GisMédical®
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FICHE TECHNIQUE

Référence

FFPBNZ

MASQUE FFP2

Blanc | Élastiques



CARACTÉRISTIQUES – DATI PRINCIPALI DEL PRODOTTO

MATERIALE	TNT 100% Latex Free
MARCA	SKYPRO
COLORE	BIANCO
MODELLO	GL001A
PRODUTTORE	SPRO Medical Products (Xiamen) Co., Ltd
CND	T0399
RDM	2826960
NOTIFIED BODY	2834 CCQS Ireland Certification
DPI	III CATEGORIA
DATA DI PRODUZIONE	06/2025
DATA DI SCADENZA	06/2028

UTILIZZO DEL PRODOTTO E CAMPO DI APPLICAZIONE

Le maschere FFP2 sono una categoria di maschere facciali filtranti che offrono un alto livello di protezione respiratoria. Sono progettate per filtrare particelle sottili, aerosol e sostanze nocive presenti nell'aria, garantendo una maggiore protezione rispetto alle maschere chirurgiche.

Le principali caratteristiche e usi delle maschere FFP2 includono:

- Protezione da particelle sottili: Le maschere FFP2 sono progettate per filtrare almeno il 95% delle particelle in sospensione nell'aria, inclusi aerosol, polveri sottili, fumi e nebbie.
- Ambienti ad alto rischio: Le maschere FFP2 sono spesso utilizzate in ambienti in cui è presente un rischio elevato di esposizione a sostanze pericolose come agenti patogeni, polveri tossiche, amianto, fumi di saldatura e altre particelle fini nocive.
- Settori industriali: Sono ampiamente utilizzate nell'industria chimica, nelle lavorazioni di metalli, nell'edilizia, nell'industria farmaceutica e in altre situazioni lavorative dove la salute dei lavoratori può essere minacciata da sostanze dannose in sospensione nell'aria.
- Procedure mediche avanzate: In alcune situazioni mediche, come l'esecuzione di procedure invasive o trattamenti su pazienti con malattie altamente contagiose, le maschere FFP2 possono essere impiegate per proteggere gli operatori sanitari.
- Protezione individuale: Le persone con sistemi immunitari compromessi o condizioni mediche che le rendono particolarmente suscettibili alle infezioni potrebbero utilizzare maschere FFP2 per una protezione aggiuntiva quando sono esposte a ambienti con potenziali patogeni.
- Emergenze ambientali: In caso di emergenze ambientali, come incendi, eruzioni vulcaniche o altre situazioni in cui l'aria è contaminata da sostanze tossiche, le maschere FFP2 possono essere utilizzate per aiutare le persone a respirare in modo sicuro.
- UTILIZZATORI: Ideale per tutti gli operatori sanitari (Infermieri, medici, Operatori veterinari, (SIAV), tecnici di laboratorio, biologi, chimici, fisici ecc.), Operatori addetti alla vigilanza, dei cantieri/aziende

CARATTERISTICHE SPECIFICHE DEL PRODOTTO

- Facciale filtrante FFP2 senza valvola che può essere impiegato anche in reparti sanitari di media e alta intensità di cura.
- dotate di cerotto ipoallergenico sotto il ferretto stringinaso
- senza valvola di espirazione
- materiale di fabbricazione privo di lattice
- di forma pieghevole, non rigida a due lembi
- grande superficie filtrante
- no utilizzo della colla - no formaldeide
- stringinaso facilmente adattabile alla linea del viso e integrato nel materiale filtrante
- garantisce una buona visibilità; Il campo visivo non è limitato verso il basso
- imbustate singolarmente in confezione singola sigillata (con presenza della marcatura di legge) in modo da permettere l'estrazione del singolo dispositivo per volta, nel rispetto delle norme di igiene
- consente l'utilizzo contemporaneo di altri DPI (visiera, occhiali ecc..)
- Provvista di elastici doppi retronucali, che sono fissati al facciale filtrante in modo da non creare fastidio all'utilizzatore; la loro tensione assicura perfetta tenuta e al contempo mantiene un alto livello di confort; durante la tensione degli elastici non si verificano rotture

- mascherine monouso non riutilizzabile, durevole per tutto il turno di lavoro
- prodotto biocompatibile
- realizzata in materiale resistente ed anallergico che non crea irritazione cutanea agli utilizzatori
- design che permette una perfetta aderenza e adattabilità al viso
- efficienza di filtraggio: velocità di filtrazione del particolato non oleoso >= 95%
- alto livello di confortevolezza
- taglia unica - ergonomica, adatta a tutti i tipi di viso
- protegge dalle particelle dannose per la salute allo stato solido;
- idonee a coprire il naso, la bocca ed il mento.
- mascherine adatto all'uso in ambito sanitario;
- ipoallergenica ed inodore, con bassa resistenza respiratoria;
- Normative di riferimento EN 149:2001+A1:2009; EN 14683 tipo IIR
- alta efficienza
- completa di resistenti elastici nucali -allaccio nucale non auricolare
- con certificazione CE rilasciata da Ente Certificatore con marcatura CE apposta su ogni DPI
- Provvisto di sistema di identificazione della classe di protezione individuabile immediatamente

CERTIFICAZIONI E TEST REPORT

CERTIFICATO CE	**Modulo B: CE rilasciato il 26/03/2024 da Notified Body n. 2834 CCQS Ireland Certification** **Certificato n. CE-PC-240131-066-04-9B conforme alla direttiva europea 2016/425**
	Modulo D: CE rilasciato il 23/04/2021 da Notified Body no. 2834 CCQS Ireland Certification **Certificato n. CE-PC-210301-080-FPC-H** **conforme alla direttiva europea 2016/425**
DICHIARAZIONE DI CONFORMITA' SECONDO LA NORMATIVA EUROPEA EU 425/2016	**A CURA DEL PRODUTTORE**
TEST DI LABORATORIO CHE ATTESTA LA CONFORMITA' ALLA NORMATIVA EUROPEA EN 149:2001 + A1:2009	**eseguito da China Academy of Safety Science and Technology** **n. test: WLH0017-2025**

CARATTERISTICHE QUALITATIVE

Apparecchio di Protezione individuale delle Vie Respiratorie (APVR) – FFP2 s/v NR con elastci nucali

- certificato CE secondo il Regolamento (UE) 2016/425 quale Dispositivo di Protezione individuale di III categoria, per le categorie di rischio di tipo chimico ("sostanze e miscele pericolose per la salute") e biologico ("agenti biologici nocivi") a cui possono essere esposti i lavoratori del settore ATECO 2019 Q 86 SANITA', in ogni ambito delle attività di assistenza al paziente compresa la diagnostica per immagini; classificata in relazione alla norma armonizzata UNI EN 149:2009 quale semimaschera filtrante FFP2 Non Riutilizzabili (NR);

Caratteristiche qualitative:

I DPI rispondono ai "Requisiti essenziali di salute e di sicurezza" (RES) di cui dell'Allegato II del Regolamento (UE) 2016/425.

È oggettivamente e documentalmente comprovato che:

- i dispositivi non presentano rischi intrinseci per gli utilizzatori, in quanto i materiali di cui sono fatti, compresi i loro eventuali prodotti di decomposizione, non determinano effetti negativi sulla salute o sulla sicurezza degli utilizzatori; nello specifico è comprovata l'assenza di sostanze allergizzanti quali il lattice e/o il nichel, ovvero l'impossibilità che l'utilizzatore possa entrarvi in contatto (es: elemento integrato nel materiale filtrante anallergico) durante l'impiego. [punto 1.2 Allegato II del Regolamento (UE) 2016/425];
- i sistemi adottati per l'adeguamento del DPI alla morfologia dell'utilizzatore hanno un funzionamento rapido ed agevole, garantendo al contempo la leggerezza, la solidità e l'efficacia del dispositivo, eliminando i possibili errori di posizionamento correlabili a regolazioni soggettive o allentamenti accidentali dopo la regolazione, questo nelle condizioni prevedibili di impiego sia durante la fase di posizionamento che durante l'uso, tenuto conto che detti DPI in determinati ambiti devono potersi indossare e rimuovere rapidamente [punti 1.3, 2.1, 2.7 Allegato II del Regolamento (UE) 2016/425];
- sono stati adottati accorgimenti che impediscono/riducono la fuoriuscita dell'espirato verso gli occhi (tra il bordo superiore del DPI e il viso verso gli occhi) in modo da ridurre l'effetto appannamento dei DPI a protezione degli occhi e/o del viso (occhiali/visiere) per permettere all'utilizzatore lo svolgimento della normale attività durante l'uso combinato dell'APVR filtrante e dei DPI di protezione degli occhi/viso, spesso necessariamente utilizzati in combinazione [punto 1.1.1 Allegato II del Regolamento (UE) 2016/425];
- è stata ridotta al minimo la resistenza respiratoria in inspirazione [punto 2.3 Allegato II del Regolamento (UE) 2016/425];
- stante la caratteristica del filtro P2, è garantita la massima protezione respiratoria e per contatto epidermico, della parte di viso coperto, dalle sostanze e dalle miscele pericolose e dagli agenti biologici a cui possono essere esposti i lavoratori del settore ATECO 2019 Q 86 SANITA', in ogni ambito delle attività di assistenza al paziente compresa la diagnostica per immagini [punto 3.10 Allegato II del Regolamento (UE) 2016/425]
- La classe di protezione è riportata sui singoli APVR filtranti monouso. La marcatura CE è apposta su ogni dispositivo e sull'imballaggio in modo visibile, leggibile e indelebile [articolo 17 comma 1 del Regolamento (UE) 2016/425]

N.B. SERVIZIO DI ASSISTENZA TECNICA E POST VENDITA - Garantita l'assistenza telefonica da parte di uno specialista del prodotto, nella seguente fascia giornaliera e oraria: dal lunedì al venerdì dalle ore 09:00 alle 18:00;

CONFEZIONAMENTO

Confezionamento (1° Livello) Le istruzioni all'uso sono riportate sulla singola confezione, e sono facilmente comprensibili e intuibili grazie alla presenza di presenza di rappresentazioni grafiche	1 (una) mascherina in una bustina sigillata di plastica
Confezionamento (2° Livello)	50 (cinquanta) bustine sigillate di plastica (50 mascherine) in una scatolina di cartone
Confezionamento (3° Livello)	20 (venti) scatoline di cartone (1000 mascherine) in uno scatolone
Dimensioni e Peso del Catone	11,1 kgs / 87*40*33 cm

- **Ogni confezione riporta tutte le informazioni previste dalla normativa vigente e quelle necessarie a garantire una utilizzazione corretta e sicura del dispositivo. Gli imballaggi esterni sono di materiale resistente, tali da poter essere impilati e riportano il tipo, la quantità, la scadenza e il codice del prodotto. Imballo e confezioni sono "a perdere".**
- **Ogni singola scatola ed ogni singola busta esterna riportano i dati previsti dalla Direttiva 2007/46/CE, D.Lgs. 25 gennaio 2010, n. 37. Sulla confezione è riportata la destinazione d'uso.**
- **I dispositivi sono contenuti in confezioni che ne garantiscano la corretta conservazione ed il facile immagazzinamento per sovrapposizione. Le singole confezioni sono imballate in scatoloni robusti e a tenuta di polvere. Il materiale di confezionamento è resistente e tale da garantire la corretta conservazione del prodotto.**
- **Tutte le singole confezioni e imballi di spedizione sono provvisti di etichette indelebili che riportano tutte le iscrizioni previste dalla normativa vigente.**
- **Sulla confezione sono riportate, in diverse lingue, tutte le informazioni previste dalla normativa vigente e necessarie per garantire una utilizzazione corretta e sicura del prodotto.**

EU Declaration of Conformity
Annex IX PPE Regulation (EU) 2016/425

This EU Declaration of conformity refers to the following products:

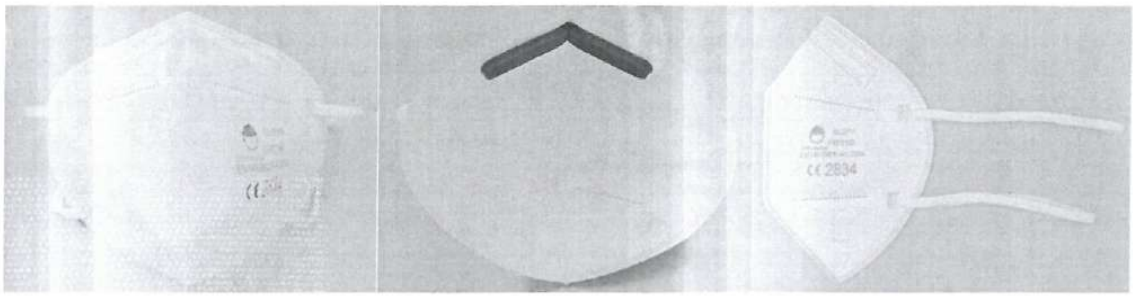
Product name	Particle filtering half mask
Model(s)	GL001A
Classification:	FFP2 NR
Batch No.:	SK24F01

The Manufacturer's name and address is as follows:

Name:	SPRO Medical Products (Xiamen) Co., Ltd.
Address:	2nd Floor of No.9 Fangqian Building, No.358, Xilin Road, Xiangping Street, Tong'an District, Xiamen City, Fujian Province, China

This Declaration of Conformity is issued under the sole responsibility of the Manufacturer.
Detailed description of the PPE to allow traceability/identification of the PPE.

White folding mask without valve



The product identified above is in conformance with **Personal Protective Equipment Regulation (EU) 2016/425** and the Harmonised standard **EN 149:2001+A1:2009**.

CCQS Certification Services Limited. (NB 2834) performed the EU Type-Examination (Module B) and issued the Type Examination Certificate as follows:

No.	EU Type-Examination (Module B) Certificate Number
1	CE-PC-240131-066-04-9A

Product Category:
☐ This product is Category III and is subject to **Module D Conformity to type based on quality assurance of the production process** and is under the surveillance of Notified Body CCQS Certification Services Limited (NB2834).

Name of signatory: Huimei Yuan
Position in company: Quality manager
Signature:

质检专用章

Date: 2025.06.18

Module B EU Type-Examination Certificate

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

Certificate No.: CE-PC-240131-066-04-9B

Certificate holder:	**SPRO Medical Products (Xiamen) Co., Ltd.** 2nd Floor of No.9 Fangqian Building, No.358, Xilin Road, Xiangping Street, Tong'an District, Xiamen City, Fujian Province, China
Product:	**Particle filtering half mask** The listed models are Category III PPE Detailed product description listed in the Annex
Model(s):	GL001A
Standard(s):	EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking
Issue date:	2024-03-26
Revision date:	2025-06-06
Expiry date:	2029-03-25

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

IVNAB ISO 17065 ACCREDITED PRODUCT CERTIFICATION

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-240131-066-04-9B

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
GL001A	Valveless folding filtering half mask with elastic head harness, internal metal nose clip, foam comfort strip Classification: FFP2 NR Mask body colour: White Test report No.: WLH0017-2025

Certificate Revision	Revision date	Revision details
A	2024-03-26	Initial issue
B	2025-06-06	Change of raw material supplier, certificate product listings updated to reflect test reports

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

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

FPC Certificate No.: CE-PC-210301-080-FPC-H

Certificate holder:	**SPRO Medical Products (Xiamen) Co., Ltd.** 2nd Floor of No.9 Fangqian Building, No.358, Xilin Road, Xiangping Street, Tong'an District, Xiamen City, Fujian Province, China
Manufacturing location:	2nd Floor of No.9 Fangqian Building, No.358, Xilin Road, Xiangping Street, Tong'an District, Xiamen City, Fujian Province, China
The scope of the certification for:	**The manufacture of respiratory protective devices** The standards relevant to this Module D certificate are list on the schedule
Valid from:	2021-04-23
Revision date:	2025-03-25
To:	2028-04-03

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

IVNAB ISO 17065 ACCREDITED PRODUCT CERTIFICATION

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.

Schedule of Module D 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-210301-080-FPC-H

Product reference and description	Reference standard
Particle filtering half mask Model(s): GL005, GL005A, GL006, GL006A, GL001, GL001A, GL003, GL003A, GL004, GL004A	EN 149:2001+A1:2009

Certificate Revision	Revision date	Revision details
A	2021-04-23	Initial issue
B	2022-04-04	Initial issue of Module D - Transferred from Module C2 after completion of satisfactory assessment
C	2022-10-14	Change of certificate holder's address
D	2024-02-26	Addition of models GL006, GL006A and change of certificate holder's address
E	2024-03-26	Addition of models GL001, GL001A, GL003, GL003A
F	2024-04-19	Clerical change of validity to complete 3-year cycle based around Module C2/Module D transition
G	2025-01-08	Addition of model GL004, GL004A
H	2025-03-25	Renewal and extension to certificate validity

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, 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.

China academy of safety science and technology (CASST) 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

EN 149:2001+A1:2009
Filtering half masks to protect against particles

Report No:	**WLH0017-2025**
Product:	**Particle Filtering Half Mask**
Model(s):	**GL001A**
Main components:	**Mask body, without exhalation valve**
Date(s) of tests:	**12nd Feb 2025～14th Mar 2025**

Client	**Manufacturer**
SPRO Medical Products (Xiamen) Co., Ltd.	**SPRO Medical Products(Xiamen) Co., Ltd.**
2nd Floor of No.9 Fangqian Building, No.358, Xilin Road, Xiangping Street, Tong'an District, Xiamen City, Fujian Province, China. Client order: / Order(s) received: Feb, 2025	2nd Floor of No.9 Fangqian Building, No.358, Xilin Road, Xiangping Street, Tong'an District, Xiamen City, Fujian Province, China. Contact: Dongmei Zheng (郑冬梅) E-mail: 475971679@qq.com Phone: +86 18259471009

Conditions:

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The results described in this test report refer to the mentioned test samples, exclusively. A copy of the test report, complete or in extracts, is not allowed without any written permission of the CASST.

Any objection should be submitted within 2 weeks from the date of receipt of the report, and it will not be accepted after the deadline.

Specimens will be disposed of 4 weeks from the date of this report, unless otherwise instructed.

Signed: **Issued:** 2025-03-14

张明明/Zhang Mingming, Authorized Signatory

中国安全生产科学研究院/China Academy of Safety Science and Technology
Address: National Safety Engineering Technology Experimental and Research Base, 100501, Beijing, China
Phone: +86 010-65116351/65116350
E-mail: ldfh@chinasafety.ac.cn
Sino-Japanese Cooperative Respiratory Protection Laboratory
Designated Testing Laboratory of the Certification of LA Mark in China

Summary of assessment*

Clause		Assessment
Model		GL001A
7.1	General	Pass
7.3	Visual inspection	Pass
7.4	Packaging	NRq
7.5	Material	Pass
7.6	Cleaning and disinfecting	NRq
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: Sodium chloride	Pass
7.9.2	Penetration of filter material: Paraffin oil	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)	NAp
7.16	Breathing resistance	Pass
7.18	Demountable parts	NAp

Key

	Shading shows the clauses requested.
NRq	The clauses were not requested.
Pass	Requirement satisfied.
Ltd	Testing requested was insufficient completely to verify compliance with the clause. Refer to the "Result details" section for more information.
Fail	Requirement not satisfied. Refer to the "Result details" section for more information.
NAs	Assessment not carried out.
NAp	Requirement not applicable.
NT	Requested but not tested due to early termination following failure.

* Assessment relates only to those specimens which were tested and are the subject of this report.

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Product characteristics

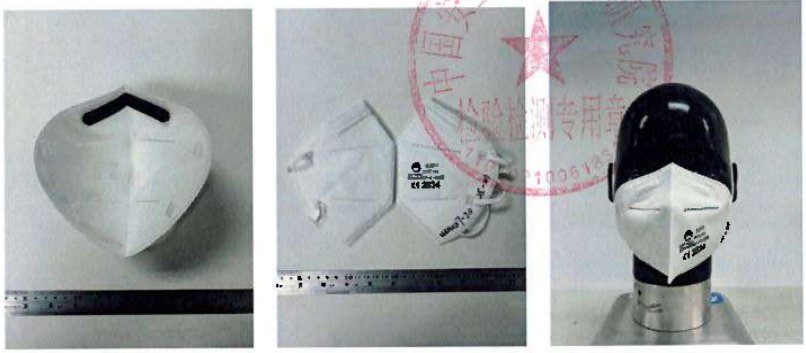
Property	Characteristic
Model	GL001A
Classification claimed	FFP2 NR
Exhalation valve(s)	None

Submission details

Product	Quantity	Date received	Specimen No.
GL001A Particle Filtering Half Mask	60	12nd Feb 2025	WLH0017-2025 -01 to -60

Photographs of the products tested

SPRO Medical Products (Xiamen) Co., Ltd.'s Model GL001A Particle Filtering Half Mask



CASST specimen number WLH0017-2025-01

Procedures

Specimens were selected at random from the submission(s) detailed above.

Testing was performed in accordance with EN 149:2001 incorporating Corrigendum No. 1 (January 2003), and amendment A1 (2009) unless otherwise specified below. Reference should be made to the standard when reading this report.

Unless stated otherwise, specimens were tested in the condition as received.

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Result details

7.1 General **Pass**

In all tests all test samples shall meet the requirements.

7.3 Visual inspection **Pass**

The visual inspection shall also include the marking and the information supplied by the manufacturer.

7.4 Packaging **NRq**

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.

7.5 Material **Pass[1]**

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.

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.

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

Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

Note1: The particle filtering half masks are not collapse. The material from the filter media released by the air flow through the filters are not constitute a hazard or nuisance for the wearer.

7.6 Cleaning and disinfecting **NRq[2]**

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.

Note2: Single shift use only.

7.7 Practical performance **Pass[3]**

The particle filtering half mask shall undergo practical performance tests under realistic conditions.

Note3: No imperfections.

Specimen and subject details:

Specimen	Subject
41	WQ
42	WXY

7.8 Finish of parts **Pass[4]**

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

Note4: No sharp edges or burrs.

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7.9.1 Total inward leakage (%)

Pass[5]

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.

Note5: All of the 50 individual exercise results for total inward leakage are not greater than 11 %. And in addition, All of the 10 individual wearer arithmetic means for the total inward leakage are not greater than 8 %

Subject	Specimen	Cond	Walk	Head side/side	Head up/down	Talk	Walk	Mean
WQ	41	A.R.	2.29	7.79	5.12	3.39	4.31	4.58
WXY	42	A.R.	8.73	7.79	5.12	3.39	4.31	5.87
LZH	43	A.R.	2.27	4.68	4.29	2.14	2.02	3.08
ZL	44	A.R.	3.36	6.32	4.72	4.61	2.80	4.36
ZRK	45	A.R.	2.65	2.58	2.58	2.07	1.88	2.35
KJ	4	T.C.	2.17	4.52	3.75	4.38	3.18	3.60
LJ	5	T.C.	1.18	1.40	0.38	1.70	2.04	1.34
HL	6	T.C.	2.58	3.84	2.59	4.34	3.65	3.40
SQ	7	T.C.	3.74	1.59	2.69	3.38	2.31	2.74
CXC	8	T.C.	4.64	1.46	2.54	2.32	1.56	2.51
Maximum permitted			**11**					**8**

Subject facial dimensions:

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
WQ	127	154	108	55
WXY	131	156	130	49
LZH	116	149	110	49
ZL	113	154	108	54
ZRK	129	146	108	53
KJ	114	140	102	47
LJ	119	154	105	57
HL	131	151	110	57
SQ	110	141	110	59
CXC	119	125	101	55

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7.9.2 Penetration of filter material

Pass

The penetration of the filter of the particle filtering half mask shall meet the requirements:

Classification	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

Sodium chloride test results: (Pass)

Specimen	Condition	Penetration (%)	
		After 3 minutes	Max. during exposure
26	A.R.	0.102	
27		0.110	
28		0.115	
14	S.W.	0.831	
15		0.742	
16		0.949	
20	M.S. + T.C.	0.292	
21		0.435	
22		0.350	
Maximum permitted		6	

Paraffin oil test results:(Pass)

Specimen	Condition	Penetration (%)	
		After 3 minutes	Max. during exposure
29	A.R.	0.179	
30		0.194	
31		0.181	
17	S.W.	0.932	
18		0.828	
19		0.917	
23	M.S. + T.C.	0.549	
24		0.895	
25		0.604	
Maximum permitted		6	

7.10 Compatibility with skin

Pass[6]

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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.

Note6: Materials that may come into contact with the wearer's skin is not be known to be likely to cause irritation or any other adverse effect to health.

7.11 Flammability — Pass

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.

Specimen	Condition	Results
32	A.R.	No burn
33		No burn
9		No burn
10		No burn

7.12 Carbon dioxide content of the inhalation air — Pass

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0 % (by volume).

Specimen	CO_2 (%)
32	0.23
33	0.22
34	0.24
Maximum permitted	0.23

7.13 Head harness — Pass[7]

The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.

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.

Note7: The head harness is designed so that the particle filtering half mask can be donned and removed easily. The head harness is self-adjusting and can 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.

7.14 Field of vision — Pass[8]

The field of vision is acceptable if determined so in practical performance tests.

Note8: The field of vision is acceptable.

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7.15 Exhalation valve

NAp[9]

A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.

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.

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.

When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.

Note9: No exhalation valve

7.16 Breathing resistance

Pass[10]

Classification	Maximum permitted resistance (mbar)		
	inhalation		exhalation
	30 l/min	95 l/min	160 l/min or (25 cycles/min×2.0 l/stroke)
FFP1	0.6	2.1	3.0
FFP2	**0.7**	**2.4**	**3.0**
FFP3	1.0	3.0	3.0

Note10: FFP2 Filtering face mask. Test results are detailed below.

Specimen	Condition	Inhalation resistance (mbar)		Exhalation resistance (mbar)				
		At 30 l/min	At 95 l/min	Breathing machine (160 l/min)				
				A	B	C	D	E
35	A.R.	0.25	1.33	1.40	1.42	1.44	1.30	1.27
36		0.27	1.39	1.34	1.40	1.42	1.35	1.32
37		0.28	1.53	1.41	1.40	1.44	1.35	1.38
11	T.C.	0.28	1.10	1.48	1.44	1.50	1.39	1.40
12		0.37	1.23	1.43	1.42	1.47	1.41	1.41
13		0.37	1.15	1.44	1.40	1.46	1.44	1.43
17	S.W.	0.32	1.05	1.31	1.33	1.29	1.39	1.41
18		0.33	1.12	1.35	1.36	1.31	1.42	1.28
19		0.33	1.09	1.31	1.35	1.34	1.40	1.37
	A.R. + F.C.							
	T.C. + F.C.							
Maximum permitted		**0.7**	**2.4**	**3.0**				

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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7.18 Demountable parts **NAp[11]**

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.

Note11: No demountable parts.

End of Test Report.

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LATEX-FREE & ALLERGEN-FREE DECLARATION

Date: June 18, 2025

Subject: Declaration of Latex-Free Material for FFP2 Foldable Mask (EN149:2001+A1:2009)

We, **SPRO Medical Products (Xiamen) Co., Ltd.**, hereby declare that our FFP2 Foldable Respirator Mask (Model: GL001A), compliant with EN149:2001+A1:2009 and CE Certificate **CE-PC-240131-066-04-9B**, are free from natural rubber latex (NRL), nickel, and other common allergens:

1. Product Components:

- Filtering media
- Inner/outer layers
- Nose clip & foam (if applicable)
- Ear loops/headbands

2. Packaging Materials:

- Individual mask packaging
- Retail box/carton
- Master outer shipping box

The above declaration applies to all materials in direct or indirect contact with the product during storage and transportation.we ensure compliance through rigorous quality control protocols.

Name of signatory: Yuan Huimei

Position in company: Quality manager

Signature:

Date:

GisMédical

SkyPro
Spro Medical Products

Particle Filtering Half Mask
GL001A **FFP2 NR**

EN 149:2001+A1:2009
PPE REGULATION EU 2016/425

CE 2834

SPRO Medical Products (Xiamen) Co., Ltd.
2nd Floor of No.9 Fangqian Building, No.358, Kilin Road, Xiangqing Street,
Tong'an District, Xiamen City, Fujian Province, China

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Notified Body No 2834
CCQS Certification Services Limited
Block 1 Blanchardstown Corporate Park, Ballycoolin Road,
Blanchardstown, Dublin 15, D15 AKK1, Ireland

LOT

SkyPro
Spro Medical Products

Particle Filtering Half Mask
GL001A **FFP2 NR**

EN 149:2001+A1:2009
PPE REGULATION EU 2016/425

CE 2834

MASCHERINE FFP2 NR

Senza valvola - Elastici Nucali - Certificate come DPI di III Categoria

[G.W.]

[N.W.]

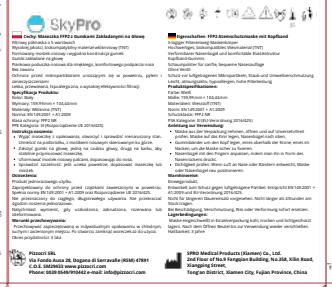
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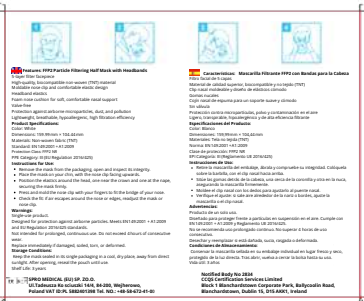
[QUANTITY]

MADE IN CHINA











LOT

REF **GL001A**

FFP2 NR

BFE >94%

SkyPro
Spro Medical Products

FILTERING HALF MASK
SEMIMASCHERA FACCIALE FILTRANTE
MASCARILLA FILTRANTE
FILTERMASKE
MASQUE FILTRANT
MASKA FILTRUJĄCA



IT Istruzioni d'uso:

1. Estrarre la maschera dalla confezione, aprirla e verificare che sia integra.
2. Posizionarla sul mento con la clip nasale in alto.
3. Indossare gli elastici nucali: uno va sopra le orecchie, l'altro sotto, entrambi dietro la testa.
4. Modellare la clip nasale premendola sul ponte del naso.
5. Verificare la tenuta: se ci sono perdite d'aria, regolare la clip o riposizionare la maschera.

FR Instructions d'utilisation :

1. Sortir le masque de son emballage et vérifier qu'il est en bon état.
2. Le placer sur le menton avec la barrette nasale vers le haut.
3. Positionner les élastiques nucaux : un au-dessus des oreilles, l'autre en dessous, tous deux à l'arrière de la tête.
4. Ajuster la barrette nasale en la pressant contre l'arête du nez.
5. Vérifier l'étanchéité : en cas de fuites d'air, ajuster la barrette ou repositionner le masque.

EN Instructions for Use:

1. Remove the mask from the packaging and check that it is intact.
2. Place it over the chin with the nose clip facing upward.
3. Position the headbands: one goes above the ears, the other below, both behind the head.
4. Shape the nose clip by pressing it against the bridge of the nose.
5. Check the fit: if there are air leaks, adjust the clip or reposition the mask.

DE Gebrauchsanweisung:

1. Nehmen Sie die Maske aus der Verpackung und überprüfen Sie, ob sie unbeschädigt ist.
2. Platzieren Sie die Maske über dem Kinn, mit dem Nasenbügel nach oben.
3. Setzen Sie die Nackenbänder auf: eines oberhalb der Ohren, das andere unterhalb – beide hinter dem Kopf.
4. Formen Sie den Nasenbügel, indem Sie ihn an den Nasenrücken drücken.
5. Dichtigkeit prüfen: Bei Luftaustritt den Nasenbügel oder die Position der Maske anpassen.

ES Instrucciones de uso:

1. Saque la mascarilla del envase y verifique que esté en buen estado.
2. Colóquela sobre el mentón con la pinza nasal hacia arriba.
3. Coloque las bandas elásticas nucales: una por encima de las orejas y otra por debajo, ambas detrás de la cabeza.
4. Moldee la pinza nasal presionándola contra el puente de la nariz.
5. Verifique el ajuste: si hay fugas de aire, ajuste la pinza o reposicione la mascarilla.

PL Instrukcja użycia:

1. Wyjmij maskę z opakowania i sprawdź, czy nie jest uszkodzona.
2. Umieść maskę na brodzie, z klipsem nosowym skierowanym ku górze.
3. Załóż elastyczne paski potyliczne: jeden powyżej uszu, drugi poniżej – oba z tyłu głowy.
4. Uformuj klips nosowy, dociskając go do grzbietu nosa.
5. Sprawdź szczelność: jeśli wyczuwasz nieszczelności, wyreguluj klips lub popraw położenie maski.

SPRO Medical Products (Xiamen) Co., Ltd.
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Tong'an District, Xiamen City, Fujian Province, China

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LOT

REF **GL001A**

BFE >94%

FFP2 NR

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