Luhepa
INTERNACIONAL, S.L.
Member of
Uhealth Medical Group

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 Nº: 2023(D) - 036
  - **Clasificación Mascarilla**: FFP2 NR
  - **Categoría EPI:** Cat. III
  - **Certificado CE Nº**: 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 de utilizar el producto y asegúrese de tocas 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

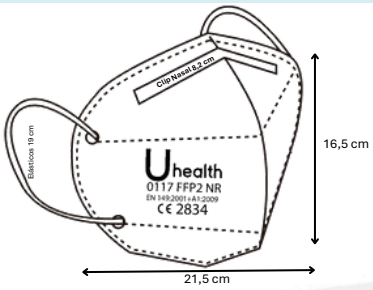
- Almacenar en un lugar seco, limpio y a temperaturas oscilantes entre 5ºC y 35ºC.
- No exponer de manera directa a la luz solar
- Caducidad - 3 años desde la fecha de Fabricación

Luhepa
INTERNACIONAL, S.L.
Member of
Uhealth Medical Group

FICHA TÉCNICA
de producto

Ref. 3600B

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

Luhepa Internacional, S.L.

Camino de la Torre, Nave 2 - CP: 45512 Portillo de Toledo (Toledo) - España
CIF: B-01985480 // Licencia Sanitaria Importador AEMPS: 8468-PS // Registro Sanitario Alimentario: 39.006740/TO
SRN Representante UE Productos Sanitarios: ES-AR-000043668 // SRN Importador Productos Sanitarios UE: ES-IM-000042791
Tlf: +34 925 678 656 - Mail: luhepa@luhepa.es - www.luhepa.es

Uhealth Medical (Beijing) Protective Products Co., LTD

Room 703, No.19 Nuilding, Mo. 16, Mazhu Road, Zhangziying Town, Daixing District, Beijing, China
T. 0086-87927887 Email: sales@uhealthbj.com Web: www.uhealthbj.com

Declaración Técninca

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			
Clasificacion	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

Uhealth Medical (Beijing) Protective Products Co., LTD

Room 703, No.19 Nuilding, Mo. 16, Mazhu Road, Zhangziying Town, Daixing District, Beijing, China
T. 0086-87927887 Email: sales@uhealthbj.com Web: www.uhealthbj.com

Declaración Técninca

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

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.

CE

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

ISO 17065 INAB ACCREDITED PRODUCT CERTIFICATION DETAILED IN SCOPE REG. NO.6031

Approved by:

Owen Bian, Director

CCQS Ireland Certification

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 Ireland Certification

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

CE

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.

CE

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

ISO 17065 IVNAB ACCREDITED PRODUCT CERTIFICATION DETAILED IN SCOPE REG NO.6028

Approved by:

CCQS Ireland Certification

Owen Bian, Director

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.

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.

CCQS Ireland Certification

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

CE

中国认可
国际互认
检测
TESTING
CNAS L1499

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

No.55 Taoranting Street, Xicheng District, Beijing, China.
Phone: +86 10 63520770 +86 10 83530311
Fax: +86 10 63520770
Email: lbzjbj@163.com http://lbzjbj.bmilp.com

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**
	FFP2 NR	White folding mask
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:

陈倬为 Chen Zhuowei
Authorized Signatory, Lab Director

Issued: 2023.04.23

Conditions:

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

This report may be reproduced and distributed to your clients, provided that it is reproduced and distributed in full.

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

Test Results

7.8 Finish of parts **Pass[1]**

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 **Pass[4]**

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 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

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 25 individual exercise results were not greater than 11 % All 5 individual wearer arithmetic means were not greater than 8 %							/	

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

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	

Table 7.16 Breathing resistance (mbar)

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

			36					37					38				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
As received	Inhalation	30 l/min	0.5	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
		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
	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
			39					40					41				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
Temperature conditioned	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
		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
	Exhalation	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