

DECLARACIÓN UE DE CONFORMIDAD

Nº. 20210105

1. Equipo de Protección Individual (EPI):

Media Máscara facial filtrante FFP2 NR (Modelos: MZC-KZ, MZC-KZ(B), MZC-KZ(P), MZC-KZ(DB), MZC-KZ(G), MZC-KZ(V))

2. Nombre y dirección del fabricante:

Nombre: Mezorison Health Science & Technology (Shenzhen) Co., Ltd.
Dirección: No.12 Yuhe Road, Shiyan Town, Baoan District, Shenzhen, China.

3. La presente declaración de conformidad se expide bajo la exclusiva responsabilidad del fabricante:

Mezorison Health Science & Technology (Shenzhen) Co., Ltd.

4. Objeto de la declaración:

Media Máscara facial filtrante FFP2 NR (Modelos: MZC-KZ, MZC-KZ(B), MZC-KZ(P), MZC-KZ(DB), MZC-KZ(G), MZC-KZ(V)). Dispositivos de protección respiratoria. Medias máscaras filtrantes de protección contra partículas.

5. El objeto de la declaración descrito en el punto 4 anterior es conforme con la legislación de armonización de la Unión aplicable:

Reglamento (UE) 2016/425 relativo a los equipos de protección individual y por el que se deroga la Directiva 89/686/CEE del Consejo.

6. Referencias a las normas armonizadas aplicables utilizadas, incluidas sus fechas, o referencias a las otras especificaciones técnicas, incluidas sus fechas, respecto a las cuales se declara la conformidad:

Norma armonizada: EN 149:2001 + A1:2009 Dispositivos de protección respiratoria. Medias máscaras filtrantes de protección contra partículas. Requisitos, ensayos, marcado.

7. El Organismo Notificado LGAI TECHNOLOGICAL CENTER (APPLUS), número 0370 ha efectuado el examen UE de tipo (módulo B) y ha expedido el certificado de examen UE de tipo (0370-4495-PPE/B)

8. El EPI está sujeto al procedimiento de evaluación de la conformidad con el tipo basada en el aseguramiento de la calidad del proceso de producción (módulo C2) bajo la supervisión del organismo notificado LGAI TECHNOLOGICAL CENTER (APPLUS), número 0370 (0370-4766-PEE/C2)

Firmado en nombre de: Mezorison Health Science & Technology (Shenzhen) Co., Ltd.

No.12 Yuhe Road, Shiyan Town, Baoan District, Shenzhen, China.

Lugar y fecha:

Shenzhen City, China 2021.10.28

Signature and Stamp by
Position : General Manager
Name : Chen Ping



(Firma autorizada, nombre, cargo y sello)



Notified Body No. 0370

CERTIFICADO DE EXAMEN UE DE TIPO

EU-TYPE EXAMINATION CERTIFICATE

No. **0370-4495-PPE/B**

ORGANISMO NOTIFICADO Nº <i>NOTIFIED BODY NUMBER</i>	0370 - LGAI TECHNOLOGICAL CENTER (APPLUS)
SOLICITANTE / FABRICANTE <i>APPLICANT / MANUFACTURER</i>	Mezorrison Health Science & Technology (Shenzhen) Co., Ltd. No.12 Yuhe Road, Shiyan Town, Baoan District, Shenzhen
PLANTA DE PRODUCCIÓN <i>PRODUCTION SITE</i>	Mezorrison Health Science & Technology (Shenzhen) Co., Ltd. 2nd floor, Gaoke building, No.8 Tangkeng Rd, Shiyan, Baoan district, Shenzhen, China
REGLAMENTO DE APLICACIÓN PARA DAR LA CONFORMIDAD APPLICABLE REGULATION TO GIVE CONFORMITY: REGLAMENTO (UE) 2016/425 SOBRE LOS EQUIPOS DE PROTECCIÓN INDIVIDUAL <i>REGULATION (EU) 2016/425 PERSONAL PROTECTIVE EQUIPMENT</i>	
PROCEDIMIENTO DE EVALUACIÓN DE LA CONFORMIDAD <i>CONFORMITY ASSESSMENT PROCEDURE</i>	Módulo // <i>Module</i> : B EXAMEN UE DE TIPO EU TYPE EXAMINATION
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ver Anexo Técnico See Technical Annex
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE	FFP2 NR
NORMAS ARMONIZADAS HARMONISED STANDARDS	EN 149:2001 + A1:2009 Dispositivos de protección respiratoria. Medias máscaras filtrantes de protección contra partículas. Requisitos, ensayos, marcado. <i>EN 149:2001 + A1:2009 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking</i>
FECHA DE EMISIÓN ISSUE DATE	29/09/2020
FECHA DE MODIFICACIÓN MODIFICATION DATE	28/04/2021
VALIDEZ HASTA VALIDITY UNTIL	29/09/2025
<p>El presente certificado se mantendrá vigente durante 5 años siempre que el producto descrito no sea modificado y cumpla los requisitos esenciales de salud y seguridad establecidos en el Reglamento (UE) 2016/425. Para asegurar dicho cumplimiento, este certificado deberá ir acompañado de la documentación correspondiente a la Evaluación de Conformidad con el tipo según módulo C2, D (realizada por un Organismo Notificado, según frecuencia establecida).</p> <p><i>This certificate will remain valid for 5 years as long as the indicated product is not modified and fulfills the essential requirements of health and safety established in (EU) Regulation 2016/425. To ensure such compliance, this certificate must be accompanied by the documentation corresponding to the Conformity Assessment to type according to C2, D(carried out by a Notified Body according, to the established frequency).</i></p>	




LGAI Technological Center, S.A.
Xavier Ruiz Peña
Managing Director, Product Conformity B.U.



Este documento carece de validez sin su anexo técnico, cuyo número coincide con el del certificado.
This document is not valid without its technical annex, whose number coincides with the number of certificate.

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www.appluslaboratories.com/certified_products

ANEXO TÉCNICO TECHNICAL ANNEX

0370-4495-PPE/B

I. MODELOS INCLUIDOS EN EL CERTIFICADO

REFERENCES INCLUDED IN THIS CERTIFICATE

MARCA <i>BRAND</i>	Mezorison
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ref.: MZC-KZ Filtering Half Mask
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI <i>PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE</i>	FFP2 NR
COLOR <i>Colour</i>	Blanco / White
DESCRIPCIÓN <i>DESCRIPTION</i>	MEDIA MÁSCARA FILTRANTE SIN VÁLVULA, DE TIPO PLEGABLE VERTICAL, DE 5 CAPAS, CON LAZOS DE OREJA Y CLIP NASAL INTERIOR. TAMAÑO: 105mm*155mm. VALVELESS FILTERING HALF MASK, VERTICAL FOLDING TYPE, 5 LAYERS, WITH EARLOOPS AND INTERIOR NOSE CLIP. SIZE: 105mm*155mm
INFORME DE ENSAYO <i>TEST REPORT</i>	S20090702301E-R1 issued by Shenzhen NTEK Testing Technology Co., Ltd.

MARCA <i>BRAND</i>	Mezorison
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ref.: MZC-KZ(B) Filtering Half Mask
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI <i>PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE</i>	FFP2 NR
COLOR <i>Colour</i>	Negro / Black
DESCRIPCIÓN <i>DESCRIPTION</i>	MEDIA MÁSCARA FILTRANTE SIN VÁLVULA, DE TIPO PLEGABLE VERTICAL, DE 5 CAPAS, CON LAZOS DE OREJA Y CLIP NASAL INTERIOR. TAMAÑO: 105mm*155mm. VALVELESS FILTERING HALF MASK, VERTICAL FOLDING TYPE, 5 LAYERS, WITH EARLOOPS AND INTERIOR NOSE CLIP. SIZE: 105mm*155mm
INFORME DE ENSAYO <i>TEST REPORT</i>	S20090702301E-R1 issued by Shenzhen NTEK Testing Technology Co., Ltd. Test report No. PTC21030502001C-EN01V01 Precise Testing & Certification (Guangdong) Co.,Ltd.(PTC)

ANEXO TÉCNICO TECHNICAL ANNEX

0370-4495-PPE/B

MARCA <i>BRAND</i>	Mezorison
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ref.: MZC-KZ(DB) Filtering Half Mask
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI <i>PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE</i>	FFP2 NR
COLOR <i>Colour</i>	Azul Oscuro / Dark Blue
DESCRIPCIÓN <i>DESCRIPTION</i>	MEDIA MÁSCARA FILTRANTE SIN VÁLVULA, DE TIPO PLEGABLE VERTICAL, DE 5 CAPAS, CON LAZOS DE OREJA Y CLIP NASAL INTERIOR. TAMAÑO: 105mm*155mm. VALVELESS FILTERING HALF MASK, VERTICAL FOLDING TYPE, 5 LAYERS, WITH EARLOOPS AND INTERIOR NOSE CLIP. SIZE: 105mm*155mm
INFORME DE ENSAYO <i>TEST REPORT</i>	S20090702301E-R1 issued by Shenzhen NTEK Testing Technology Co., Ltd. Test report No. PTC21031702702C-EN01 Precise Testing & Certification (Guangdong) Co.,Ltd.(PTC)

MARCA <i>BRAND</i>	Mezorison
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ref.: MZC-KZ(P) Filtering Half Mask
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI <i>PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE</i>	FFP2 NR
COLOR <i>Colour</i>	Rosa / Pink
DESCRIPCIÓN <i>DESCRIPTION</i>	MEDIA MÁSCARA FILTRANTE SIN VÁLVULA, DE TIPO PLEGABLE VERTICAL, DE 5 CAPAS, CON LAZOS DE OREJA Y CLIP NASAL INTERIOR. TAMAÑO: 105mm*155mm. VALVELESS FILTERING HALF MASK, VERTICAL FOLDING TYPE, 5 LAYERS, WITH EARLOOPS AND INTERIOR NOSE CLIP. SIZE: 105mm*155mm
INFORME DE ENSAYO <i>TEST REPORT</i>	S20090702301E-R1 issued by Shenzhen NTEK Testing Technology Co., Ltd. Test report No. PTC21031702701C-EN01 Precise Testing & Certification (Guangdong) Co.,Ltd.(PTC)



Organismo Notificado N° 0370

CERTIFICADO DE CONFORMIDAD CON EL TIPO CONFORMITY TO TYPE CERTIFICATE

No. **0370-4766-PPE/C2**

ORGANISMO NOTIFICADO N° <i>NOTIFIED BODY NUMBER</i>	0370 - LGAI TECHNOLOGICAL CENTER (APPLUS)
SOLICITANTE / FABRICANTE <i>APPLICANT / MANUFACTURER</i>	Mezorrison Health Science & Technology (Shenzhen) Co., Ltd. No.12 Yuhe Road, Shiyan Town, Baoan District, Shenzhen
PLANTA DE PRODUCCIÓN <i>PRODUCTION SITE</i>	Mezorrison Health Science & Technology (Shenzhen) Co., Ltd. 2nd floor, Gaoke building, No.8 Tangkeng Rd, Shiyan, Baoan district, Shenzhen, China
REGLAMENTO DE APLICACIÓN PARA DAR LA CONFORMIDAD APPLICABLE REGULATION TO GIVE CONFORMITY: REGLAMENTO (UE) 2016/425 SOBRE LOS EQUIPOS DE PROTECCIÓN INDIVIDUAL <i>REGULATION (EU) 2016/425 PERSONAL PROTECTIVE EQUIPMENT</i>	
PROCEDIMIENTO DE EVALUACIÓN DE LA CONFORMIDAD CON EL TIPO <i>CONFORMITY ASSESSMENT PROCEDURE TO TYPE</i>	Módulo // <i>Module:</i> C2 BASADA EN EL CONTROL INTERNO DE LA PRODUCCIÓN MÁS EL CONTROL SUPERVISADO DE LOS PRODUCTOS A INTERVALOS ALEATORIOS <i>BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED CONTROL OF PRODUCTS AT ALEATORY INTERVALS</i>
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ver Anexo Técnico See Technical Annex
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI / PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE	FFP2 NR
FECHA DE EMISIÓN / ISSUE DATE	15/10/2021
VALIDEZ HASTA / VALIDITY UNTIL:	15/10/2022
El presente certificado se mantendrá vigente durante 1 año siempre que no se modifiquen las condiciones establecidas en el Certificado de Examen UE de Tipo referenciado en el Anexo. <i>This certificate will remain in force for 1 year as long as the conditions established in the EU Type certificate referenced in the annex are not modified.</i>	



Xavier Ruiz Peña
Managing Director, Product Conformity B.U.



Este documento carece de validez sin su anexo técnico, cuyo número coincide con el del certificado.

This document is not valid without its technical annex, whose number coincides with the number of certificate.

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ANEXO TÉCNICO TECHNICAL ANNEX

0370- 4766-PPE/C2

I. MODELOS INCLUIDOS EN EL CERTIFICADO

REFERENCES INCLUDED IN THIS CERTIFICATE

Nº CERTIFICADO DE EXAMEN UE DE TIPO <i>NR. EU TYPE EXAMINATION CERTIFICATE</i>	0370-4495-PPE/B
EMITIDO POR <i>ISSUED BY</i>	LGAI TECHNOLOGICAL CENTER S.A. (APPLUS) (Organismo notificado nº 0370 / Notified Body nr. 0370).
FECHA EMISIÓN <i>ISSUE DATE</i>	29/09/2020
FECHA DE MODIFICACIÓN <i>MODIFICATION DATE</i>	28/04/2021
VALIDEZ HASTA <i>VALIDITY UNTIL</i>	29/09/2025
MARCA <i>BRAND</i>	Mezorison
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI / PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE	FFP2 NR
DESCRIPCIÓN <i>DESCRIPTION</i>	MEDIA MÁSCARA FILTRANTE SIN VÁLVULA, DE TIPO PLEGABLE VERTICAL, DE 5 CAPAS, CON LAZOS DE OREJA Y CLIP NASAL INTERIOR. TAMAÑO: 105mm*155mm. VALVELESS FILTERING HALF MASK, VERTICAL FOLDING TYPE, 5 LAYERS, WITH EARLOOPS AND INTERIOR NOSE CLIP. SIZE: 105mm*155mm
INFORME DE ENSAYO <i>TEST REPORT</i>	S20110203701E issued by Shenzhen NTEK Testing Technology Co., Ltd.

IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ref.: MZC-KZ Filtering Half Mask
Color <i>Colour</i>	Blanco / White

ANEXO TÉCNICO TECHNICAL ANNEX

0370- 4766-PPE/C2

IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ref.: MZC-KZ(B) Filtering Half Mask
Color <i>Colour</i>	Negro / Black

IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ref.: MZC-KZ(DB) Filtering Half Mask
Color <i>Colour</i>	Azul Oscuro / Dark Blue

IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ref.: MZC-KZ(P) Filtering Half Mask
Color <i>Colour</i>	Rosa / Pink

IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ref.: MZC-KZ(G) Filtering Half Mask
Color <i>Colour</i>	Gris / Grey

IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ref.: MZC-KZ(V) Filtering Half Mask
Color <i>Colour</i>	Violeta / Violet

Test Report

Applicant: Mezorrison Health Science & Technology (Shenzhen) Co.,Ltd.
Address: No.12 Yuhe Road, Shiyan Town, Baoan District, Shenzhen

The following sample(s) was/were submitted and identified on behalf of the client as:

Product name: Filtering Half Mask
Model: MZC-KZ
Trade mark: Mezorrison
Manufacturer: Mezorrison Health Science & Technology (Shenzhen) Co.,Ltd.
Address: 2nd floor, Gaoke building, No.8 Tangkeng Rd, Shiyan, Baoan district, Shenzhen, China
Classification: FFP2 NR
Sample quantity: 120 Pcs

Sample Received Date: Sep. 07, 2020
Testing Period: Sep. 07, 2020~ Sep. 13, 2020

Test Requirement:

According to the requirement of the client, the test item(s) of the sample is according to the standard EN 149:2001+A1:2009.

Test Result(s): Please refer to the following page(s)

Test Method: Please refer to the following page(s)

Compiled by: _____

Reviewed by: _____

Approved by: _____

Date: _____

May



Summary of assessment*

Clause	Assessment
7.3 Visual inspection	NRq
7.4 Packaging	Pass
7.5 Material	Pass
7.6 Cleaning and disinfecting	N.A.
7.7 Practical performance	Pass
7.8 Finish of parts	Pass
7.9.1 Total inward leakage	Pass
7.9.2 Penetration of filter material	Pass
7.10 Compatibility with skin	Pass
7.11 Flammability	Pass
7.12 Carbon dioxide content of the inhalation air	Pass
7.13 Head harness	Pass
7.14 Field of vision	Pass
7.15 Exhalation valve(s)	N.A.
7.16 Breathing resistance	Pass
7.17 Clogging	N.A.
7.18 Demountable parts	N.A.

Key

Pass	Requirement satisfied.
NRq	The clauses were not required.
Fail	Requirement not satisfied. Refer to the "Result details" section for more information.
N.A.	Requirement not applicable.

Test	Uncertainty
Total inward leakage	6.40 %
Penetration of filter material (NaCl)	1.60 %
Penetration of filter material (Paraffin Oil)	1.78 %
Carbon dioxide content of the inhalation air	5.34 %
Breathing resistance (30 L/min)	3.60 %
Breathing resistance (95 L/min)	2.20 %
Breathing resistance (160 L/min)	2.00 %

* Assessment relates only to those specimens which were tested and are the subject of this report.

Test Result

Respiratory Protective Devices — Filtering Half Masks to Protect against Particles — Requirements, Testing, Marking
(EN 149:2001+A1:2009)

Clause 7.3 Visual inspection

Test Requirement	Results	Comment
Marking and the information supplied by the manufacturer, requirements refer to clause 9 and clause 10.	The clauses were not required.	NRq

Clause 7.4 Packaging

(EN 149:2001+A1:2009 Clause 8.2)

Test Requirement	Results	Comment
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.	Comply	Pass

Clause 7.5 Material

(EN 149:2001+A1:2009, Clause 8.2 & 8.3.1 & 8.3.2)

Test Requirement	Results	Comment
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.	Comply	Pass
After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	Comply	Pass
When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Comply	Pass
Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Comply	Pass

Clause 7.6 Cleaning and Disinfecting

(EN 149:2001+A1:2009, Clause 8.4 & 8.5 & 8.11)

Test Requirement	Results	Comment
<p>If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.</p> <p>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.</p>	<p>Not applicable (Not designed to be re-usable)</p>	<p>N.A.</p>

Clause 7.7 Practical Performance

(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
	Sample 11#~12#:	
<p>General:</p> <p>a) head harness comfort</p> <p>b) security of fastenings</p> <p>c) field of vision</p> <p>d) any other comments reported by the wearer on request.</p>	<p>No imperfections</p>	<p>Pass</p>
<p>Walking Test:</p> <p>The subjects wearing normal working clothes and wearing the particle filtering half mask shall walk at a regular rate of 6 km/h on a level course. The test shall be continuous, without removal of the particle filtering half mask, for a period of 10 min.</p>	<p>No imperfections</p>	
<p>Work Simulation Test:</p> <p>a) walking on the level with headroom of (1.3 ± 0.2)m for 5min</p> <p>b) crawling on the level with headroom of (0.7 ± 0.05)m for 5min</p> <p>c) filling a small basket (see Figure 1, approximate volume = 8 L) with chippings or other suitable material from a hopper which stands 1.5 m high and has an opening at the bottom to allow the contents to be shovelled out and a further opening at the top where the basket full of chippings is returned.</p>	<p>No imperfections</p>	

Clause 7.8 Finish of Parts

EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	No sharp edges or burrs	Pass

Clause 7.9.1 Total Inward Leakage

(EN 149:2001+A1:2009 Clause 8.5)

Test Requirement	Results	Comment
<p>For particle filtering half masks fitted in accordance with the manufacturer's information, 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:</p> <p style="padding-left: 40px;">25% for FFP1 11% for FFP2 5% for FFP3</p> <p>and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than:</p> <p style="padding-left: 40px;">22% for FFP1 8% for FFP2 2% for FFP3</p>	Detail refer to Appendix 1	Pass

Appendix 1: Summarization of Test Data

Subject	Sample	Condition	Normal Breathing (%)	Head Side/Side (%)	Head Up/Down (%)	Speak Loudly (%)	Normal Breathing (%)	Mean (%)
Huang	1#	A.R.	3.3	3.4	3.3	3.9	3.2	3.42
Zhou	2#	A.R.	2.5	2.7	2.9	3.0	2.5	2.72
Ma	3#	A.R.	2.2	2.4	2.6	2.8	2.4	2.48
Wu	4#	A.R.	3.9	4.0	4.1	4.3	3.7	4.00
Li	5#	A.R.	3.2	3.6	3.6	3.8	3.2	3.48
Wu	6#	T.C.	2.7	2.9	3.2	3.5	2.8	3.02
Zhai	7#	T.C.	2.6	2.9	3.4	3.7	2.7	3.06
Zheng	8#	T.C.	2.5	2.7	2.9	3.6	2.5	2.84
Huang	9#	T.C.	3.0	3.7	3.6	4.1	3.1	3.50
Wu	10#	T.C.	3.7	3.9	4.7	4.9	3.6	3.36

Facial Dimension:

Subject	Length of Face (mm)	Width of Face (mm)	Depth of Face (mm)	Width of Mouth (mm)
Huang	130	140	125	53
Zhou	100	148	125	55
Ma	120	158	110	50
Wu	110	148	121	44
Li	112	146	112	50
Wu	120	154	128	54
Zhai	135	165	125	53
Zheng	106	155	112	54
Huang	105	157	118	51
Wu	112	172	118	55

Clause 7.9.2 Penetration of Filter Material

(EN 149:2001+A1:2009, Clause 8.11 & EN 13274-7:2019)

Test Requirement			Results	Comment
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.			Detail refer to Appendix 2	Pass
Classification	Maximum penetration of test aerosol(%)			
	Sodium chloride test 95 L/min	Paraffin oil test 95 L/min		
FFP1	20	20		
FFP2	6	6		
FFP3	1	1		

Appendix 2: Summarization of Test Data

Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)		Assessment
			Average in 30s after 3 min	Max. during exposure	
Sodium chloride test	A.R.	13#	0.9	/	Pass
		14#	0.8	/	
		15#	0.9	/	
	S.W.	19#	0.9	/	
		20#	0.9	/	
		21#	0.9	/	
	M.S. + T.C.	25#	/	0.9	
		26#	/	0.9	
		27#	/	1.0	
Paraffin oil test	A.R.	16#	0.5	/	Pass
		17#	0.3	/	
		18#	0.3	/	
	S.W.	22#	0.5	/	
		23#	0.4	/	
		24#	0.3	/	
	M.S. + T.C.	28#	/	3.3	
		29#	/	4.3	
		30#	/	3.7	
Flow conditioning: 95.0 L/min					

Clause 7.10 Compatibility with Skin

(EN 149:2001+A1:2009, Clause 8.4 & 8.5)

Test Requirement	Results	Comment
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.	No irritation or any other adverse effect to health.	Pass

Clause 7.11 Flammability

(EN 149:2001+A1:2009, Clause 8.6)

Test Requirement	Results	Comment
The material used shall not present a danger for the wearer and shall not be of highly flammable nature when tested, the particle filtering half mask shall not burn or not to continue on burn for more than 5 s after removal from the flame.	Detail refer to Appendix 3	Pass

Appendix 3: Summarization of Test Data

Flammability

Condition	Sample No.	Result	Assessment
A.R.	31#	Flammable, burn for no more than 5 s	Pass
	32#	Flammable, burn for no more than 5 s	
T.C.	33#	Flammable, burn for no more than 5 s	
	34#	Flammable, burn for no more than 5 s	

Clause 7.12 Carbon Dioxide Content of The Inhalation Air

(EN 149:2001+A1:2009, Clause 8.7)

Test Requirement	Results	Comment
The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0 % (by volume)	Detail refer to Appendix 4	Pass

Appendix 4: Summarization of Test Data

Carbon Dioxide Content of The Inhalation Air

Condition	Sample No.	Result	Assessment
A.R.	35#	0.27%	Pass
	36#	0.32%	
	37#	0.35%	
		Mean value: 0.31%	

Clause 7.13 Head Harness

(EN 149:2001+A1:2009, Clause 8.4 & 8.5)

Test Requirement	Results	Comment
The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.	Comply	Pass
The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.	Comply	

Clause 7.14 Field of Vision

(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The field of vision is acceptable if determined so in practical performance	Comply	Pass

Clause 7.15 Exhalation Valve(s)

(EN 149:2001+A1:2009, Clause 8.2 & 8.9.1 & 8.3.4 & 8.8)

Test Requirement	Results	Comment
a) A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	No valves.	N.A.
b) 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 valves.	
c) 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 valves.	
(d) When the exhalation valve housing is attached to the face blank, it shall withstand axially a tensile force of 10N applied for 10 s.	No valves.	

Clause 7.16 Breathing Resistance

EN 149:2001+A1:2009, Clause 8.9)

Test Requirement				Results	Comment
The breathing resistances apply to valved and valveless filtering half masks and shall meet the requirements as the following table.				Detail refer to Appendix 5	Pass
Classification	Maximum permitted resistance (mbar)				
	Inhalation		Exhalation		
	30 L/min	95 L/min	160 L/min		
FFP1	0.6	2.1	3.0		
FFP2	0.7	2.4	3.0		
FFP3	1.0	3.0	3.0		

Appendix 5: Summarization of Test Data

Specimen	Condition	Inhalation(mbar)		Exhalation resistance(mbar)				
		At 30 L/min	At 95 L/min	At 160 L/min				
				A	B	C	D	E
38#	A.R.	0.4	1.5	2.1	2.1	2.1	2.1	2.1
39#		0.4	1.5	2.0	2.0	2.0	2.0	2.0
40#		0.4	1.4	2.0	2.0	2.0	2.0	2.0
41#	S.W.	0.5	1.6	2.2	2.2	2.2	2.2	2.2
42#		0.5	1.6	2.2	2.2	2.2	2.2	2.2
43#		0.5	1.6	2.2	2.2	2.2	2.2	2.2
44#	T.C.	0.4	1.5	2.1	2.1	2.1	2.1	2.0
45#		0.4	1.5	2.0	2.0	2.0	2.0	2.0
46#		0.4	1.5	2.0	2.0	2.0	2.0	2.0
/	F.C.	/	/	/	/	/	/	/
/		/	/	/	/	/	/	/
/		/	/	/	/	/	/	/

A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side

Clause 7.17 Clogging

(EN 149:2001+A1:2009, Clause 8.9 & 8.10)

Test Requirement			Results	Comment
Clause 7.17.2 Breathing resistance Valved particle filtering half masks: After clogging the inhalation resistances shall not exceed: FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95L/min continuous flow The exhalation resistance shall not exceed 3 mbar at 160 L/min continuous flow. 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 95L/min continuous flow			Requirement not applicable.	N.A.
Test Requirement			Results	Comment
Clause 7.17.3 Penetration of filter material All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements.			Requirement not applicable.	N.A.
Classification	Maximum penetration of test aerosol			
	Sodium chloride test 95 L/min	Paraffin oil test 95 L/min		
	%	%		
	max.	max.		
FFP1	20	20		
FFP2	6	6		
FFP3	1	1		

Clause 7.18 Demountable Parts

(EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
All demountable parts (if fitted) shall be readily connected and secured, where possible by hand	No detachable part	N.A.

Sample photo(s):



Fig.1



Fig.2

This test report displaces the original report No. S20090702301E, and the original one was invalid since the date of this test report No. S20090702301E-R1 released.

****End of Report****

The test report is effective only with both signature and specialized stamp, the result(s) shown in this report refer only to the sample(s) tested. Without written approval of NTEK, this report can't be reproduced except in full; The laboratory is not responsible for the authenticity of the sample information provided by the customer; The laboratory is not responsible for any deviation of results due to methods/standards provided by the customer.

Test Report

Applicant: Mezorrison Health Science & Technology (Shenzhen) Co.,Ltd.
Address: No.12 Yuhe Road, Shiyan Town, Baoan District, Shenzhen

The following sample(s) was/were submitted and identified on behalf of the client as:

Product name: Filtering Half Mask
Model: MZC-KZ
Trade mark: Mezorrison
Manufacturer: Mezorrison Health Science & Technology (Shenzhen) Co.,Ltd.
Address: 2nd floor, Gaoke building, No.8 Tangkeng Rd, Shiyan, Baoan district, Shenzhen, China
Classification: FFP2 NR
Sample quantity: 80 Pcs
C2 Sampling done by APPLUS+ with ID number : 20/32302101

Sample Received Date: Nov. 02, 2020
Testing Period: Nov. 02, 2020~ Nov. 08, 2020

Test Requirement:

According to the requirement of the Module C2 (SPC CE-062_EN M3 PPE) of Applus+, the test item(s) of the sample is according to the standard EN 149:2001+A1:2009.

Test Result(s): Please refer to the following page(s)

Test Method: Please refer to the following page(s)

Compiled by: _____

Reviewed by: _____

Approved by: _____

Date: 2020-11-09



Summary of assessment*

Clause	Assessment
7.3 Visual inspection	Pass
7.5 Material	Pass
7.8 Finish of parts	Pass
7.9.1 Total inward leakage	Pass
7.9.2 Penetration of filter material	Pass
7.12 Carbon dioxide content of the inhalation air	Pass
7.16 Breathing resistance	Pass

Key

Pass	Requirement satisfied.
NRq	The clauses were not required.
Fail	Requirement not satisfied. Refer to the "Result details" section for more information.
N.A.	Requirement not applicable.

Test	Uncertainty
Total inward leakage	6.40 %
Penetration of filter material (NaCl)	1.60 %
Penetration of filter material (Paraffin Oil)	1.78 %
Carbon dioxide content of the inhalation air	5.34 %
Breathing resistance (30 L/min)	3.60 %
Breathing resistance (95 L/min)	2.20 %
Breathing resistance (160 L/min)	2.00 %

* Assessment relates only to those specimens which were tested and subjects in this report.

Test Result

Respiratory Protective Devices — Filtering Half Masks to Protect against Particles — Requirements, Testing, Marking
(EN 149:2001+A1:2009)

Clause 7.3 Visual inspection

Test Requirement	Results	Comment
Marking and the information supplied by the manufacturer, requirements refer to clause 9 and clause 10.	Comply	Pass

Clause 7.5 Material

(EN 149:2001+A1:2009, Clause 8.2 & 8.3.1 & 8.3.2)

Test Requirement	Results	Comment
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.	Comply	Pass
After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the face piece or straps.	Comply	Pass
When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Comply	Pass
Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Comply	Pass

Clause 7.8 Finish of Parts

(EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	No sharp edges or burrs	Pass

Clause 7.9.1 Total Inward Leakage
(EN 149:2001+A1:2009 Clause 8.5)

Test Requirement	Results	Comment
<p>For particle filtering half masks fitted in accordance with the manufacturer's information, 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:</p> <p style="padding-left: 40px;">25% for FFP1 11% for FFP2 5% for FFP3</p> <p>and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than:</p> <p style="padding-left: 40px;">22% for FFP1 8% for FFP2 2% for FFP3</p>	Detail refer to Appendix 1	Pass

Appendix 1: Summarization of Test Data

Subject	Sample	Condition	Normal Breathing (%)	Head Side/Side (%)	Head Up/Down (%)	Speak Loudly (%)	Normal Breathing (%)	Mean (%)
Zhang	1#	A.R.	3.4	3.5	3.7	3.8	3.5	3.58
Fan	2#	A.R.	2.8	2.9	3.1	3.2	2.9	2.98
Yan	3#	A.R.	3.6	3.7	3.9	4.0	3.7	3.78
Huang	4#	A.R.	4.4	4.5	4.6	4.7	4.5	4.54
Yang	5#	A.R.	2.2	2.3	2.5	2.6	2.3	2.38
Shi	6#	T.C.	5.7	5.8	5.9	6.0	5.8	5.84
Huang	7#	T.C.	2.5	2.6	2.7	2.9	2.6	2.66
Chen	8#	T.C.	3.7	3.8	3.9	4.1	3.8	3.86
Lei	9#	T.C.	4.3	4.4	4.6	4.7	4.4	4.48
Shen	10#	T.C.	2.6	2.7	2.9	3.1	2.7	2.80

Facial Dimension:

Subject	Length of Face (mm)	Width of Face (mm)	Depth of Face (mm)	Width of Mouth (mm)
Zhang	138	148	125	55
Fan	108	145	125	55
Yan	128	158	140	58
Huang	110	148	121	44
Yang	114	148	114	50
Shi	120	165	115	46
Huang	130	187	117	52
Chen	110	144	105	57
Lei	103	137	121	53
Shen	115	136	110	54

Clause 7.9.2 Penetration of Filter Material

(EN 149:2001+A1:2009, Clause 8.11 & EN 13274-7:2019)

Test Requirement			Results	Comment
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.			Detail refer to Appendix 2	Pass
Classification	Maximum penetration of test aerosol (%)			
	Sodium chloride test 95 L/min	Paraffin oil test 95 L/min		
FFP1	20	20		
FFP2	6	6		
FFP3	1	1		

Appendix 2: Summarization of Test Data

Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)		Assessment
			Average in 30s after 3 min	Max. during exposure	
Sodium chloride test	A.R.	11#	0.90	/	Pass
		12#	0.76	/	
		13#	0.79	/	
	S.W.	17#	0.89	/	
		18#	0.82	/	
		19#	0.80	/	
	M.S. + T.C.	23#	/	0.81	
		24#	/	0.80	
		25#	/	0.87	
Paraffin oil test	A.R.	14#	0.49	/	
		15#	0.49	/	
		16#	0.40	/	
	S.W.	20#	0.26	/	
		21#	0.25	/	
		22#	0.26	/	
	M.S. + T.C.	26#	/	1.03	
		27#	/	1.12	
		28#	/	1.11	
Flow conditioning: 95.0 L/min					

Clause 7.12 Carbon Dioxide Content of The Inhalation Air

(EN 149:2001+A1:2009, Clause 8.7)

Test Requirement	Results	Comment
The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).	Detail refer to Appendix 3	Pass

Appendix 3: Summarization of Test Data
Carbon Dioxide Content of The Inhalation Air

Condition	Sample No.	Result		Assessment
A.R.	29#	0.39%	Mean value 0.38%	Pass
	30#	0.35%		
	31#	0.39%		

Clause 7.16 Breathing Resistance
EN 149:2001+A1:2009, Clause 8.9)

Test Requirement				Results	Comment
The breathing resistances apply to valved and valveless filtering half masks and shall meet the requirements as the following table.				Detail refer to Appendix 4	Pass
Classification	Maximum permitted resistance (mbar)				
	Inhalation		Exhalation		
	30 L/min	95 L/min	160 L/min		
FFP1	0.6	2.1	3.0		
FFP2	0.7	2.4	3.0		
FFP3	1.0	3.0	3.0		

Appendix 4: Summarization of Test Data

Specimen	Condition	Inhalation(mbar)		Exhalation resistance(mbar)				
		At 30 L/min	At 95 L/min	At 160 L/min				
				A	B	C	D	E
32#	A.R.	0.48	1.44	2.03	2.04	2.03	2.04	2.05
33#		0.48	1.46	2.01	2.02	2.03	2.02	2.01
34#		0.50	1.45	2.02	2.02	2.03	2.04	2.03
35#	S.W.	0.53	1.48	2.07	2.08	2.09	2.08	2.08
36#		0.51	1.50	2.07	2.07	2.08	2.07	2.09
37#		0.51	1.51	2.09	2.10	2.11	2.10	2.11
38#	T.C.	0.43	1.40	1.96	1.97	1.98	1.98	1.97
39#		0.45	1.41	2.00	2.01	1.99	2.02	2.01
40#		0.45	1.39	1.98	1.99	1.98	1.97	1.99
/	T.C.+F.C.	/	/	/	/	/	/	/
/		/	/	/	/	/	/	/
/	F.C.	/	/	/	/	/	/	/

A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side

Sample photo(s):



Fig.1



Fig.2



Fig.3



Fig.4



Fig.5

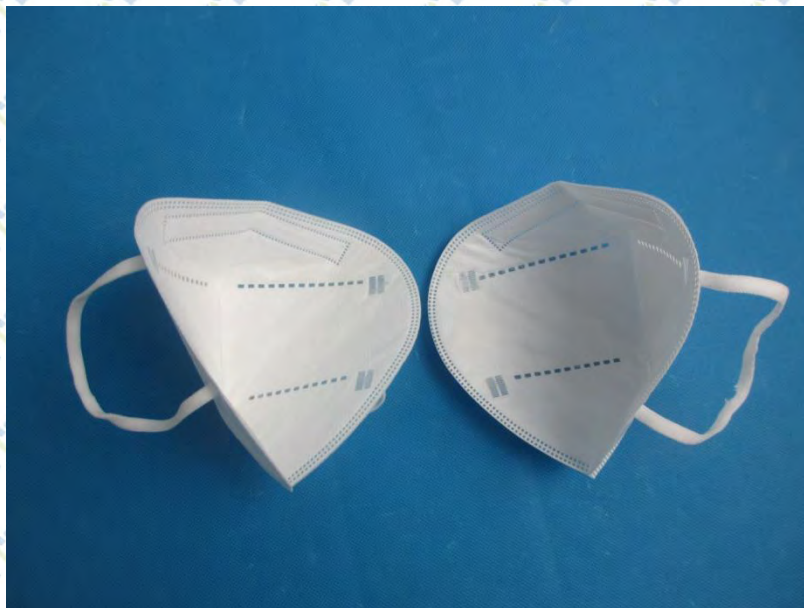


Fig.6

****End of Report****

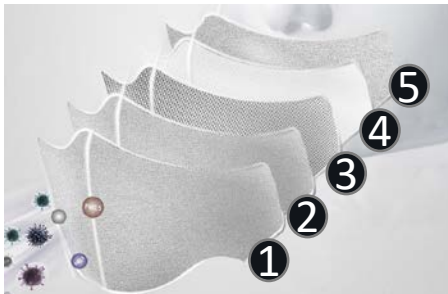
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Media Máscara Facial Filtrante FFP2 NR

Modelo: MZC-KZ/(B)/(P)/(DB)

Tejido no tejido, antibacteriano, de aire caliente, tela soplada por fusión. Diseño 3D según el contorno de la cara, aumenta el espacio para boca y nariz, reducen la resistencia respiratoria. Material poroso conformado para ajuste facial completo para adultos. Capa interior suave no irritante. Resistente a la rotura. Sin grapas.

Uso previsto: Proteger de la inhalación de aerosoles, sólidos y líquidos a la persona que la lleva puesta.



Cinco Capas de Protección

Talla única adulto

3 capas de:

Tejido no tejido

2 capas de :

Tejido de polipropileno fundido soplado

Especificaciones

Eficiencia de filtración de partículas PFE 0.3 μm \geq 97%
Propiedades de las gomas. Elásticas y sujeción tras las orejas
Ajuste facial. Sellado facial total
Exenta de ingredientes tóxicos, látex, PVC y silicona
Apta para uso sanitario

Material

Melt Blown:

Polipropileno
Poliuretano-Ácido poliláctico

Resto de capas:

Tejido no tejido (PP)

Recomendaciones uso

Mascarilla filtrante no reutilizable, usable hasta 12 horas o un turno de trabajo
No deben compartirse.

Gomas

Elastano

Clip nasal:

Aluminio

Embalaje

50 uds (50 bolsas x 1ud) Peso: (5gr/ud)

Dimensiones-peso caja

130x115x175mm – 340gr

Caja master

30 cajas (1500uds) 665x360x370mm (11,9Kg)

Certificados

Norma EN 149:2001+A1:2009

Dispositivos de protección respiratoria. Medias máscaras filtrantes para proteger contra partículas

Módulo B 0370-4495-PPE/B

Módulo C2 0370-4766-PPE/C2

Fabricante

Mezorison Health Science & Technology (Shenzhen) Co., Ltd.
No.12 Yuhe Road, Shiyuan Town, Baoan District, Shenzhen, China

Importador

SOLFIX ENGINEERING, S.L.

C/ Fco. Medina Mendoza, nº 10A, Puerta 29 19171 Cabanillas del Campo (Guadalajara)

Web: www.solfixair.es – Email: comercialcovid19@sol-fix.es

Made In China.

Fabricado en China

INSTRUCCIONES DE LAS MASCARILLAS

IMPORTANTE:

Antes de leer la información que se detalla a continuación compruebe qué tipo de mascarilla tiene intención de utilizar. Es responsabilidad del usuario elegir el modelo de mascarilla que le proporcione el nivel de protección adecuado frente al tipo y concentración del contaminante o contaminantes presentes en la zona de trabajo en la que va a desarrollar su actividad. Las máscaras filtrantes cumplen con la siguiente certificación **EN 149:2001+A1:2009**.



INSTRUCCIONES DE USO:

- Coloque la mascarilla y verifique la estanquidad antes de entrar en el área contaminada.
- Lleve la mascarilla puesta durante todo el tiempo de exposición a los contaminantes.
- Use la mascarilla de acuerdo a las regulaciones aplicables de salud y seguridad.
- Deseche la mascarilla y sustitúyala por una nueva si: la mascarilla se retira mientras está en el área contaminada, si la obstrucción excesiva de la mascarilla causa dificultad o incomodidad para respirar, si la mascarilla se daña (para mascarillas que protegen contra vapores, el olor del vapor se vuelve detectable).
- Salga del área contaminada si se marea, nota irritación u otro malestar.
- Válida sólo para un uso. No se necesita mantenimiento. No lo almacene/reutilice después de cada uso.
- Deseche la mascarilla después de cada uso (1 turno de trabajo como máximo).
- No apto para niños. Solo uso en adultos.

INSTRUCCIONES DE COLOCACIÓN:

1. Coloque la mascarilla en la mano, permitiendo que las bandas cuelguen libremente.
2. Sostenga la mascarilla debajo de la barbilla con la pieza metálica de aluminio nasal mirando hacia afuera.
3. Coloque las bandas por detrás de las orejas.
4. Moldee la pieza metálica de aluminio nasal a la forma de la cara, pasando las puntas de los dedos de ambas manos desde la parte superior de la nariz hacia ambos lados mientras presiona hacia adentro.
5. Verifique la estanquidad (ajuste facial), como sigue: Coloque ambas manos sobre la mascarilla y exhale. Debe haber presión positiva dentro de la mascarilla. Si siente que el aire escapa alrededor de los bordes vuelva a ajustar el respirador apretando en la nariz.

LIMITACIONES DE USO:

No use las mascarillas, ni entre o permanezca en la zona de riesgo si:

- La mascarilla está deteriorada
- La concentración de oxígeno es inferior al 19,5% (en volumen)
- Desconoce la naturaleza y/o concentración del agente contaminante o si ésta es inmediatamente peligrosa para la salud y/o la vida.
- La concentración de partículas supera los límites fijados por la legislación aplicable o si ésta es superior a 12,5 veces el valor TLV/MAC/OEL del contaminante(s).
- Detecta la presencia de gases o vapores en la zona de riesgo, en cuyo caso deberá emplear una mascarilla con carbón activo y en ese caso la concentración del contaminante deberá ser inferior a su valor TL/MAC/OEL.

AVISO IMPORTANTE:

No usar en caso de incendio. Estos EPI no aportan oxígeno. No usar en atmósferas con baja concentración de oxígeno, por ejemplo, en tanques o zonas poco ventiladas. No utilizar en atmósferas explosivas. En caso de usuarios con alguna característica física especial o vello facial abundante (barbas, bigotes o patillas) es muy probable que no se alcancen los requisitos necesarios para conseguir un correcto ajuste de la mascarilla. Durante el transporte mantener el equipo en su embalaje original y alejado de riesgos mecánicos y químicos.

ALMACENAMIENTO:

Mantenga las mascarillas sin usar en su embalaje cerrado y guárdelas en un área seca no contaminada entre 0 y +50°C a una humedad relativa por debajo del 50%.