



Notified Body No. 0370

CERTIFICADO DE EXAMEN UE DE TIPO

EU-TYPE EXAMINATION CERTIFICATE

No. **0370-5079-PPE/B**

ORGANISMO NOTIFICADO Nº <i>NOTIFIED BODY NUMBER</i>	0370 - LGAI TECHNOLOGICAL CENTER (APPLUS)
SOLICITANTE / FABRICANTE <i>APPLICANT / MANUFACTURER</i>	PI MEDICAL LABS SL TORRICELLI 26 - 06400 DON BENITO BADAJOZ ESPAÑA
PLANTA DE PRODUCCIÓN <i>PRODUCTION SITE</i>	PI MEDICAL LABS SL TORRICELLI 26 - 06400 DON BENITO BADAJOZ ESPAÑA
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>	Ref.: PI 5
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	15/01/2021
VALIDEZ HASTA / VALIDITY UNTIL	15/01/2026
<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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ANEXO TÉCNICO
TECHNICAL ANNEX

0370-5079-PPE/B

I. MODELOS INCLUIDOS EN EL CERTIFICADO

REFERENCES INCLUDED IN THIS CERTIFICATE

MARCA <i>BRAND</i>	PI MEDICAL
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ref.: PI 5
NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI <i>PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE</i>	FFP2 NR
DESCRIPCIÓN <i>DESCRIPTION</i>	MEDIA MÁSCARA FILTRANTE SIN VÁLVULA, TIPO PLEGABLE VERTICAL, DE 5 CAPAS, DE COLOR BLANCO, CON LAZOS DE OREJA Y CLIP NASAL INTERNO. TAMAÑO: 105mm*160mm / VALVELESS FILTERING HALF MASK, VERTICAL FOLDABLE TYPE, 5 LAYERS, WHITE COLOUR, WITH EARLOOPS AND INTERIOR NOSE CLIP. SIZE: 105mm*160mm
INFORME DE ENSAYO <i>TEST REPORT</i>	S21010801001E issued by Shenzhen NTEK Testing Technology Co., Ltd.



Organismo Notificado N° 0370

CERTIFICADO DE CONFORMIDAD CON EL TIPO CONFORMITY TO TYPE CERTIFICATE

No. **0370-5214-PPE/C2**

ORGANISMO NOTIFICADO N° <i>NOTIFIED BODY NUMBER</i>	0370 - LGAI TECHNOLOGICAL CENTER (APPLUS)
SOLICITANTE / FABRICANTE <i>APPLICANT / MANUFACTURER</i>	PI MEDICAL LABS SL TORRICELLI 26 - 06400 DON BENITO BADAJOZ ESPAÑA
PLANTA DE PRODUCCIÓN <i>PRODUCTION SITE</i>	PI MEDICAL LABS SL TORRICELLI 26 - 06400 DON BENITO BADAJOZ ESPAÑA
REGLAMENTO DE APLICACIÓN PARA DAR LA CONFORMIDAD / <i>APPLICABLE REGULATION TO GIVE CONFORMITY:</i> 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>	Ref.: PI 5
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 / <i>ISSUE DATE</i>	08/02/2021
VALIDEZ HASTA / <i>VALIDITY UNTIL:</i>	08/02/2022
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

0370-5214-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>	0370-5079-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>	15/01/2021
VALIDEZ HASTA <i>VALIDITY UNTIL</i>	15/01/2026
MARCA <i>BRAND</i>	PI MEDICAL
IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO) <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ref.: PI 5
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, TIPO PLEGABLE VERTICAL, DE 5 CAPAS, DE COLOR BLANCO, CON LAZOS DE OREJA Y CLIP NASAL INTERNO. TAMAÑO: 105mm*160mm / VALVELESS FILTERING HALF MASK, VERTICAL FOLDABLE TYPE, 5 LAYERS, WHITE COLOUR, WITH EARLOOPS AND INTERIOR NOSE CLIP. SIZE: 105mm*160mm
INFORME DE ENSAYO DE CONFORMIDAD CON EL TIPO <i>CONFORMITY TO TYPE TEST REPORT</i>	S21012900801E issued by Shenzhen NTEK Testing Technology Co., Ltd.



DECLARACIÓN UE DE CONFORMIDAD
(REGLAMENTO (UE) 2016/425 RELATIVO A LOS EQUIPOS DE PROTECCIÓN INDIVIDUAL)

Fabricante/ Manufacturer: **PI MEDICAL LABS, S.L**
Dirección/ Address: **Polígono Industrial Las Cumbres**
C/ Torricelli 26
06400 Don Benito (Badajoz)
España

Declara bajo su exclusiva responsabilidad que el producto:

TIPO DE PRODUCTO: MASCARILLA AUTOFILTRANTE DE UN SOLO TURNO SIN VÁLVULA

MARCA: PI MEDICAL

MODELO: PI 5

CLASE: FFP2 de acuerdo con la clasificación de la norma EN 149:2001+A1:2009.

TIPO: NR de acuerdo con la clasificación de la norma EN 149:2001+A1:2009.

Es conforme con los requisitos del reglamento:

REGLAMENTO (UE) 2016/425 RELATIVO A LOS EQUIPOS DE PROTECCIÓN INDIVIDUAL

Referencias de especificaciones comunes utilizadas en la evaluación de conformidad del producto:

UNE EN 149 y familia de normas UNE EN 13274

UNE EN 149:2001+A1:2009

El organismo notificado **LGAI TECHNOLOGICAL CENTER, S. A./Applus** (nº **0370**), ha efectuado el Examen UE de tipo (módulo B) y ha expedido certificado de examen UE de tipo con nº 0370-5079-PPE/B (en fecha 15/01/2021, con vigencia de 5 años),

El organismo notificado **LGAI TECHNOLOGICAL CENTER, S. A./Applus** con nº **0370**, ha efectuado, la Evaluación de Conformidad (módulo C2) y ha expedido el certificado con nº 0370-5214-PPE/C2 (en fecha 08/02/2021, con vigencia de 1 año).

Firmado por Dña. Carlota Pérez Sáez, en nombre de PI MEDICAL LABS, S.L, en Don Benito, a 8 de Febrero de 2021



Directora General

Test Report

Applicant: PI MEDICAL LABS
Address: C/TORRICELLI 26 · 06400 · DON BENITO·BADAJOZ · SPAIN

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

Product name: Half mask
Model: PI 5
Trade mark: PI MEDICAL
Manufacturer: PI MEDICAL LABS
Address: C/TORRICELLI 26 · 06400 · DON BENITO·BADAJOZ · SPAIN
Classification: FFP2 NR
Sample quantity: 129 Pcs
Sample Received Date: Jan. 08, 2021
Testing Period: Jan. 08, 2021~ Jan. 14, 2021

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: _____

2021-01-14

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 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.	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 (%)
Zhang	1#	A.R.	7.3	7.4	7.6	7.7	7.2	7.44
Fan	2#	A.R.	5.6	5.7	5.9	6.0	5.5	5.74
Yang	3#	A.R.	6.2	6.3	6.4	6.6	6.3	6.36
Yan	4#	A.R.	6.7	6.8	6.9	7.0	6.6	6.80
Huang	5#	A.R.	7.1	7.2	7.4	7.5	7.0	7.24
Shi	6#	T.C.	5.9	6.1	6.2	6.3	6.0	6.10
Huang	7#	T.C.	5.4	5.6	5.7	5.8	5.5	5.60
Chen	8#	T.C.	6.5	6.6	6.7	6.8	6.4	6.60
Lei	9#	T.C.	6.7	6.8	6.9	7.1	6.6	6.82
Shen	10#	T.C.	6.3	6.4	6.6	6.7	6.4	6.48

Facial Dimension:

Subject	Length of Face (mm)	Width of Face (mm)	Depth of Face (mm)	Width of Mouth (mm)
Zhang	120	175	115	57
Fan	120	155	115	55
Yang	125	165	120	55
Yan	104	163	115	52
Huang	116	187	126	57
Shi	110	144	117	46
Huang	103	136	105	52
Chen	115	135	121	57
Lei	111	137	121	53
Shen	112	138	110	54

Clause 7.9.2 Penetration of Filter Material

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

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#	0.74	/	Pass
		14#	0.74	/	
		15#	0.75	/	
	S.W.	19#	0.74	/	
		20#	0.74	/	
		21#	0.77	/	
	M.S. + T.C.	25#	/	0.78	
		26#	/	0.79	
		27#	/	0.78	
	Paraffin oil test	A.R.	16#	0.48	
17#			0.48	/	
18#			0.47	/	
S.W.		22#	0.48	/	
		23#	0.60	/	
		24#	0.61	/	
M.S. + T.C.		28#	/	4.44	
		29#	/	4.26	
		30#	/	4.29	
Flow rate of test aerosol: 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#	Nonflammable	Pass
	32#	Nonflammable	
T.C.	33#	Flammable, burn for no more than 5 s	
	34#	Nonflammable	

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#	0.31%	
	37#	0.27%	
		Mean value: 0.28%	

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 300L/min over a period of 30 s.	No valves.	
(d) When the exhalation valve housing is attached to the faceblank, 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.	0.49	1.29	1.94	1.93	1.94	1.93	1.92
39#		0.48	1.30	1.95	1.95	1.94	1.94	1.93
40#		0.50	1.31	1.95	1.94	1.95	1.94	1.93
41#	S.W.	0.50	1.30	1.94	1.93	1.94	1.93	1.92
42#		0.49	1.30	1.95	1.94	1.95	1.94	1.93
43#		0.50	1.31	1.96	1.96	1.95	1.95	1.94
44#	T.C.	0.47	1.26	1.88	1.87	1.88	1.87	1.86
45#		0.46	1.24	1.87	1.87	1.86	1.85	1.85
46#		0.46	1.25	1.89	1.89	1.88	1.87	1.87
/	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																		
<p>Clause 7.17.2 Breathing resistance</p> <p>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.</p> <p>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.</p>	Requirement not applicable.	N.A.																		
Test Requirement	Results	Comment																		
<p>Clause 7.17.3 Penetration of filter material</p> <p>All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements.</p> <table border="1" data-bbox="164 1137 922 1480"> <thead> <tr> <th rowspan="4">Classification</th> <th colspan="2">Maximum penetration of test aerosol</th> </tr> <tr> <th>Sodium chloride test 95 L/min</th> <th>Paraffin oil test 95 L/min</th> </tr> <tr> <th>%</th> <th>%</th> </tr> <tr> <th>max.</th> <th>max.</th> </tr> </thead> <tbody> <tr> <td>FFP1</td> <td>20</td> <td>20</td> </tr> <tr> <td>FFP2</td> <td>6</td> <td>6</td> </tr> <tr> <td>FFP3</td> <td>1</td> <td>1</td> </tr> </tbody> </table>	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	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):

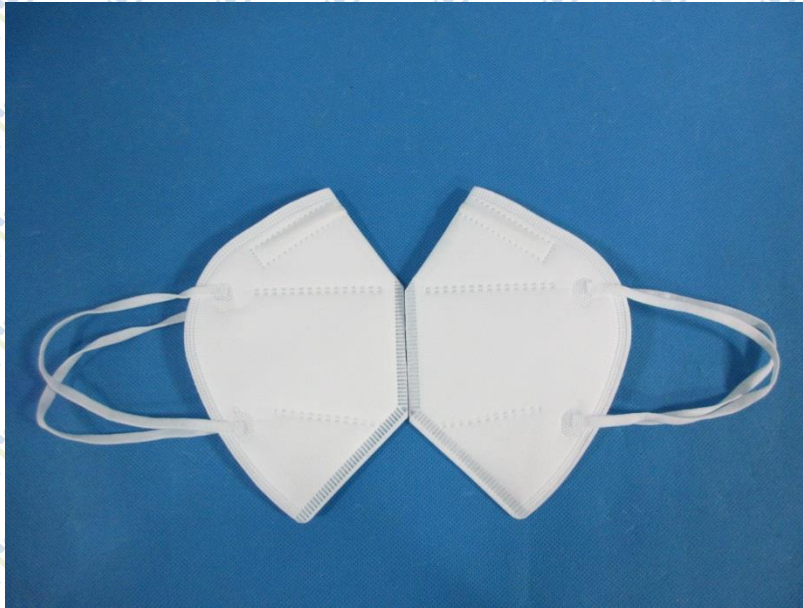


Fig.1



Fig.2

****End of Report****

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Test Report

Applicant: PI MEDICAL LABS
Address: C/TORRICELLI 26 · 06400 · DON BENITO·BADAJOZ ·SPAIN

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

Product name: Half mask
Model: PI 5
Trade mark: PI MEDICAL
Manufacturer: PI MEDICAL LABS
Address: C/TORRICELLI 26 · 06400 · DON BENITO·BADAJOZ ·SPAIN
Classification: FFP2 NR
Sample quantity: 60 Pcs
C2 Sampling done by
APPLUS+ with ID 21/32300162
number :

Sample Received
Date: Jan. 29, 2021
Testing Period: Jan. 29, 2021~ Feb. 04, 2021

Test Requirement:

According to the requirement of the Module C2 (SPC CE-062_EN M4 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: _____

2021-02-08

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
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: 25% for FFP1 11% for FFP2 5% for FFP3 and, 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	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.	6.3	6.4	6.6	6.7	6.4	6.48
Zhou	2#	A.R.	7.1	7.2	7.4	7.6	7.2	7.30
Ma	3#	A.R.	5.9	6.2	6.4	6.6	6.1	6.24
Wu	4#	A.R.	6.5	6.6	6.7	6.9	6.4	6.62
Li	5#	A.R.	6.7	6.8	6.9	7.1	6.6	6.82
Wu	6#	T.C.	6.2	6.5	6.7	6.8	6.3	6.50
Zhai	7#	T.C.	7.4	7.5	7.6	7.7	7.3	7.50
Zheng	8#	T.C.	5.6	5.7	5.9	6.2	5.5	5.78
Huang	9#	T.C.	6.8	6.9	7.1	7.3	6.7	6.96
Wu	10#	T.C.	7.2	7.4	7.6	7.7	7.3	7.44

Facial Dimension:

Subject	Length of Face (mm)	Width of Face (mm)	Depth of Face (mm)	Width of Mouth (mm)
Huang	120	175	115	57
Zhou	120	155	115	55
Ma	125	165	120	55
Wu	116	187	126	57
Li	104	163	115	52
Wu	110	144	117	46
Zhai	103	136	105	52
Zheng	115	135	121	57
Huang	111	137	121	53
Wu	112	138	119	54

Clause 7.9.2 Penetration of Filter Material

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

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#	0.75	/	Pass
		12#	0.74	/	
		13#	0.75	/	
	S.W.	17#	0.73	/	
		18#	0.74	/	
		19#	0.72	/	
	M.S. + T.C.	23#	/	0.80	
		24#	/	0.82	
		25#	/	0.79	
Paraffin oil test	A.R.	14#	0.50	/	
		15#	0.49	/	
		16#	0.49	/	
	S.W.	20#	0.48	/	
		21#	0.48	/	
		22#	0.48	/	
	M.S. + T.C.	26#	/	3.49	
		27#	/	3.02	
		28#	/	2.89	
Flow rate of test aerosol: 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#	0.28%	Mean value: 0.29%	Pass
	30#	0.29%		
	31#	0.29%		

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.	0.41	1.45	2.16	2.15	2.16	2.17	2.17
33#		0.40	1.44	2.15	2.16	2.17	2.17	2.18
34#		0.41	1.45	2.17	2.16	2.15	2.16	2.16
35#	S.W.	0.43	1.48	2.21	2.20	2.21	2.20	2.20
36#		0.44	1.50	2.20	2.19	2.19	2.20	2.21
37#		0.43	1.50	2.19	2.20	2.21	2.20	2.21
38#	T.C.	0.38	1.37	2.10	2.11	2.12	2.13	2.12
39#		0.38	1.38	2.10	2.10	2.11	2.10	2.12
40#		0.37	1.37	2.09	2.10	2.11	2.10	2.11
/	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

****End of Report****

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