de emisión / First issued on 2021-01-21
Fecha de expiración / Validity date 2026-01-21

Rafael GARCÍA MEIRO
Director General / CEO

Original Electronic Certificate



Certificado de Examen UE de Tipo

EU Type-Examination Certificate

A18/000350

Anexo al Certificado

Annex to Certificate

Norma armonizada / Harmonized standard EN 149:2001+A1:2009

Marca Comercial / Trade Mark	Referencia / Reference	Clasificación / Classification	Descripción / Description
XAcare, aposan	LXME02	FFP 2 NR	MEDIA MASCARILLA, DE CINCO CAPAS DE FILTRADO, DOS LAZOS FIJOS DE SUJECIÓN A OREJAS, DE TIPO PLEGABLE. DISEÑADA PARA PROTEGER CONTRA PARTÍCULAS SÓLIDAS O LÍQUIDAS SUSPENDIDAS EN EL AIRE. NO REUTILIZABLE / FILTERING HALF MASK, FIVE FILTERING LAYERS, TWO EARLOOPS, FOLDING STYLE. DESIGNED TO PROTECT AGAINST AIRBORNE SOLID OR LIQUID PARTICLES. NON-REUSABLE.

Fecha de emisión / First issued on 2021-01-21
Fecha de expiración / Validity date 2026-01-21

AENOR INTERNACIONAL S.A.U.
Génova, 6. 28004 Madrid. España
Tel. 91 432 60 00.- www.aenor.com

Organismo de control acreditado por ENAC con acreditación N° 1/C-PR354
Control body accredited by ENAC. Accreditation number 1/C-PR354

Original Electronic Certificate



Certificado de Conformidad Certificate of Conformity



A18/000365

AENOR, como organismo notificado (nº 0099) para el Reglamento (UE) 2016/425, ha emitido este certificado a favor de
In compliance with Regulation (EU) 2016/425, the notified body AENOR (nº 0099) has issued this certificate to

LABORATORIOS XACARA, S.L.

Domicilio social / Registered office CALLE IMPRESORES, 20 28660 BOADILLA DEL MONTE (Madrid - España)

para aprobar el Sistema de aseguramiento de la calidad del proceso de producción
in order to approve the (módulo D)
Quality assurance system of the production process (module D)

conforme con el Reglamento (UE) 2016/425, Anexo VIII
in compliance with Regulation (EU) 2016/425, Annex VIII

Referencias / References Detalladas en el Anexo al Certificado / Specified in Annex to the Certificate

Centro de producción / Production site CALLE MARIO ROSO DE LUNA, 29 NAVE 5 28022 MADRID (España)

Esquema de evaluación Este certificado se limita al sistema de aseguramiento de la calidad del
Assessment scheme proceso de producción para los equipos amparados por los certificados de
examen UE de tipo detallados en el anexo a este Certificado y fabricados
en el centro indicado más arriba.

This certificate is exclusively limited to the quality assurance of the
production process for personal protective equipment covered by the EU
type-examination certificates detailed in annex to the present certificate
and to the above mentioned production site.

Fecha de emisión / First issued on 2021-02-01
Fecha de expiración / Validity date 2024-02-01

Rafael GARCÍA MEIRO
Director General / CEO

Original Electronic Certificate

AENOR

Certificado de Conformidad Certificate of Conformity

A18/000365

Anexo al Certificado Annex to Certificate

Protección / Protection	Certificados UE de tipo cubiertos / EU type examination certificates covered	Organismo notificado emisor / Issuing notified body	Fecha Validez / Validity date	Prenda / Garment
RESPIRATORIA / RESPIRATORY	A18/000350	AENOR 0099	2026-01-21	MASCARILLA / MASK

Fecha de emisión / First issued on 2021-02-01
Fecha de expiración / Validity date 2024-02-01

AENOR INTERNACIONAL S.A.U.
Génova, 6. 28004 Madrid. España
Tel. 91 432 60 00.- www.aenor.com

Organismo de control acreditado por ENAC con acreditación Nº 1/C-PR354
Control body accredited by ENAC. Accreditation number 1/C-PR354

Original Electronic Certificate



中国认可
国际互认
检测
TESTING
CNAS L10118



国检检测
CHINA COMPONENTS TEST

Test Report

Report No.: [2020] WSZ FHL NO.8275

Product Name Particle filtering half mask

Applicant LABORATORIOS XACARA S.L.

Manufacturer LABORATORIOS XACARA S.L.

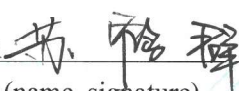
Test Type Entrusted inspection

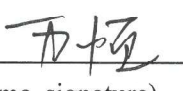
Jiangsu Guojian Testing Technology Co., Ltd
3/F., Unit D, Xingye Building, Taihu International Tech-Park, Wuxi, Jiangsu, China

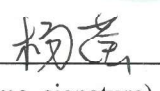


Test Report

Product name	Particle filtering half mask	Model name	LXME02
		Brand	apocan
Laboratory/ Add.	Jiangsu Guojian Testing Technology Co., Ltd/ 3/F., Unit D, Xingye Building, Taihu International Tech-Park, Wuxi, Jiangsu, China		
Applicant/ Add.	LABORARIOS XACARA S.L./Calle Impresores 20, 28660, Boadilla del Monte, Madrid, Spain		
Manufacturer/ Add.	Same as the applicant		
Sample classification	FFP2	Sample number	GW8275-2020
Sample quantity	90 pcs	Date of receipt of sample	16/10/2020
Test type	Entrusted inspection	Article/Batch/Style number	—
Date (s) of performance of tests	16/10/2020~24/10/2020	Testing location	Same as the Laboratory
Sample state	Meeting the requirements of testing	Sample description	Refer to page 3
Test standard(s)	EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking		
Test items	Packaging, visual inspection, practical performance, finish of parts, compatibility with skin, flammability, carbon dioxide content of the inhalation air, material, head harness, field of vision, penetration of filter material, breathing resistance, total inward leakage		
Test conclusion	The samples upon testing don't comply with FFP2 classification requirements according to the standard EN 149:2001+A1:2009. The details of test results see on Pages 3-16.		
Note	The test results presented in this report relate only to the submitted sample as received, tested on samples without marking.		

 Su Hequn 
 Approver (name, signature)

 Wan Heng 
 Reviewer (name, signature)

 Yang Ying 
 Chief Tester (name, signature)

Copy of marking:

apocan
LXME02 FFP2 NR
UNE-EN 149:2001+A1:2009
CE0477

Note 1: The marking contents were inspected according to the submitted artwork provided by manufacturer.

Test item particulars:

Type of use: ☐ re-useable particle filtering half mask
☒ single shift only particle filtering half mask

Classes of devices..... : ☐ FFP1 ☒ FFP2 ☐ FFP3

Exhalation valve(s)..... : ☐ Yes ☒ No

Inhalation valve(s)..... : ☐ Yes ☒ No

Designed to protect against both solid & liquid aerosols.: ☒ Yes ☐ No

Possible test case verdicts:

- Test case does not apply to the test object.....: N/A (Not Applicable)

- Test object does meet the requirement.....: P (Pass)

- Test object does not meet the requirement.....: F (Fail)

General remarks:

The test results presented in this report relate only to the submitted sample as received.

This report shall not be reproduced, except in full, without the written approval of the issuing Laboratory can provide assurance that parts of a report are not taken out of context.

Determination of the test results includes consideration of measurement uncertainty from the test equipment and methods.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

Environmental condition of the testing in this report:

1) Unless otherwise specified, the ambient temperature for testing shall be 25 °C;

2) T.C. Temperature conditioned:

a) for 24 h to a dry atmosphere of 70 °C; b) for 24 h to a temperature of -30 °C;

and return to room temperature 25 °C for 4 h between exposures and prior to subsequent testing.

S.No. (Cl.No.)	Test item		Unit	Technical requirements	Test result	Single item decision
1 (7.3)	Visual inspection	Marking/ information	—	Marking and the information supplied by the manufacturer, requirements refer to Cl.9 and Cl.10	No marking available printed on the mask. The draft artwork of marking plate & information supplied by the manufacturer, comply with the requirements.	Fail
2 (7.4)	Packaging	Visual inspection	—	Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Particle filtering half masks packaged and protected against mechanical damage and contamination.	Pass
3 (7.5)	Material	Visual inspection	—	Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.	Materials were suitable withstand handling and wear.	Pass
			—	After undergoing S.W., none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	Sample 1: neither facepiece nor straps have mechanical failure	
					Sample 2: neither facepiece nor straps have mechanical failure	
					Sample 3: neither facepiece nor straps have mechanical failure	
			—	After undergoing S.W. and T.C., none of the particle filtering half masks shall not collapse.	Sample 4: no collapse	
					Sample 5: no collapse	
—	Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Not constitute a hazard or nuisance for the wearer				
4 (7.6)	Cleaning and disinfecting		—	Particle filtering half mask designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. Testing shall be done in accordance with 8.4 and 8.5.	☐ Fulfil the requirements after testing, or ☒ The Particle filtering half mask is NOT re-usable according to information supplied by manufacturer	Not Applicable

S.No. (Cl.No.)	Test item		Unit	Technical requirements	Test result				Single item decision
			—	With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class. Testing shall be done in accordance with 8.11.	☐ Tests results refer to S. No. 7(7.9.2), or ☒ The Particle filtering half mask is NOT re-usable according to information supplied by manufacturer				
5 (7.7)	Practical performance	Head harness comfort	—	Head harness should be comfort.	Sample 1: has the feeling of comfortable wearing				Pass
					Sample 2: has the feeling of comfortable wearing				
		Security of fastenings	—	Fastenings are safe and reliable	Sample 1: All fastenings are firm				
					Sample 2: All fastenings are firm				
	Field of vision	—	Field of vision is acceptable	Sample 1: Having a wider visual field					
					Sample 2: Having a wider visual field				
6 (7.8)	Finish of parts	Visual inspection	—	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Parts of the device have no sharp edges and burrs				Pass
7 (7.9.2)	Leakage— Penetration of filter material	Sodium chloride	—	$\leq 6\%$	A.R. ¹⁾	0.1%	0.1%	0.2%	Pass
					S.W. ¹⁾	0.2%	0.1%	0.1%	
					M.S+ T.C. ²⁾	0.2%	0.2%	0.3%	
		Paraffin oil	—	$\leq 6\%$	A.R. ¹⁾	0.5%	0.4%	0.5%	Pass
					S.W. ¹⁾	0.5%	0.5%	0.6%	
					M.S+ T.C. ²⁾	1.4%	1.5%	1.3%	
	1) average penetration over a time of 30s, beginning 3 min after the start of the test reported 2) max. penetration during exposure test reported; 3) Flow conditioning: single filter 95 l/min.								--
8 (7.10)	Compatibility with skin	—	Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	A.R.	5 pcs all don't cause irritation			Pass	
				T.C.	5 pcs all don't cause irritation				

S.No. (Cl.No.)	Test item	Unit	Technical requirements	Test result		Single item decision
9 (7.11)	Flammability	—	When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5s after removal from the flame.	A.R.	The Sample is burning. Burning time:0.4s	Pass
					The Sample is burning. Burning time:0.5s	
				T.C.	The Sample is burning. Burning time:0.5s	
					The Sample is burning. Burning time:0.4s	
10 (7.12)	Carbon dioxide content of the inhalation air	—	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0 % (by volume). Remark: 3 half masks (S1, S2 and S3) A.R. tested.	Sample 1	0.7031%	Pass
				Sample 2	0.7025%	
				Sample 3	0.7013%	
				average	0.70%	
11 (7.13)	Head harness	—	The head harness shall be designed so that the particle filtering half mask can be donned and removed easily. The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position	A.R.	All of 5 pieces particle filtering half mask meet the requirements	Pass
				T.C.	All of 5 pieces particle filtering half mask meet the requirements	
12 (7.14)	Field of vision	—	The field of vision is acceptable if determined so in practical performance tests.	The two samples both have a wider visual field		Pass

S.No. (Cl.No.)	Test item	Unit	Technical requirements	Test result	Single item decision
13 (7.15)	Exhalation valve(s)	—	A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	No exhalation valve(s)	Not applicable
		—	If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage, and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.	No exhalation valve(s)	
		—	Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.	No exhalation valve(s)	
		—	When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.	No exhalation valve(s)	
14 (7.17)	Clogging— Breathing resistance & Penetration of filter material	—	Optional for single shift use devices, mandatory for re-usable devices. Tested by Cl. 7.17.1/2/3.	☐ Tests results refer to Table C&D, or ☒ Tests not requested for single shift use face mask	Not applicable
15 (7.18)	Demountable parts	—	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	No demountable parts	Not applicable

Table A- Leakage—Total Inward Leakage

S.No. (CLNo.)	Test item	Unit	Technical requirements ¹⁾	Test result							Single item decision
				Exercises	E1 (%)	E2 (%)	E3 (%)	E4 (%)	E5 (%)	TIL (%)	
16 (7.9.1)	Leakage— Total inward leakage	—	At least 46 out of the 50 individual exercise results shall be not greater than 11% ; And in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 8% .	A.R.	10.5	11.7	13.6	16.1	12.0	12.8	Fail
					13.1	16.5	19.2	21.2	14.3	16.9	
					9.6	12.5	16.4	18.7	10.5	13.5	
					11.3	14.2	15.7	17.3	12.5	14.2	
					9.1	12.7	14.8	15.7	10.6	12.6	
				T.C.	10.7	14.2	17.2	19.3	12.5	14.8	
					12.7	14.9	16.3	18.7	13.2	15.2	
					7.8	9.6	12.5	17.0	9.2	11.2	
					11.3	14.7	16.9	19.2	12.5	14.9	
					13.7	16.9	19.2	20.1	14.2	16.8	

Note 1:
 at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than 25 % for FFP1 11 % for FFP2 5 % for FFP3
 in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 22 % for FFP1 8 % for FFP2 2 % for FFP3.

Table A-1- Test subjects—Facial dimension

Test Subject No.	Length of face (mm)	Width of face (mm)	Depth of face (mm)	Width of mouth (mm)
1	120	130	109	59
2	122	140	115	65
3	119	160	139	55
4	112	122	119	63
5	110	130	118	60
6	115	119	110	59
7	112	123	113	55
8	103	130	100	50
9	118	139	130	63
10	120	135	125	50

Table B- Breathing Resistance

(Cl.No.)	Test item		Unit	Technical requirements ^{ts1)}	Test result						Single item decision
					Exercises	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	
17 (7.16)	Breathing resistance	Inhalation 30 L/min	mbar	≤ 0.7	A.R.	0.6	0.5	0.6	0.6	0.5	Pass
						0.6	0.6	0.6	0.5	0.6	
						0.6	0.5	0.6	0.6	0.6	
					S.W.	0.6	0.5	0.6	0.6	0.6	
						0.6	0.6	0.6	0.6	0.6	
						0.6	0.5	0.6	0.5	0.6	
					T.C.	0.6	0.6	0.6	0.5	0.6	
						0.6	0.5	0.6	0.6	0.5	
						0.6	0.5	0.6	0.6	0.5	
		Inhalation 95 L/min	mbar	≤ 2.4	A.R.	1.7	1.6	1.7	1.6	1.6	Pass
						1.6	1.6	1.7	1.6	1.6	
						1.6	1.6	1.7	1.7	1.6	
					S.W.	1.7	1.6	1.6	1.6	1.6	
						1.7	1.6	1.7	1.6	1.7	
						1.6	1.6	1.6	1.6	1.7	
					T.C.	1.6	1.6	1.7	1.6	1.6	
						1.6	1.6	1.7	1.7	1.6	
						1.7	1.7	1.6	1.7	1.6	
		Exhalation 160 L/min	mbar	≤ 3.0	A.R.	2.9	2.8	2.9	2.9	2.8	Pass
						2.9	2.8	2.9	2.9	2.9	
						2.9	2.8	2.9	2.8	2.8	
					S.W.	2.9	2.9	2.9	2.9	2.9	
						2.9	2.8	2.9	2.9	2.8	
						2.9	2.8	2.9	2.9	2.8	
					T.C.	2.9	2.9	2.9	2.9	2.9	
						2.9	2.8	2.9	2.8	2.9	
						2.9	2.8	2.9	2.8	2.9	

Note 1: Limitation may need be changed according to classification, refer to Table 2 — Breathing resistance of EN 149:2001 +A1:2009 for the Technical requirements.

Table C- Clogging Test—Breathing resistance

S.No. (Cl.No.)	Test item ^{1) 2)}		Unit	Technical requirements ^{1) 2)} (mbar)	Test result						Single item decision
					Exercises	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	
18 (7.17)	Clogging test— Breathing resistance	Inhalation 95 L/min	mbar	≤ 3.0	A.R.						Not applicable
					T.C.						
		Exhalation 95 L/min	mbar	≤ 3.0	A.R.						Not applicable
					T.C.						

Note 1: Valved particle filtering half masks

 After clogging the inhalation resistances shall not exceed FFP1: 4 mbar FFP2: 5 mbar FFP3: 7 mbar at 95 l/min continuous flow;
 The exhalation resistance shall not exceed 3 mbar at 160 l/min continuous flow.

Note 2: Valveless particle filtering half masks

After clogging the inhalation and exhalation resistances shall not exceed FFP1: 3 mbar, FFP2: 4 mbar FFP3: 5 mbar at 95 l/min continuous flow.

Table D- Clogging Test—Penetration of filter material

S.No. (Cl.No.)	Test item		Unit	Technical requirements	Test result		Single item decision
19 (7.17)	Clogging test— Penetration of filter material	Paraffin oil	—	$\leq 20\%$	A.R.		Not applicable
					T.C.		
					T.C.		

Note: Maximum penetration of test aerosol test 95 l/min max. FFP1: 20%, FFP2: 6%, FFP3: 1%

Abbreviations :

A.R. As received

M.S. Mechanical strength

S.W. Simulated wearing treatment

T.C. Temperature conditioned

F.C. Flow conditioned

C.D. Cleaning and Disinfecting

Annex A- Sample Photo

Photo 1

Description: Front view of face mask



Photo 2

Description: Side view of face mask

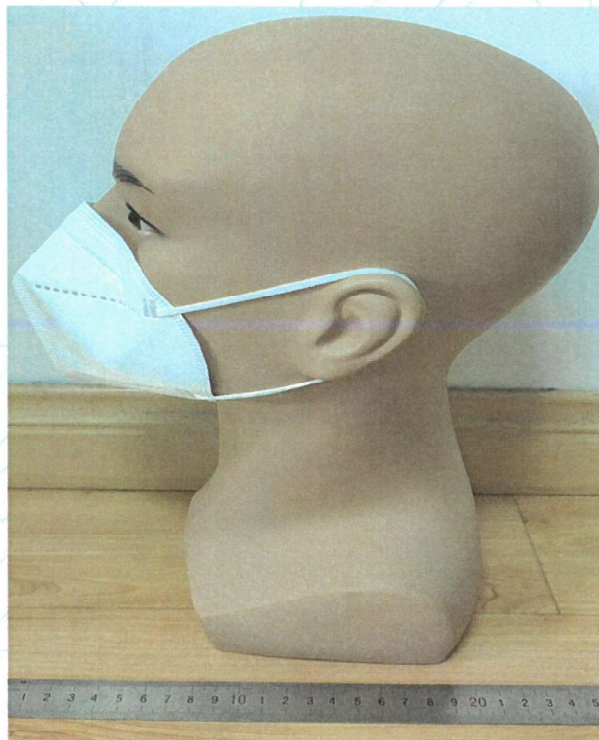


Photo 3

Description: side view of face mask



Photo 4

Description: side view of face mask



Photo 5

Description: Front view of face mask

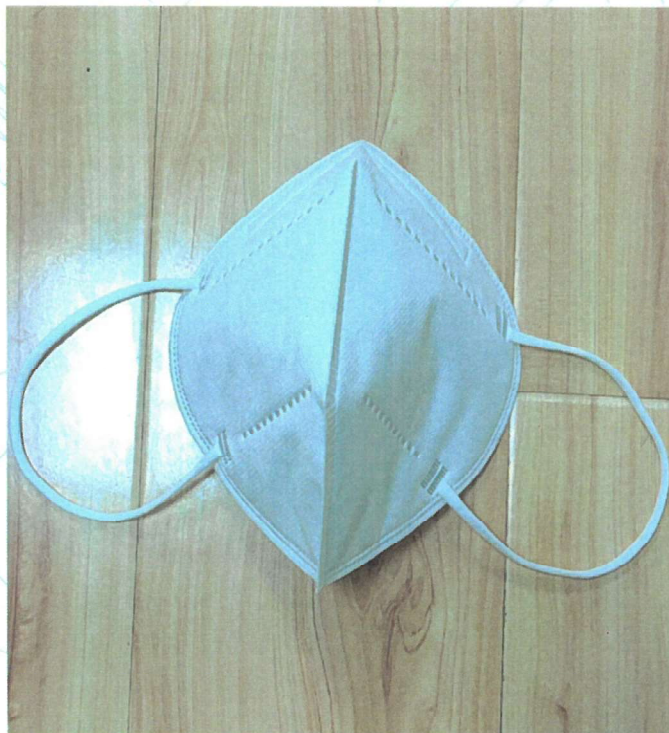


Photo 6

Description: Inner view of face mask



Annex B: Packaging marking



aposan



FFP2 NR

MASCARILLAS
FILTRANTES

i Advertencia: Un solo uso

Las mascarillas EPI tienen como finalidad filtrar el aire inhalado evitando la entrada de partículas contaminantes en nuestro organismo.

La máscara no ofrece protección contra aerosoles a base de aceite.

La media máscara debe desecharse después de su uso.



1 Lave las manos durante 40 segundos antes de manipularla.



2 Toca solo las gomas de la mascarilla.



3 Póntela sobre la nariz y boca, asegurándote de que no queden grandes espacios entre la cara y la mascarilla.



4 Pon los brazos extendidos por detrás de la cabeza.



5 Pálmalo la persona hacia para ajustarla bien a la cara.



6 Evita tocar la parte exterior de la mascarilla si la tocas, lávala las manos antes y después.



7 Antes de quitarte la mascarilla, lávala las manos.



8 Retírala tirando sólo de las bandas elásticas.



9 Para desecharla, introdúcela en un fondo de plástico. Después, córtala en la bolsa y sácala las manos.

Por cuestiones de comodidad e higiene, se suele recomendar no usar la mascarilla durante más de 8 h. En caso de que se humedezca o deteriore por el uso, se recomienda sustituirla por otra.

Producto EPI, NO SANITARIO

Laboratorios XACARA S.L.
Dirección fiscal: C/ Impresores, 20,
28660 Boadilla del Monte (Madrid)
Fábrica: C/ Mario Roso de Luna,
29, Nave 5, 28022 Madrid



LOT LXME02 EXP 2022/10

1 uds.
Mascarilla
Filtrante FFP2

CE 0477
EN149:2001+A1:2009
Producto EPI, NO SANITARIO

 Tela no tejida agradable a la pi

 Fácil Respiración

Eficacia filtración de partículas > 92%

Annex C: Instruction information supplied by manufacturer

aposan**INFORMATION MASKS AND INSTRUCTIONS****Laboratorios XACARA S.L.**

Fiscal address: C/ Impresores, 20. 28660 Boadilla del Monte (Madrid)

Factory: C/ Mario Roso de Luna, 29. Nave 5. 28022 Madrid

CE 0477**LXME02**

This product has been made according to health and security general requirements, specified in Rules (EU) 2016/425, in particular the specifications in the Rule EN 149:2001 + A1:2009. Requirements, tests, consent mark with the certificate **CE 0477** by EUROFINS.

This filtration mask is made up to protect against respiratory particles, except for escape situation particles. According to WHO's recommendations, for this specific use, the nominal protection factor given by these masks, is the same as the FFP2 nominal protection factor defined in EN 149:2001 + A1:2009.

Use recommendations:

The **PPE** is made up in a non-woven material with:

- 260mm 50GSM Spunbond Non-woven fabrics.
- 260mm 25GSM Melt Blown. Pure PP white.
- 260mm 50 GSM Hot Air Cotton.
- 260mm 25 GSM Melt Blown. Pure PP white.
- 260mm 25GSM Spunbond Non-woven fabrics.
- 5mm Holding elastic flat band to the ears.
- 5mm thick metal band for the nose.

Achieve levels

The FFP2 level is a guiding parameter of the rule EN 149:2001+A1, not usable for RFU PPE-R 02.075 VERSION 2 because the final validity for the certification COVID-19 method is according to PASS/NOT PASS.

Precautions:

This mask is made up to protect against respiratory particles, except for escape situation particles.

Mask adjustment (verified before use):

- It is improbable that the escape requirements will be achieved if the facial hair is below the facial shape.
- Not valid mask in low air quality conditions (pollutants, oxygen deficiency).
- Not valid mask in explosive atmospheres.
- This product is not resistant to flames and must not be used in areas with opened flames.
- Do not use in high risk explosion zones.

This **PPE** must not be used for different risks than the ones mentioned above.

Storage: Keep the piece far from non-necessary solar light, in dry places and protected from aggressive agents.

Packing: Plastic bag with printed cardboard inside.

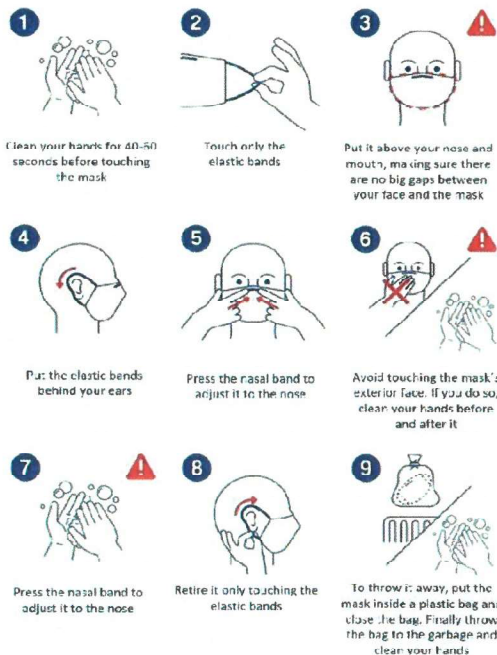
apocan

Warning: ONE USE ONLY.

The EPI masks purpose is to filter the inhaled air, avoiding pollutant particles to enter in our organism.

The mask does not offer protection against oil-made aerosols/sprays.

The mask must be thrown away its first use.



The purpose of EPI masks is to filter the inhaled air, preventing the entry of contaminating particles into our bodies.

For comfortability and hygiene, it is recommendable not to use the mask more than 8 hours. In the case that the mask gets humid or broke, because of its use, it is recommendable to substitute it.

Pictogram explanation:



2021/10
(Useful life)



<70% Storage maximum partial humidity

+40°C



-10°C

Storage temperature interval.



Consult information given by the manufacturer.

The end



中国认可
国际互认
检测
TESTING
CNAS L10116



国检检测
CHINA COMPONENTS TEST

Test Report

Report No.: [2020] WSZ FHL NO.8580

Product Name

EPI MASK

Applicant

LABORATORIOS XACARA

Manufacturer

LABORATORIOS XACARA

Test Type

Entrusted inspection

Jiangsu Guojian Testing Technology Co., Ltd

3/F., Unit D, Xingye Building, Taihu International Tech. Park, Wuxi, Jiangsu, China





Test Report

Product name	EPI MASK	Model name	FFP2
		Brand	—
Laboratory/Add	Jiangsu Guojian Testing Technology Co., Ltd/ 3/F., Unit D, Xingye Building, Taihu International Tech-Park, Wuxi, Jiangsu, China		
Applicant/Add/Tel	LABORATORIOS XACARA/CALLE IMPRESORES,20 BOADILLA DEL MONTE/629239233		
Manufacturer/Add/Tel	LABORATORIOS XACARA/CALLE IMPRESORES,20 BOADILLA DEL MONTE/629239233		
Sample classification	FFP2	Sample number	GW8580-2020
Sample quantity	20 pcs	Date of receipt of sample	10/11/2020
Test type	Entrusted inspection	Article/Batch/Style number	—
Date(s) of performance of tests	10/11/2020~13/11/2020	Testing location	Same as the Laboratory
Sample state	Meeting the requirements of testings	Sample description	Refer to page 3
Test standard(s)	EN 149:2001+A1:2009 Respiratory protective devices -Filtering half masks to protect against particles -Requirements,testing,marking		
Test items	Total inward leakage		
Test result	The details of test results see on Pages 3-5.		
Note	Reference of client:20_016906 LAB.XACARA REF. LXME02		
	The test results presented in this report relate only to the submitted sample as received.		

Su Hequn

Approver(name,signature)

Wan Heng

Reviewer(name,signature)

Yang Ying

Chief Tester(name,signature)



Sample description:	white
Test item particulars:	
Type of useuse	☐ re-useable particle filtering half mask ☒ single shift only particle filtering half mask
Classes of devices.....	☐ FFP1 ☒ FFP2 ☐ FFP3
Exhalation valve(s).....	☐ Yes ☒ No
Inhalation valve(s).....	☐ Yes ☒ No
Designed to protect against both solid & liquid aerosols. :	☒ Yes ☐ No
Possible test case verdicts:	
- Test case does not required to the test object..... :	NRq(Not required)
- Test case does not apply to the test object..... :	N/A (Not Applicable)
- Test object does meet the requirement..... :	P (Pass)
- Test object does not meet the requirement..... :	F (Fail)
General remarks:	
The test results presented in this report relate only to the submitted sample as received. This report shall not be reproduced, except in full, without the written approval of the issuing Laboratory can provide assurance that parts of a report are not taken out of context. Determination of the test results includes consideration of measurement uncertainty from the test equipment and methods. Throughout this report a ☐ comma / ☒ point is used as the decimal separator.	
Environmental condition of the testing in this report:	
1) Unless otherwise specified, the ambient temperature for testing shall be 25 °C; 2) T.C. Temperature conditioned: a) for 24 h to a dry atmosphere of 70 °C; b) for 24 h to a temperature of -30 °C; and return to room temperature 25 °C for 4 h between exposures and prior to subsequent testing.	

**Table A- Leakage—Total Inward Leakage**

S.No. (Cl.No.)	Test item	Unit	Technical requirement	Test result							Single item decision
16 (7.9.1)	Leakage—Total inward leakage	—	At least 46 out of the 50 individual exercise results shall be not greater than 11%; And in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 8%.	Exercises	E1 (%)	E2 (%)	E3 (%)	E4 (%)	E5 (%)	TIL (%)	Pass
				A.R.	2.3	3.7	4.6	3.8	3.2	3.5	
					0.9	5.9	5.0	4.4	1.6	3.6	
					2.5	6.8	7.6	7.3	2.8	5.4	
					1.6	2.0	3.4	4.0	2.0	2.6	
					1.8	2.5	3.4	4.0	2.1	2.8	
				T.C.	3.0	5.1	6.4	5.6	4.2	4.9	
					2.1	3.6	4.2	3.8	2.5	3.2	
					3.4	5.8	5.1	6.4	3.6	4.9	
					3.0	3.4	4.8	5.1	3.2	3.9	
					2.1	2.8	3.6	4.2	2.5	3.0	

Note 1:
at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than 25 % for FFP1 11 % for FFP2 5 % for FFP3
in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 22 % for FFP1 8 % for FFP2 2 % for FFP3.

Table A-1- Test subjects—Facial dimension

Subject	Face Length(mm)	Face Width(mm)	Face Depth(mm)	Mouth Width(mm)
1	120	130	109	59
2	122	140	115	65
3	119	160	139	55
4	112	122	119	63
5	110	130	118	60
6	115	119	110	59
7	112	123	113	55
8	103	130	100	50
9	118	139	130	63
10	115	129	120	50



Abbreviations :

A.R. As received

M.S. Mechanical strength

S.W. Simulated wearing treatment

T.C. Temperature conditioned

F.C. Flow conditioned

C.D. Cleaning and Disinfecting

Annex A- Estimates of the uncertainty of measurement

Test item	Uncertainty
Total inward leakage	2.98%

Annex B- Sample Photo



The end

Por la presente declaro que los Test Report entregado a AENOR y con el que hemos conseguido los Certificados "Examen UE de Tipo- Módulo B "de Producto y del Sistema de aseguramiento de la calidad del proceso de producción – Módulo D" son los mismos Test Report que hemos enviado a la empresa de COFARES en el proceso de homologación de proveedores que pertenecen al Modelo LXME02 y están identificados como:

- Test Report [2020] WSZ FHL NO.8275-LABROATORIOS cuyo resultado es "pasa" para todos los puntos de la norma salvo el Pto 7.9.1 Test de Fugas Totales hacia el interior.
- Test Report:" [2020]WSZ FHL NO.8580Y-LABORATORIOS". el Test Report parcial de la norma del Pto 7.9.1 Test de Fugas Totales hacia el interior.

Además, como parte del compromiso de control de Calidad con AENOR hemos incluido en nuestro sistema de Calidad el compromiso de pasar 1 vez al año un test Report completo de la Norma EN-149:2001+A1:2009, a lo largo de los 5 años del Certificado, para comprobar que no nos hemos desviado del mismo. Por la misma nos comprometemos a enviar a COFARES este Test Report completo anual.

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Rafael Rivero

Gerencia y Dirección Técnica.