



Notified Body No. 0370

# CERTIFICADO DE EXAMEN UE DE TIPO

## EU-TYPE EXAMINATION CERTIFICATE

No. **0370-5198-PPE/B**

<b>ORGANISMO NOTIFICADO Nº</b> <i>NOTIFIED BODY NUMBER</i>	<b>0370 - LGAI TECHNOLOGICAL CENTER (APPLUS)</b>
<b>SOLICITANTE / FABRICANTE</b> <i>APPLICANT / MANUFACTURER</i>	<b>Zhejiang Allta Industry Co., Ltd</b> No.108, Jinqiao Road, Yucheng Town, Haiyan County, Jiaxing City, Zhejiang Province, China
<b>PLANTA DE PRODUCCIÓN</b> <i>PRODUCTION SITE</i>	<b>Zhejiang Allta Industry Co., Ltd</b> No.108, Jinqiao Road, Yucheng Town, Haiyan County, Jiaxing City, Zhejiang Province, China
<b>REGLAMENTO DE APLICACIÓN PARA DAR LA CONFORMIDAD / APPLICABLE REGULATION TO GIVE CONFORMITY:</b> <b>REGLAMENTO (UE) 2016/425 SOBRE LOS EQUIPOS DE PROTECCIÓN INDIVIDUAL</b> <i>REGULATION (EU) 2016/425 PERSONAL PROTECTIVE EQUIPMENT</i>	
<b>PROCEDIMIENTO DE EVALUACIÓN DE LA CONFORMIDAD</b> <i>CONFORMITY ASSESSMENT PROCEDURE</i>	Módulo // <i>Module</i> : <b>B</b> <b>EXAMEN UE DE TIPO / EU TYPE EXAMINATION</b>
<b>IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO)</b> <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ref.: 9513 Particle filtering half mask
<b>NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI / PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE</b>	FFP2 NR
<b>NORMAS ARMONIZADAS / HARMONISED STANDARDS</b>	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>
<b>FECHA DE EMISIÓN / ISSUE DATE</b>	<b>05/02/2021</b>
<b>VALIDEZ HASTA / VALIDITY UNTIL</b>	<b>05/02/2026</b>
<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.*

Puede comprobarse la validez de este certificado en nuestra página web / *You can check the validity of this certificate on our website:*  
[www.appluslaboratories.com/certified\\_products](http://www.appluslaboratories.com/certified_products)



## ANEXO TÉCNICO TECHNICAL ANNEX

0370-5198-PPE/B

### I. MODELOS INCLUIDOS EN EL CERTIFICADO

#### REFERENCES INCLUDED IN THIS CERTIFICATE

<b>MARCA</b> <i>BRAND</i>	Allta
<b>IDENTIFICACIÓN DEL EPI (NÚMERO DE TIPO)</b> <i>IDENTIFICATION OF THE PPE (TYPE NUMBER)</i>	Ref.: 9513 Particle filtering half mask
<b>NIVEL O NIVELES DE RENDIMIENTO O LA CLASE DE PROTECCIÓN DEL EPI</b> <i>PERFORMANCE LEVEL OR PROTECTION CLASS OF THE PPE</i>	FFP2 NR
<b>DESCRIPCIÓN</b> <i>DESCRIPTION</i>	MEDIA MÁSCARA FILTRANTE SIN VÁLVULA DE TIPO PLEGABLE VERTICAL, DE 4 CAPAS, DE COLOR NEGRO, CON LAZOS DE OREJA CON GANCHO Y CLIP NASAL INTERIOR. TAMAÑO: 158mm*110mm. // VALVELESS FILTERING HALF MASK, VERTICAL FOLDING TYPE, 4 LAYERS, BLACK COLOUR, WITH EARLOOPS WITH HOOK AND INTERIOR NOSE CLIP. SIZE: 158mm*110mm
<b>INFORME DE ENSAYO</b> <i>TEST REPORT</i>	MTI210118026P001 issued by Shenzhen Microtest Co.,Ltd.

# Test Report

**Report No.: MTI210118026P001**

**Date of Issue: 2021.01.28**

**Client: Zhejiang Allta Industry Co., Ltd.**

**Product: Particle filtering half mask**

**Test Type: Commissioned Inspection**

**Shenzhen Microtest Co., Ltd.**

<http://www.mtitest.com>



## Instructions

1. The report shall not be partially reproduced without the written consent of the Laboratory ;
2. The test results of this report are only responsible for the samples submitted ;
3. This report is invalid without the seal and signature of the laboratory ;
4. This report is invalid if transferred, altered or tampered with in any form without authorization ;
5. Any objection to this report shall be submitted to the laboratory within 15 days from the date of receipt of the report.

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Basic Information			
Client	Zhejiang Allta Industry Co., Ltd.		
Client Address	No.108, Jinqiao Road, Yucheng Town, Haiyan County, Jiaxing City, Zhejiang Province, China		
Manufacturer	Zhejiang Allta Industry Co., Ltd.		
Manufacturer Address	No.108, Jinqiao Road, Yucheng Town, Haiyan County, Jiaxing City, Zhejiang Province, China		
Sample Information			
Product	Particle filtering half mask	Sample No.	MTI210118026-1-S0001
Brand/ Trademark	allta	Model	9513
Sample Number	80 Pcs	Sample Description	Black ear wearing type, folding type mask
Testing Information			
Sample Receive Date	2021.01.22	Sample Source	Customer provided
Test Specification	EN 149:2001+A1:2009		
Classification	FFP2 NR		
Date of Tests	2021.01.22~2021.01.28		
Test Address	Medical protection laboratory		
Test Result	The sample has been tested and the test items meet the requirements of EN 149:2001+A1:2009.		
Remarks	"/" in the report means this item is blank, "N/A" in the report means this item is not application.		
Compiled:	<i>Hong Pu</i>	Reviewed:	<i>Daniel Shi</i>
		Approved:	<i>Tom Xue</i>

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No.	Test Items	Spec Chapter	Requirements	Test Data	Assesment
1	Visual inspection	7.3	The visual inspection shall also include the marking and the information supplied by the manufacturer.	Meet the requirements.	Pass
2	Material	7.5	Meet the requirements of 7.5	Meet the requirements.	Pass
3	Practical performance	7.7	The particle filtering half mask shall undergo practical performance tests under realistic conditions.	Meet the requirements.	Pass
4	Finish of parts	7.8	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Meet the requirements.	Pass
5	Total inward leakage	7.9.1	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.	Test results are shown in Annex A Table 7.9.1-A&B.	Pass
6	Penetration of filter material	7.9.2	Sodium chloride test 95L/min: FFP1 ≤ 20%, FFP2 ≤ 6% , FFP3 ≤ 1%. Paraffin oil test 95L/min: FFP1 ≤ 20%, FFP2 ≤ 6%	Test results are shown in Annex A Table 7.9.2.	Pass

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			,FFP3≤1%.		
7	Compatibility with skin	7.10	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.	Meet the requirements.	Pass
8	Flammability	7.11	When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.	A.R.: 29#:not burn 30#: not burn T.C.: 31#: not burn 32#: not burn	Pass
9	Carbon dioxide content of the inhalation air	7.12	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).	A.R.: 33#:0.52% 34#:0.53% 35#:0.55% Mean:0.54%	Pass
10	Head harness	7.13	Meet the requirements of 7.13	Meet the requirements.	Pass
11	Field of vision	7.14	The field of vision is acceptable if determined so in practical performance tests.	Meet the requirements.	Pass
12	Exhalation valve(s)	7.15	Meet the requirements of 7.15	Only applicable to Exhalation valve(s) Particle filtering half mask.	N/A
13	Breathing resistance	7.16	Inhalation30L/min: FFP1≤0.6mbar,FFP2≤0.7mbar ,FFP3≤1.0mbar. Inhalation95L/min: FFP1≤2.1mbar,FFP2≤2.4mbar ,FFP3≤3.0mbar. Exhalation160L/min: FFP1≤3.0mbar,FFP2≤3.0mbar ,FFP3≤3.0mbar.	Test results are shown in Annex A Table 7.16.	Pass
14	Demountable parts	7.18	All demountable parts (if fitted) shall be readily connected and	Meet the requirements.	Pass

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			secured, where possible by hand.		
Note: A.R.:As received      S.W.: Simulated wearing treatment      M.S.:Mechanical strength T.C.:Temperature conditioning      F.C.:Flow conditioning					

Item Name	File No	Uncertainty	
Penetration of filter material	MTI-SOP-PH-U005	$U_{rel} = 2.1\%, k=2$	
Carbon dioxide content of the inhalation air	MTI-SOP-PH-U007	$U_{rel} = 1.8\%, k=2$	
Total inward leakage	MTI-SOP-PH-U008	$U_{rel} = 1.8\%, k=2$	
Breathing resistance	MTI-SOP-PH-U006	30L/min	$U_{rel} = 2.5\%, k=2$
		95L/min	$U_{rel} = 2.4\%, k=2$
		160L/min	$U_{rel} = 2.3\%, k=2$



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## Annex A: Summarization of Test Data

**Table 7.9.1-A Total inward leakage test data**

Test specification: EN 149:2001+A1:2009 Clause 8.5

Subject	No.	Condition	Walk(%)	Head Side/side(%)	Head Up/down(%)	Talk(%)	Walk(%)	Mean(%)
Lani	1#	A.R.	0.88	1.46	1.54	1.14	2.58	1.52
Noak	2#	A.R.	2.75	4.20	2.64	2.08	3.11	2.96
Elaine	3#	A.R.	1.11	1.31	4.71	2.85	1.53	2.30
Hong	4#	A.R.	2.67	1.77	1.02	2.21	2.87	2.11
Shane	5#	A.R.	1.16	1.07	0.88	1.00	1.55	1.13
Lucy	6#	T.C.	0.57	1.16	0.98	0.94	0.58	0.85
Micro	7#	T.C.	2.24	4.08	4.18	5.23	4.93	4.13
Harper	8#	T.C.	2.43	3.26	2.11	1.60	0.97	2.07
Robert	9#	T.C.	3.75	4.84	4.15	6.90	5.93	5.11
Olina	10#	T.C.	3.28	5.45	6.65	5.98	5.81	5.43

**Table 7.9.1-B Facial dimension**

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
Lani	135	150	130	51
Noak	110	138	115	57
Elaine	102	142	103	59
Hong	106	138	115	57
Shane	110	142	122	60
Lucy	99	142	108	55
Micro	125	135	126	50
Harper	133	149	116	65
Robert	112	155	108	60
Olina	120	125	125	50

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**Table 7.9.2 Penetration of filter material**

Test specification: EN 149:2001+A1:2009 Clause 8.11

Aerosol	Condition	Sample No.	Average penetration after 3min (%)	Maximum penetration during exposure (%)
Sodium chloride test Aerosol concentration: 10 mg/m <sup>3</sup>	As received	11#	0.47	/
		12#	0.26	/
		13#	0.26	/
	Simulated wearing treatment	14#	0.92	/
		15#	0.92	/
		16#	1.31	/
	Mechanical strength+ Temperature conditioned	17#	/	0.68
		18#	/	0.50
		19#	/	0.95
Paraffin oil Test Aerosol concentration: 22 mg/m <sup>3</sup>	As received	20#	0.86	/
		21#	1.13	/
		22#	1.02	/
	Simulated wearing treatment	23#	3.01	/
		24#	3.86	/
		25#	3.66	/
	Mechanical strength+ Temperature conditioned	26#	/	4.31
		27#	/	3.60
		28#	/	4.49

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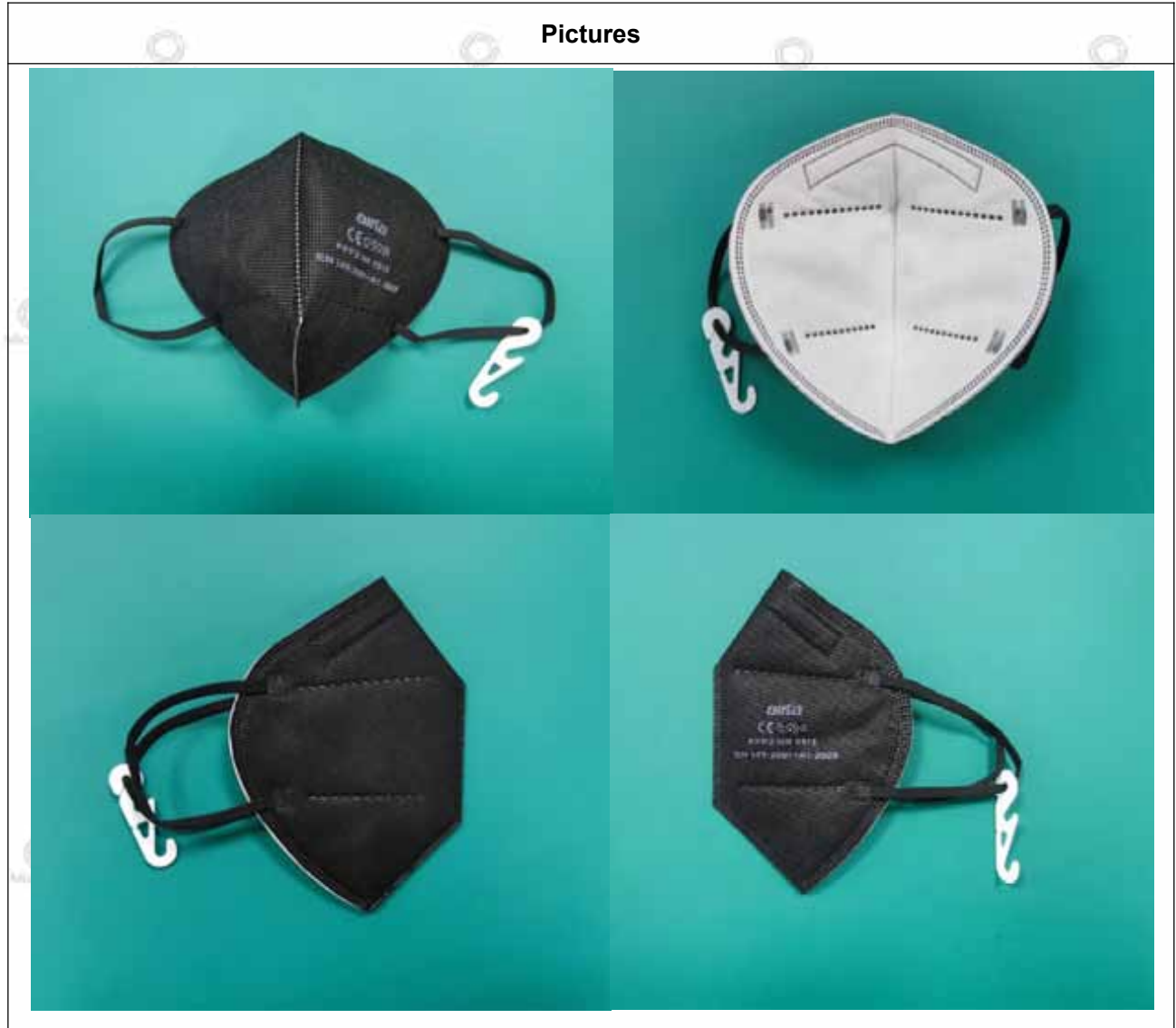
**Table 7.16 Breathing resistance(mbar)**

Test specification: EN 149:2001+A1:2009 Clause 8.9

	Flow rate		36#					37#					38#				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
As received	Inhalation	30 l/min	0.23	0.22	0.23	0.24	0.24	0.22	0.22	0.22	0.23	0.23	0.21	0.21	0.21	0.22	0.22
		95 l/min	0.92	0.91	0.92	0.92	0.93	0.91	0.91	0.92	0.92	0.93	0.90	0.90	0.89	0.89	0.89
	Exhalation	160l/min	1.59	1.58	1.59	1.59	1.60	1.58	1.57	1.57	1.58	1.59	1.56	1.57	1.57	1.57	1.58
Simulated Wearing treatment	Flow rate		39#					40#					41#				
	Inhalation	30 l/min	0.22	0.23	0.23	0.23	0.22	0.21	0.21	0.22	0.22	0.22	0.21	0.21	0.21	0.22	0.22
		95 l/min	0.89	0.89	0.89	0.88	0.88	0.87	0.88	0.88	0.89	0.89	0.87	0.88	0.87	0.86	0.86
	Exhalation	160l/min	1.56	1.56	1.56	1.57	1.57	1.58	1.57	1.58	1.58	1.59	1.56	1.55	1.56	1.56	1.57
Temperature conditioned	Flow rate		42#					43#					44#				
	Inhalation	30 l/min	0.24	0.24	0.24	0.23	0.23	0.23	0.22	0.23	0.23	0.24	0.25	0.25	0.25	0.24	0.24
		95 l/min	0.93	0.92	0.92	0.93	0.94	0.92	0.91	0.92	0.92	0.93	0.95	0.95	0.94	0.94	0.94
	Exhalation	160l/min	1.60	1.61	1.61	1.61	1.62	1.59	1.60	1.59	1.59	1.58	1.61	1.61	1.62	1.62	1.62

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

**Pictures**



\*\*\*\*\* END \*\*\*\*\*