



FICHA TÉCNICA

de producto

Ref. 3600B

Mascarilla de Protección FFP2 NR

Mascarilla Protección Personal y Máxima filtración, fabricada en cuatro capas de tela no tejida y tejido filtrante, con tira nasal moldeable en acero plastificado y dos gomas de ajuste suaves (Salva orejas incluido en cada bolsita Individualizada)

Características

- **Modelo Fabricante: 0117FFP2 NR**
- **Materia Prima:**
 - 1ª Capa - Tela No Tejida 50grs
 - 2ª Capa - Spunlace 50grs
 - 3ª Capa - Melt-Blown 50grs
 - 4ª Capa - Tela No Tejida 50grs
- Clip Nasal: 8,2 cm
- Elásticos de Ajuste 19 cm
- UN SOLO USO
- Producto Hipoalergénico
- Producto Libre de Látex, Grafeno, Ftalatos y Fibra de Vidrio, no produce irritaciones.



Colores Disponibles



Normativas

- Producto Conforme Reglamento **UE 2016/425** relativo a los equipos de protección personal - **EPI Cat. III**
- Producto Fabricado bajo los estándares de la Norma **ISO 13485:2016**.
- Producto Fabricado bajo las exigencias de la Norma **EN 149:2001+A1:2009**
- Ensayo Mascarilla N°: 2023(D) - 036
 - **Clasificación Mascarilla:** FFP2 NR
 - **Categoría EPI:** Cat. III
 - **Certificado CE N°:** CE-PC-200320-067-01-9F

Instrucciones de uso

- Comprobar antes del uso es estado del embalaje y la fecha de caducidad del mismo.
- Lávese las manos antes de utilizar el producto y asegúrese de tocar únicamente la goma de las mascarilla
- Colocar la Mascarilla sobre la nariz/boca y pasar las gomas por detrás de las orejas o usando el salva orejas.
- Ajustar adecuadamente la tira nasal y zona del mentón.
- Evitar en todo momento tocar o manipular la mascarilla durante su uso, que no debe exceder de un tiempo máximo de 4 horas

Almacenaje

- Almacenar en un lugar seco, limpio y a temperaturas oscilantes entre 5°C y 35°C.
- No exponer de manera directa a la luz solar
- Caducidad - 3 años desde la fecha de Fabricación



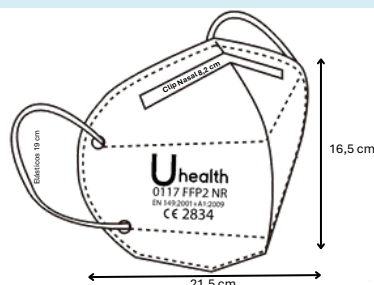
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Especificaciones Técnicas y Fotos Técnicas del Embalaje



CE 2834



Información Logística

- Etiquetado conforme a las diferentes normas de aplicación en términos de descripciones y pictogramas.
- Presentación:
 - Sobre higiénico individualizado
 - Estuche Dispensador de 50 unidades
 - 12 Dispensadores por embalaje
 - Embalaje master (Caja) con un total de 600 unidades
 - Indicaciones de Referencia, Descripción de Producto, Lote, Fabricación y Caducidad en embalaje interior y caja exterior.
 - Medidas de la Caja: 44x38,5x42 cm
 - Peso de la Caja: 10,00 Kg
 - Euro Palets de 25 Cajas
 - 5 Filas por Palet - 5 Cajas por Fila.
- Códigos informativos de los embalajes:

Referencia	Color	EAN-13 Dispensador	GTIN-14 Caja Exterior
3600B	Blanco	6 974100 42118 5	(01)169 741004 2118 2

Declaración Técnica

Modelo 0117 FF2NR

Ref. 3600B

Nosotros, Uhealth Medical (Beijing) Protective Products Co., Ltd. declaramos bajo nuestra responsabilidad que la mascarilla comercializada por la comercial Luhepa Internacional, S.L. (B01985480), corresponde a nuestro modelo y especificaciones que siguen:

	Composición						
	Capas				Clip Nasal	Grosor Nasal	Acolchado Nariz
	1	2	3	4			
Material	Non-Woven	Melt-Blown	Non-Woven	Spunlace	PP+Acero		N
Peso	50 gr	50 gr	50 gr	50 gr			
Clasificación	FFP2						
Medida	Talla Adulto - Elástico 19 cm				8,2 cm	5 mm	N

Detalles del Embalaje



Bolsa Higiénica Individualizada



Dispensador de 50 bolsitas



Caja de 600 unidades (12x50)

For and on behalf of
Uhealth Medical (Beijing) Protective Products Co., Ltd.
北京联合康力医疗防护用品有限公司


Authorized Signature(s)

Cybil Zhai / General Manager

En Beijing/China a 01 de Enero de 2025

Declaración Técnica

Modelo 0117 FF2NR

Ref. 3600B

Especificaciones:

Talla	Clip Nasal	Goma	Color	Materiales	PFE
Adulto	8,2 cm	19 cm	Blanca	50grs+50grs+50grs+50grs	>=95%
Packing: 1 unidad por bolsa - 50 unidades por dispensador - 12 dispensadores por caja. Total 600 unidades por Caja					

Certificaciones/ Organismo Notificador: CCQS Certifications Services Limited
Block 1 Blanchardstown corporate park, Ballycoolin Road, Blanchardstown, Dublin 15, D15 AKK1, Irlanda

Test Report: 2023 (D) - 036 (Documento Adjunto)

Normativa: EN149:2001+A1:2009

Módulo C2 del Certificado: CE-PC-200320-067-FPC-F (Documento Adjunto)

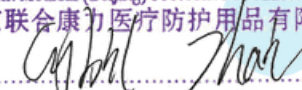
Módulo B del Certificado: CE-PC-200320-067-01-9F (Documento Adjunto)

Declaración de Conformidad - Anexo IX del Reglamento (EU) 2016/425 (Documento Adjunto)

Imágenes Mascarilla:



For and on behalf of
Uhealth Medical (Beijing) Protective Products Co., Ltd.
北京联合康力医疗防护用品有限公司


Authorized Signature(s)

Cybil Zhai / General Manager

En Beijing/China a 01 de Enero de 2025

EU Declaración de Conformidad

Anexo IX - Reglamento (EU) 2016/425

1.- Esta EU Declaración de Conformidad es referente a los siguientes productos:

Nombre del Producto: Mascarilla de Protección FFP2

Modelo: 0117

Clasificación: FFP2 NR

Número de Lote: YYYYMMDD

2.- Información relativa al fabricante - Nombre y Dirección:

Nombre: Uhealth Medical (Beijing) Protective Products Co., Ltd.

Dirección: Room 703, No.19 Nuilding, Mo. 16, Mazhu Road, Zhangziying Town, Daixing District, Beijing, China

3.- Esta Declaración de Conformidad es emitida únicamente bajo la única responsabilidad del Fabricante

4.- Información Detallada del Equipo de Protección Individual (EPI) para su correcta identificación y trazabilidad

0117 - Mascarilla de Protección FFP2 Sin Válvula, Color Blanco - Gomas a Oreja

(En el Mercado Español Modelo 0117 = Ref. 3600B)



El artículo identificado en el punto 4 es conforme al Legislación referente al **Reglamento (EU) 2016/425**.

Referencias a las normas armonizadas pertinentes utilizadas, incluida la fecha de la norma, o referencias a otras especificaciones técnicas, incluida la fecha de las especificaciones, en relación con las cuales se declara la conformidad con: **EN 149:2001+A1:2009**

CCQS Certification Services Limited. (NB 2834), realizó el Examen Tipo EU (Modulo B) y emitió el consecuente Certificado con número:

CE-PC-200320-067-01-9F

Categoría del Producto:

Este producto es de Categoría III y está sujeto a un estricto control de producción interno acorde al Módulo C2(CE-PC-200320-067-FPC-F), además de controles supervisados en intervalos aleatorios bajo la vigilancia de CCQS Certification Services Limited. (NB2834)

En Beijing a 01 de Enero de 2025.

For and on behalf of
Uhealth Medical (Beijing) Protective Products Co., Ltd.
北京联合康力医疗防护用品有限公司

[Signature]
Authorized Signature(s)

Firma y Sello de la Empresa:



Module B EU Type-Examination Certificate

For the requirements of Personal Protective Equipment
Regulation (EU) 2016/425

Certificate No.: CE-PC-200320-067-01-9F

Certificate holder: **Uhealth Medical (Beijing) Protective Products Co., Ltd.**
Room 703, No.19 Building, No.16, Mazhu Road,
Zhangziying Town, Daxing District, Beijing, China

Product: **Particle filtering half mask**
The listed models are Category III PPE
Detailed product description listed in the Annex

Model(s): 0117

Standard(s): EN 149:2001+A1:2009 Respiratory protective devices -
Filtering half masks to protect against particles - Requirements,
testing, marking

Issue date: 2020-05-05

Revision date: 2024-06-13

Expiry date: 2025-05-04

The product(s) on this certificate and the Technical File have been assessed and found to be in conformance with the applicable Essential Health and Safety Requirements in Annex II of the Personal Protective Equipment Regulation (EU) 2016/425.

Any changes to the design, manufacturing location or manufacture of the PPE product certified here must be advised to CCQS Certification Services Limited for review.

CE marking shall not be applied until the requirements of all the Personal Protective Equipment Regulation (EU) 2016/425 and relevant EN Harmonised standards and/or Technical specifications have been met.

If the certified product is Category III then this certificate is only valid if used in conjunction with Conformity Assessment against Module C2 or Module D.

This certificate remains the property of CCQS and maybe withdrawn at any time if it is considered that the equipment is no longer in conformity with the requirements of the Personal Protective Equipment Regulation (EU) 2016/425.



Approved by Ireland
Government
as a Notified Body
for CE Marking No.2834



CCQS Certification Services Limited

Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown,
Dublin15, D15 AKK1, Ireland

Tel: +00 353 1 588 6920

Website: www.ccqs.co.uk

E-mail: verify@ccqs.ie

If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.



Module B EU Type-Examination Certificate Annex

For the requirements of Personal Protective Equipment
Regulation (EU) 2016/425

Certificate No.: CE-PC-200320-067-01-9F

Applicable standards and specification

EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

Model reference	Product description
0117	Valveless folding filtering half mask fitted with ear loops and head harness retaining clip, internal metal nose clip Mask body colour: White or Black variant Classification: FFP2 NR Test report No.: 2020(F)-0350

Certificate Revision	Revision date	Revision details
A	2020-05-05	Initial issue
B	2020-07-15	Certificate validity extended to one year
C	2020-08-31	Change the mask body design
D	2021-06-21	Extension to certificate validity following Module C2 assessment, editorial changes to certified listing to include colour description, change of certificate holder's address
E	2022-01-25	Addition of mask body colour variant Black
F	2024-06-13	Change of certificate holder's address

This schedule has no validity without the accompanying certificate.

This schedule and the accompanying certificate remain the property of CCQS and may be withdrawn or revised at any time if CCQS considers that the equipment is no longer in conformity with the requirements of the applicable standard(s) and the Regulation.



CCQS Certification Services Limited

Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown,
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E-mail: verify@ccqs.ie

If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.





Certificate of Module C2 Production monitoring for equipment within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III

FPC Certificate No.: CE-PC-200320-067-FPC-F

Certificate holder:	Uhealth Medical (Beijing) Protective Products Co., Ltd. Room 703, No.19 Building, No.16, Mazhu Road, Zhangziying Town, Daxing District, Beijing, China
Manufacturing location:	Room 12A, 1st Floor, Jingsheng South Second Street, Tongzhou District, Beijing, China
The scope of the certification for:	The manufacture of respiratory protective devices See annex for articles covered by this certificate
Valid from:	2020-05-05
Revision date:	2024-06-13
To:	2026-05-04

CCQS Certification Services Limited in its role as a Notified Body for Personal Protective Equipment Regulation (EU) 2016/425, is monitoring that the manufacturer is producing PPE in conformity with the type described in the EU Type-Examination certificate and associated technical file and which satisfies the Essential Health and Safety Requirements of the Regulation.

The equipment covered by this certificate is listed in the accompanying schedule. This certificate is not complete and has no validity without the accompanying schedule and revision index.

The manufacturer is hereby authorized to affix our Notified Body number, 2834, to each item of PPE mentioned in the schedule which accompanies this certificate whilst this certificate remains valid.

This certificate and the accompanying schedule remain the property of CCQS and maybe withdrawn or revised at any time if CCQS considers that the equipment is no longer in conformity with the requirements of the Regulation.



Approved by Ireland
Government
as a Notified Body
for CE Marking No.2834



CCQS Certification Services Limited

Block 1 Blanchardstown Corporate Park, Ballycoolin Road, Blanchardstown,
Dublin15, D15 AKK1, Ireland

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If in any doubt about the integrity of this certificate, please contact CCQS by email to verify.



Schedule of Module C2 Production monitoring for equipment within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III

Schedule to CCQS FPC Certificate No.: CE-PC-200320-067-FPC-F

Product reference and description		Reference standard
Particle filtering half mask	Model: 0117	EN 149:2001+A1:2009

Certificate Revision	Revision date	Revision details
A	2020-05-05	Initial issue
B	2020-07-15	Certificate validity extended to one year
C	2021-06-21	Extension to certificate validity following Module C2 assessment and change the certificate holder's address
D	2022-05-14	Re-issued following successful Year 2 Module C2 assessment
E	2023-05-03	Re-issued following successful Year 3 Module C2 assessment
F	2024-06-13	Re-issued following Module C2 assessment and change the certificate holder's address and manufacturing location

This schedule has no validity without the accompanying certificate.

This schedule and the accompanying certificate remain the property of CCQS and may be withdrawn or revised at any time if CCQS considers that the equipment is no longer in conformity with the requirements of the applicable standard(s) and the Regulation.



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(Fm 220-015, Rev4,
31.10.22)



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Testing Center for Personal Protective Equipment,
Institute of Urban Safety and Environmental Science,
Beijing Academy of Science and Technology

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Email: lbzjbj@163.com http://lbzjbj.bmilp.com

The Testing Center is accredited for compliance with ISO/IEC 17025.

The results of tests, calibrations and/or measurements included in this document are traceable to Chinese/national standards.

CNAS is a signatory to the ILAC mutual recognition arrangement for the mutual recognition of the equivalence of testing, calibration and inspection reports.

TEST REPORT

Particulate respirator-half facepiece

EN 149: 2001 +A1: 2009 Respiratory protective devices — Filtering half masks to protect against particles —
Requirements, testing, marking

Product: Particle filtering half mask

Report No: 2023 (D) – 036

Client: CCQS

Model (s): 0117

Date of sample received: 2023.04.11

Date(s) of tests: 2023.04.12 - 2023.04.20

DESCRIPTION OF SAMPLES

General Information

Classification

Main Components

Manufacturer

Uhealth Medical (Beijing) Protective Products Co., Ltd.

Manufacturer Address

1st Floor, Building 2, No. 15, Jingsheng South Fourth Street, Tongzhou District, Beijing, China.

Signed:

Issued: 2023.04.23

陈倬为 Chen Zhuowei

Authorized Signatory, Lab Director

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北京市科学技术研究院城市安全与环境科学研究所劳动保护用品检验中心

检验检测专用章
(劳动保护用品检验中心)

11010210022188

Conditions:

The test results presented in this report relate to the samples tested only.

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The authenticity of this test report and its contents can be verified by contacting the laboratory.



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Test Results

7.8 Finish of parts

Pass¹

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.

Note1: No sharp edges or burrs.

7.9.1 Total inward leakage

/ ²

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

Note2: FFP2 respirator. Test results are shown in Annex A Table 7.9.1-A&B.

Testing requested was insufficient completely to verify compliance with the clause. Refer to the Annex A section for more information.

7.9.2 Penetration of filter material

/ ³

The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

Sodium chloride test 95 l/min

Paraffin oil test 95 l/min

FFP1 ≤20%

≤20%

FFP2 ≤6%

≤6%

FFP3 ≤1%

≤1%

Note3: FFP2 respirator. Test results are shown in Annex A Table 7.9.2.

Testing requested was insufficient completely to verify compliance with the clause. Refer to the Annex A section for more information.

7.11 Flammability

Pass⁴

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.

Note4: Test results are shown in Annex A Table 7.11.

Testing requested was insufficient completely to verify compliance with the clause. Refer to the Annex A section for more information.

7.16 Breathing resistance

/ ⁵

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

Note5: FFP2 respirator. Test results are shown in Annex A Table 7.16.

Testing requested was insufficient completely to verify compliance with the clause. Refer to the Annex A section for more information.

End of Test Results

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Annex A: Summarization of Test Data**Able 7.9.1-A Inward leakage test data**

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

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Gong	1	A.R.	1.72	2.29	2.96	2.35	1.78	2.2
Yu	2	A.R.	1.03	1.56	2.09	1.62	1.05	1.5
Yuan	3	A.R.	2.59	3.05	3.28	3.09	2.67	2.9
Xu	4	A.R.	1.62	2.38	2.97	1.94	1.68	2.1
Gao	5	A.R.	2.29	2.67	3.28	2.77	2.41	2.7
All <u>25</u> individual exercise results were not greater than <u>11</u> % All <u>5</u> individual wearer arithmetic means were not greater than <u>8</u> %							/	

Table 7.9.1-B Facial dimension

Subject	Face length	Face Width	Face Depth	Mouth Width
Gao	120	138	113	62
Gong	122	140	115	65
Yu	119	160	139	55
Yuan	112	132	115	61
Xu	110	130	118	60
Zhao	114	117	108	57
Zhang	112	123	113	55
Liu	103	130	100	50
Zhi	118	139	130	63
Fang	115	129	120	50
Chen	116	150	132	56
Lv	110	121	110	53

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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.	Penetration (%) after 3 minutes	Assessment
Sodium chloride test	As received	7	0.092	/
		8	0.141	
		9	0.080	
Paraffin oil test	As received	10	0.193	
		11	0.324	
		12	0.181	
		13	0.171	
		14	0.229	
		15	0.261	
		16	0.136	
		17	0.221	
		18	0.293	
		19	0.357	
	Mechanical strength + Temperature conditioned	20	0.978	
		21	1.14	
		22	0.909	
Flow conditioning: Single filter: 95.0 L/min				

Table 7.11 Flammability

Test specification: EN 149: 2001+A1: 2009 Clause 8.6

Condition	Sample No.	Result	Assessment
As received	23	Didn't burn	Pass
	24	Didn't burn	
Temperature conditioned	25	Didn't burn	
	26	Didn't burn	

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Table 7.16 Breathing resistance (mbar)

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

As received	Flow rate		36					37					38				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.5	0.5	0.6	0.5	0.5	0.5	0.6	0.6	0.5	0.5	0.5	0.5	0.6	0.5	0.5
Temperature conditioned	Inhalation	95 l/min	1.7	1.8	1.9	1.8	1.7	1.7	1.8	1.8	1.7	1.7	1.7	1.8	1.9	1.8	1.7
		160 l/min	2.7	2.8	2.8	2.7	2.7	2.7	2.7	2.8	2.7	2.7	2.7	2.7	2.8	2.8	2.7
	Exhalation	160 l/min	2.7	2.8	2.8	2.7	2.7	2.7	2.7	2.8	2.7	2.7	2.7	2.7	2.8	2.8	2.7
Temperature conditioned	Flow rate		39					40					41				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.4	0.5	0.5	0.5	0.5	0.4	0.5	0.6	0.5	0.5	0.4	0.5	0.6	0.5	0.5
Temperature conditioned	Inhalation	95 l/min	1.6	1.7	1.7	1.7	1.7	1.6	1.7	1.7	1.6	1.7	1.7	1.8	1.8	1.7	1.7
		160 l/min	2.6	2.7	2.7	2.7	2.6	2.6	2.7	2.7	2.6	2.6	2.7	2.8	2.8	2.7	2.7
Assessment	/																

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

Test	Uncertainty
Total inward leakage	4.1%
Penetration of filter material	1.1%
Flammability	5.0%
Breathing resistance	1.8%

End of Annex A

ANNEX B PHOTOS OF SAMPLES



End of Annex B

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