

MASCARILLA FFP-2 PLEGADA SIN VÁLVULA

Presentación	  		
Caja de 10 Unidades. Cartón: 560 u 840 Uds.			
Dimensiones			
CARTÓN: 840 Unidades Peso bruto: 9,1 kg. Largo: 65 cm. Ancho: 42 cm. Alto: 29 cm.			
CARTÓN: 560 Unidades Peso bruto: 6,13 kg. Largo: 56 cm. Ancho: 36 cm. Alto: 30 cm.			
Modelos / Referencias	Modelo	Referencia	EAN13
	FFP-2 PLEGADA SIN VÁLVULA	040252	 8 435125 415392
Características Técnicas	✖ Mascarilla de protección FFP-2 sin válvula. Equipo de Protección Individual ✖ Fabricadas en fibra sintética no tejida hipoalergénica. ✖ 5 capas. TNT + Meltblown. ✖ Exentas de látex. ✖ No estériles ✖ Con alto poder de filtración $\geq 94\%$. ✖ Color blanco. ✖ Un solo uso. ✖ Plegada, en bolsas individuales (ver imagen). ✖ Cubre totalmente boca, nariz y mentón. ✖ Lámina nasal para mejor ajuste. ✖ Bordes termo sellados. ✖ Gomas de sujeción redondeadas y suaves para sujeción en orejas. ✖ Modelo: HGTN952. ✖ País de origen: Turquía		
Regulación	✖ Marcado “CE” Equipo de Protección Individual. ✖ Incluidos en la Categoría de EPI, según la directiva 2016/425. ✖ Certificado CE Módulo B: adjunto		

Regulación	✓ Certificado CE Módulo C2: adjunto ✓ Cumplen con los requisitos según norma: - EN ISO 149:2001+A1: 2009: Requisitos generales para dispositivos de protección respiratoria. Ver Test Report adjunto.
Uso	✓ FFP2: Esta mascarilla está clasificada en función de su eficacia de filtración y de su fuga total máxima hacia el interior, como mascarilla de protección contra las partículas sólidas, líquidas y gases de alta toxicidad. Puede utilizarse para concentraciones que lleguen a alcanzar 20 x el Valor Medio de Exposición (VME). ✓ Poder de filtración del medio filtrante $\geq 94\%$ ✓ No utilizar más de 8 horas seguidas y tirar después de su uso. No quitar la mascarilla de su embalaje antes de su uso. Utilizar sólo cuando la concentración de contaminantes no ponga ni la vida ni la salud en peligro y únicamente de conformidad con las normas aplicables en términos de salud y seguridad. ✓ Utilizar en zonas ventiladas, sin carencias de oxígeno y que no presenten peligro de explosión. ✓ El contacto con la piel es susceptible de provocar reacciones alérgicas en algunos usuarios. En este caso, dejar la zona de riesgos, retirar la mascarilla y consultar a un médico. ✓ Desechar en las siguientes circunstancias: - Rotura de elásticos de sujeción. - Rasgados, roturas en cualquier parte del tejido interno o externo. - Manchas en el tejido.
Conservación / Almacenaje	✓ Almacenar en envase original al resguardo de la luz y de la helada, sin contacto con productos disolventes y sin contacto directo con áreas o artículos duros que puedan dañar el embalaje.
Instrucciones de uso	Diagrama de instrucciones de uso de la mascarilla FFP2: 1. Preparar la mascarilla. 2. Desmenujar la parte superior. 3. Colocar la mascarilla sobre la nariz. 4. Colocar la mascarilla sobre la boca. 5. Ajustar la mascarilla. 6. No tocar la mascarilla. 7. Retirar la mascarilla. 8. Tirar de la mascarilla. 9. Tirar de la mascarilla.

Anhui Huaguotang Biotechnology Co., Ltd

East of Xianweng Road, south of Hehuan Road,
Bowu Industrial Park, Bozhou City, Anhui Province
China

It is certified that the manufacturer's technical file and the PPE product detailed on
page 2 have been assessed and found to be in accordance with

Regulation (EU) 2016/425 Module B, EU type-examination

This certificate is valid from 19 October 2020 until 19 October 2025
1. Certified since 19 October 2020

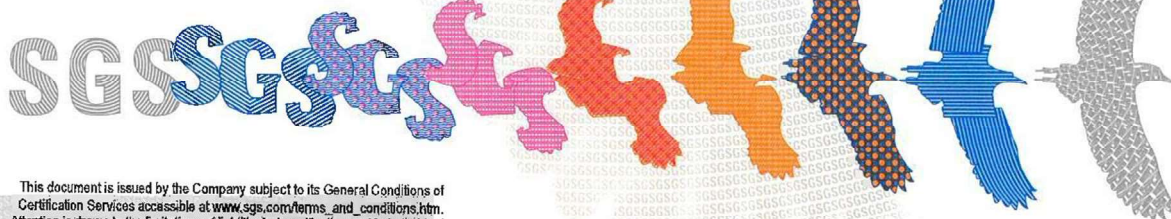
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Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

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Anhui Huaguotang Biotechnology Co., Ltd

Regulation (EU) 2016/425 Module B, EU type-examination

Issue 1

PPE Product

HUAGOUTANG (logo) Model: HGTN952, Particle filtering half mask.

It is certified that the manufacturer's technical file and the above mentioned PPE have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 Personal Protective Equipment

The following have been applied:

EN 149:2001+A1:2009 (Respiratory protective devices - filtering half masks to protect against particles) device classification: FFP2 NR.

This certificate is issued on the strict condition that appropriate checks on manufactured PPE, as detailed in Article 19 (c) of the Regulation are implemented and maintained while the model is in production



Certification is based on technical file reference:

HGT002 Technical File, Revision No.A3 dated: 2020/7/28.

SGS Reference Number UK/CRS 241674.

This certificate remains the property of SGS Fimko Oy to whom it must be returned on request

Certificate CN20/42605

The management system of

Anhui Huaguotang Biotechnology Co., Ltd

East of Xianweng Road, south of Hehuan Road,
Bowu Industrial Park, Bozhou City, Anhui Province
China

has been assessed and certified as meeting the requirements of

Regulation (EU) 2016/425 Module C2

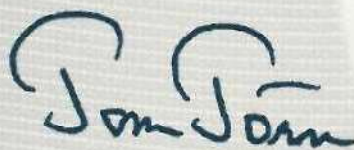
For the following activities

**Manufacture of HUAGUOTANG (logo) Model:HGTN952, Particle
filtering half mask.**

**(Note: All products marked CE0598 must have a valid EU type-
examination certificate issued under Module B or a valid EC type-
examination certificate issued under Article 10 of Directive
89/686/EEC.)**

This certificate is valid from 30 November 2020
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 30 November 2020

Authorised by



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Page 1 of 1



Test Report SL52025245806701TX

Date: June 12, 2020

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ANHUI HUAGUOTANG BIOTECHNOLOGY CO., LTD.

EAST OF XIANWENG ROAD, SOUTH OF HEHUAN ROAD, BOWU INDUSTRIAL PARK, BOZHOU HIGH
TECH ZONE, BOZHOU, ANHUI, 236800, CHINA

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

Sample Description : (A)FACE MASK Non medicine

SGS Internal Ref No. : SHHL2004511973MD

Style No. : HGTD952

Sample Color : (A)WHITE

Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Apr 24, 2020

Testing Period : Apr 26, 2020 - Jun 12, 2020

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the
sample(s) tested, for further details, please refer to the following page(s).**Conclusion:**

Sample No.	Recommendation Level
(A)	FFP2 NR

Signed for and on behalf of

SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center



Sara Guo (Account Executive)

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Testing Center

Test Result

Respiratory Protective Devices — Filtering Half Masks to Protect against Particles — Requirements, Testing, Marking

(EN 149:2001+A1:2009)

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	
When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Comply	
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	

Clause 7.6 Cleaning and Disinfecting

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

Test Requirement	Results	Comment
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. 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.	Not applicable (Not designed to be re-usable)	N.A.

Clause 7.7 Practical Performance#

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

Test Requirement	Results	Comment
The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard.	No imperfections	Pass



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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
The total inward leakage consists of three components: face seal leakage, exhalation value leakage(if exhalation value fitted) and filter penetration. 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	Meet FFP1 Meet FFP2

Appendix 1: Summarization of Test Data

Inward Leakage Test Data

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
1	1	A.R.	6.1	7.0	7.1	6.9	6.5	6.7
2	2	A.R.	6.8	7.4	7.4	7.5	7.0	7.2
3	3	A.R.	5.7	6.4	6.7	6.6	6.0	6.3
4	4	A.R.	6.0	7.0	7.3	7.2	6.5	6.8
5	5	A.R.	5.6	6.5	6.8	6.5	6.1	6.3
6	6	T.C.	6.5	7.3	7.6	7.6	6.9	7.2
7	7	T.C.	6.2	6.8	7.0	6.7	6.2	6.6
8	8	T.C.	6.9	7.8	7.9	7.5	7.1	7.4
9	9	T.C.	6.0	6.7	6.8	6.9	6.3	6.5
10	10	T.C.	6.3	7.2	6.9	7.0	6.5	6.8

Facial Dimension

Subject	Face length	Face Width	Face Depth	Mouth Width
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

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9	118	139	130	63
10	120	135	125	50

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	Meet FFP1 Meet FFP2
Classifica tion	Maximum penetration of test aerosol			
	Sodium chloride test 95 l/min % max.	Paraffin oil test 95 l/min % max.		
FFP1	20	20		
FFP2	6	6		
FFP3	1	1		

Appendix 2: Summarization of Test Data

Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)
Sodium chloride test	As received	1	0.2
		2	0.3
		3	0.2
	Simulated wearing treatment	4	0.2
		5	0.2
		6	0.3
	Mechanical strength +Temperature conditioned	7	1.2
		8	1.2
		9	1.3
Paraffin oil test	As received	10	1.1
		11	1.0
		12	1.1
	Simulated wearing treatment	13	1.2
		14	1.1
		15	1.0
	Mechanical strength +Temperature conditioned	16	2.8
		17	2.9
		18	2.8
Flow conditioning: Single filter: 95.0 L/min			



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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 to 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
As received	1	Burning time: 0.1s
	2	Burning time: 0.1s
Temperature conditioned	3	Burning time: 0.1s
	4	Burning time: 0.1s

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
As received	1	0.6650%
	2	0.6660%
	3	0.6670%
		Mean value: 0.67%

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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 tests.	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.	Not applicable due to No exhalation valve	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.	Not applicable due to No exhalation valve	
(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.	Not applicable due to No exhalation valve	
(d) When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10N applied for 10 s.	Not applicable due to No exhalation valve	



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Clause 7.16 Breathing Resistance#

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

Test Requirement				Results	Comment																						
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table. <table><tr><th rowspan="3">Classification</th><th colspan="3">Maximum permitted resistance (mbar)</th></tr><tr><th colspan="2">Inhalation</th><th>Exhalation</th></tr><tr><th>30 l/min</th><th>95 l/min</th><th>160 l/min</th></tr><tr><td>FFP1</td><td>0.6</td><td>2.1</td><td>3.0</td></tr><tr><td>FFP2</td><td>0.7</td><td>2.4</td><td>3.0</td></tr><tr><td>FFP3</td><td>1.0</td><td>3.0</td><td>3.0</td></tr></table>				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	Detail refer to Appendix 5	Meet FFP1 Meet FFP2 Meet FFP3
					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

Breathing resistance (mbar)

As received	Flow rate		1					2					3				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.3	0.3	0.2	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.2	0.3	0.3	0.3
		95 l/min	0.8	0.9	0.9	0.8	0.8	0.8	0.8	0.8	0.8	0.9	0.9	0.8	0.8	0.8	0.8
	Exhalation	160 l/min	1.3	1.2	1.3	1.4	1.3	1.3	1.3	1.3	1.4	1.3	1.3	1.4	1.3	1.3	1.3
Simulated wearing treatment	Flow rate		4					5					6				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.3	0.2	0.2	0.2	0.2	0.3	0.2	0.2	0.2	0.2	0.2	0.2	0.3	0.2	0.2
		95 l/min	0.8	0.8	0.9	0.9	0.8	0.8	0.8	0.9	0.9	0.9	0.8	0.8	0.8	0.9	0.8
	Exhalation	160 l/min	1.4	1.4	1.3	1.3	1.3	1.3	1.3	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.3
Temperature conditioned	Flow rate		7					8					9				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.2	0.2	0.2	0.3	0.3	0.2	0.3	0.2	0.2	0.3	0.3	0.2	0.2	0.2	0.3
		95 l/min	0.8	0.8	0.9	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.9	0.9	0.8
	Exhalation	160 l/min	1.3	1.3	1.4	1.4	1.4	1.4	1.4	1.3	1.3	1.3	1.3	1.3	1.3	1.4	1.4

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



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Clause 7.17 Clogging

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

Test Requirement	Results	Comment																			
<u>Clause 7.17.2 Breathing resistance</u> <u>Valved particle filtering half masks:</u> 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. <u>Valveless particle filtering half masks:</u> After clogging the inhalation and exhalation resistances shall not exceed: FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95L/min continuous flow	Optional for single shift device only	N.A.																			
<u>Clause 7.17.3 Penetration of filter material</u> All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements. <table border="1"> <thead> <tr> <th rowspan="3">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> </thead> <tbody> <tr> <td></td><td>max.</td><td>max.</td></tr> <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	Optional for single shift device only	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 demountable parts	N.A

Test	Uncertainty
Total inward leakage	2.98%
Penetration of filter material	1.00%
Flammability	1.00%
Carbon dioxide content of the inhalation air	0.93%
Breathing resistance	1.90%

This test standard is not within the accredited scope in SGS Shanghai testing centre, it is carried out by external laboratory accredited by CNAS (China National Accreditation Service for Conformity Assessment) L10118.



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Sample Photo



End of Report



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