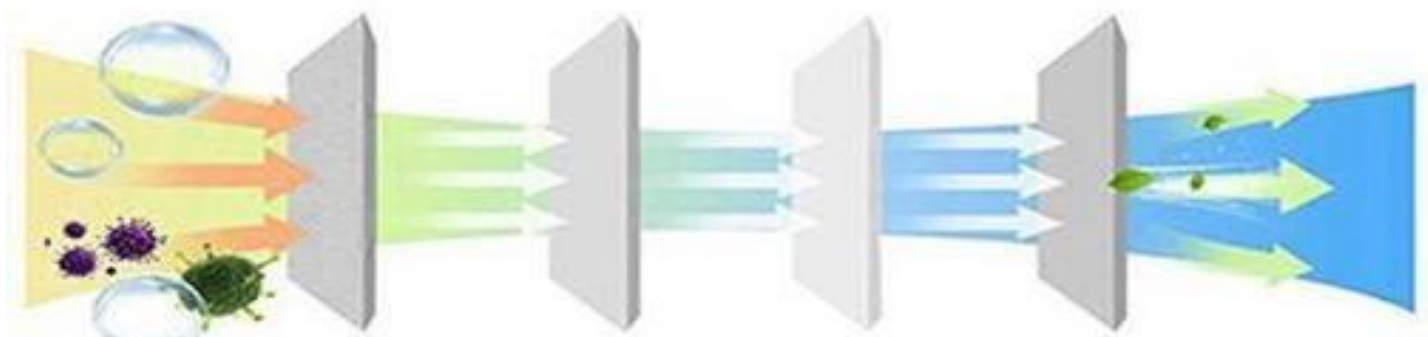


Semimaschera facciale FFP2 NR

Standard: EN149: 2001+A1: 2009

- *Clip di fissaggio per aggancio nucale per una perfetta tenuta facciale*
- *Bassa resistenza respiratoria*
- *4 Strati*
- *FFP2 con livello di protezione ad alta efficienza*



TNT in PP

Filtro soffiato a fusione in PP

Filtro di cotone ad aria calda

TNT in PP

Informazioni per gli ordini

Nome del prodotto

SEMIMASCHERA FACCIALE FILTRANTE

FFP2 NR III SENZA VALVOLA MONOUSO

NON STERILE

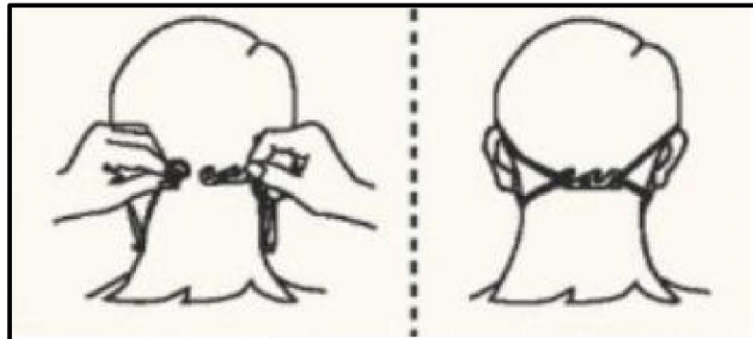
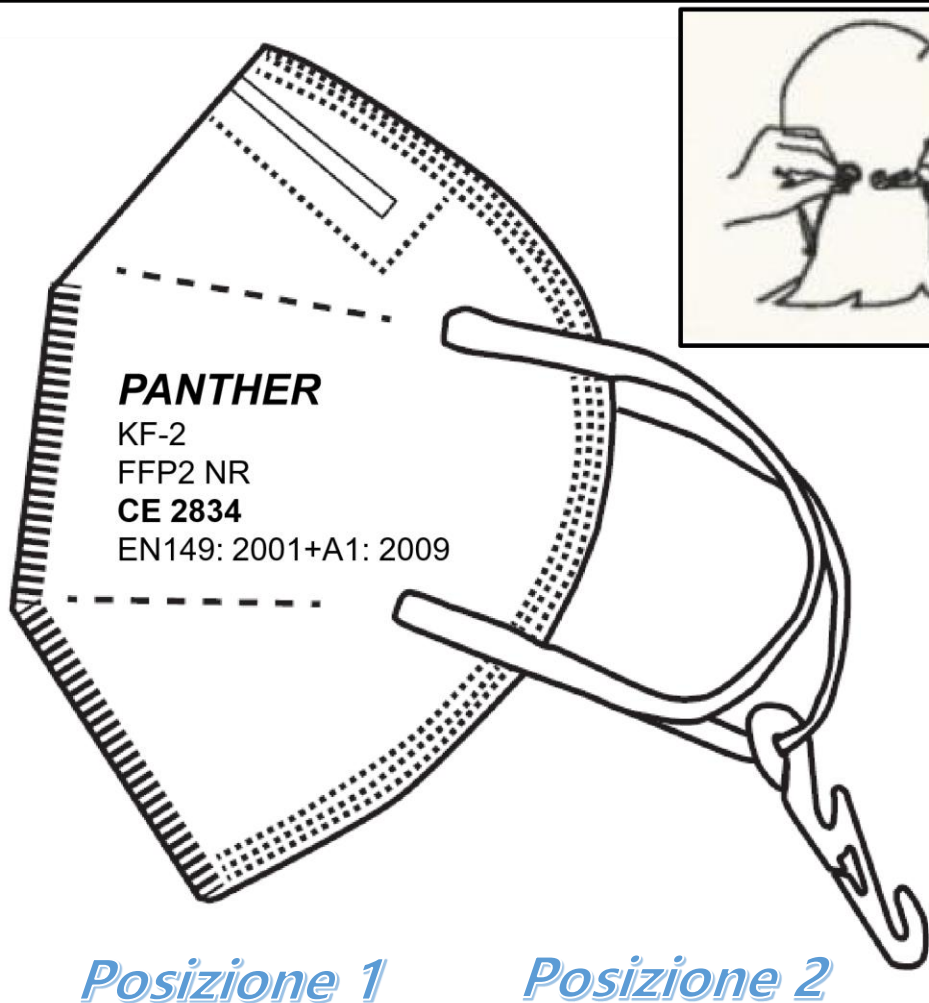
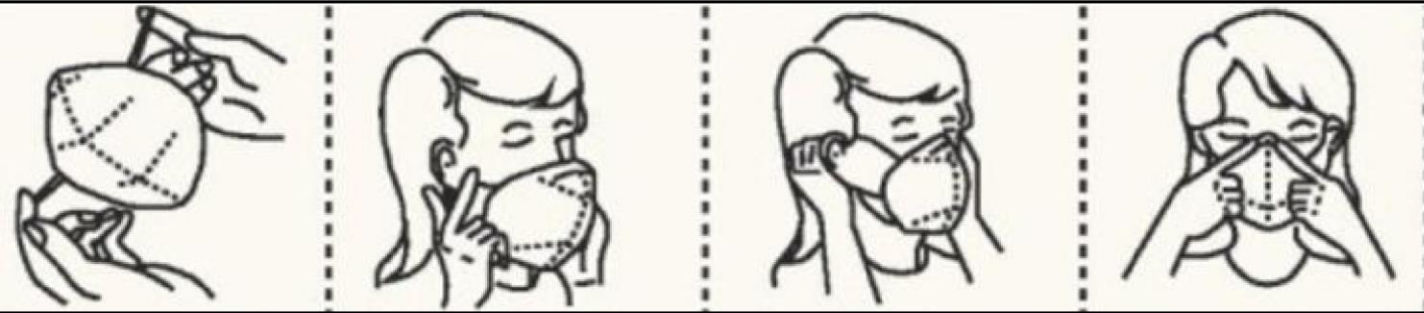
Codice prodotto KF-2

Confezione di vendita:

1 Scatola da 20 pezzi in busta singola



KF-2 Montaggio Semimaschera FFP2 NR



*Per tenere la Clip
in posizione*

Posizione 1

Posizione 2

Posizione 3



CE CERTIFICATE

**Module B EU Type-Examination Certificate**

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200526-433-01-9B

Certificate holder:	B.J.ZH.F.PANTHER MEDICAL EQUIPMENT CO., LTD. Floor 3, Building 1, 28 Huoju Street, Changping Science and Technology Park, Changping District, 102200 Beijing, China
Product:	Particle Filtering Half Mask Detailed product description listed in the Annex
Model(s):	KF-2
Standard(s):	EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking
Issue date:	2020-06-15
Revision date:	2020-08-10
Expiry date:	2021-06-14

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 PPE regulation 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 PPE Regulation 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 PPE Regulation 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, Dublin 15,
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.

CE CERTIFICATE



Module B EU Type-Examination Certificate

Annex

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200526-433-01-9B

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
KF-2	Folding filtering half mask fitted with ear loops with head harness clip, no valves, internal metal nose clip Classification: FFP2 NR Test report No.: 2020(D) - 0732

Certificate Revision	Revision date	Revision details
A	2020-06-15	Initial issue
B	2020-08-10	Certificate validity extended to one year



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.

CE CERTIFICATE



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-200717-556-FPC-B

Certificate holder:	B.J.ZH.F.PANTHER MEDICAL EQUIPMENT CO., LTD. Floor 3, Building 1, 28 Huoju Street, Changping Science and Technology Park, Changping District, 102200 Beijing, China
Manufacturing location:	Floor 3, Building 1, 28 Huoju Street, Changping Science and Technology Park, Changping District, 102200 Beijing, China Westside No.2, White Bridge Industrial Area, Jinzhan Street, Chaoyang District, 100018 Beijing, China 1-A, 1-06, 1-07, 1-08, 1-11, 1-12, 1-13, 2-A, 2-12, 3-A, No. 8, Shangcheng Road, Beiqijia Town, Changping District, 102209 Beijing, China
The scope of the certification for:	The manufacture of respiratory protective device See annex for articles covered by this certificate
Validity from:	2020-06-15
Revision date:	2020-08-10
To:	2021-06-14

CCQS Certification Services Limited in its role as a Notified Body for PPE Regulation, 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

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.

EU Declaration of Conformity

EU Declaration of Conformity

Annex IX PPE Regulation (EU) 2016/425

This EU Declaration of conformity refers to the following products

(1)	Product Name	Model	Classification/Type	Batch No./Serial No./Identifier
	Particle Filtering half mask	KF-2	FFP2 NR	XXXXXX

(2) The Manufacturer's name and address is as follows:

Name:	B.J.ZH.F.PANTHER MEDICAL EQUIPMENT CO., LTD
Address:	Floor 3, Building 1, 28 Huoju Street, Changping Science and Technology Park, Changping District, 102200 Beijing, China.
	Westside No.2, White Bridge Industrial Area, Jinzhan Street, Chaoyang District, 100018 Beijing, China.

(3) This Declaration of Conformity is issued under the sole responsibility of the Manufacturer.

(4) Detailed description of the PPE to allow traceability/identification of the PPE.

Model: KF-2, Classification: FFP2 NR, White folder half mask without valve



(5) The article identified in (4) above is in conformance with the relevant Union Harmonization Legislation Regulation (EU) 2016/425.

(6) References to the relevant harmonized standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:

No.	Harmonized standard name
1	EN 149:2001+A1:2009

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

No.	EU Type Examination (Module B) Certificate Number
1	CE-PC-200526-433-01-9A

(8) Product Category:

- This product is Category II.
- This product is Category III and is subject to Module C2 internal production control plus supervised product checks at random intervals and is under the surveillance of CCQS Certification Services Limited. (NB 2834)
- 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 CCQS Certification Services Limited. (NB 2834)

Signature: Vicky Lee Date: 2020.06.15 Company stamp and/or legal signature: 

Test report: EN149:2001 +A1:2009



中国认可
国际互认
检测
TESTING
CNAS L1499

National Quality Supervision and Testing Center for Personal Protective Equipment (Beijing)
(Testing Laboratory for Labour Protection Products of Beijing Municipal Institute for Labour Protection)

No.55 Taoranting Street, Xicheng District, Beijing, China.
Phone: +86 10 63519250 +86 10 63520770 +86 10 83530311
Fax: +86 10 63519250 +86 10 63520770

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: 2020 (D) - 0732
Client: B. J. ZH. F. PANTHER MEDICAL EQUIPMENT CO., LTD
Model (s): KF-2
Date(s) of tests: 2020.05.15-2020.05.29

FFP2 NR

DESCRIPTION OF SAMPLES

General Information

Manufacturer

Manufacturer Address

Classification

FFP2 NR

B. J. ZH. F. PANTHER MEDICAL EQUIPMENT CO., LTD

Floor 3, Building 1, 28 Huojia Street, Changping Science and Technology Park, Changping District, 102200 Beijing, China.

Main Components

White folding mask

Signed:



Issued: 2020.5.29

陈倬为 Chen Zhuowei
Authorized Signatory, Lab Director

Page 1 of 10



Test report: EN149:2001 +A1:2009

Report No: 2020 (D) - 0732

Page 8 of 10

Table -7.9.2 Penetration of filter material

Test specification: EN 149-2001 Clause 8.11

Aerosol	Condition	Sample No.	Penetration (%)	Assessment
Sodium chloride test	As received	11	0.379	Pass
		12	0.448	
		13	0.312	
	Simulated wearing treatment	14	0.498	
		15	0.512	
		16	0.507	
	Mechanical strength+ Temperature conditioned	17	0.618	
		18	0.632	
		19	0.668	
Paraffin oil test	As received	20	3.71	Pass
		21	3.87	
		22	3.64	
	Simulated wearing treatment	23	4.57	
		24	4.64	
		25	4.51	
	Mechanical strength+ Temperature conditioned	26	4.85	
		27	4.71	
		28	4.94	
Flow conditioning: Single filter: 95.0 L/min				

Table 7.11 Flammability

Test specification: EN 149-2001 Clause 8.6

Condition	Sample No.	Result	Assessment
As received	29	Burn for 1 s	Pass
	30	Burn for 1 s	
Temperature conditioned	31	Burn for 1 s	
	32	Burn for 1 s	

Test report: EN149:2001 +A1:2009

Report No: 2020 (D) - 0732

Page 9 of 10

Table 7.12 Carbon dioxide content of the inhalation air

Test specification: EN 149-2001 Clause 8.7

Condition	Sample No.	Result	Assessment
As received	33	0.45%	Mean value 0.4%
	34	0.40%	
	35	0.41%	

Table 7.16 Breathing resistance (mbar)

Test specification: EN 149-2001 Clause 8.9

	Flow rate	36					37					38					
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E	
As received	Inhalation	30 l/min	0.4	0.5	0.4	0.5	0.5	0.4	0.5	0.6	0.5	0.6	0.4	0.5	0.6	0.4	0.5
		95 l/min	1.4	1.5	1.4	1.5	1.5	1.6	1.4	1.5	1.5	1.5	1.6	1.4	1.4	1.6	1.6
	Exhalation	160 l/min	1.8	1.8	1.8	1.8	1.8	1.9	1.8	1.8	1.8	1.8	1.9	1.8	1.8	1.9	1.9
Simulated wearing treatment	Inhalation	30 l/min	0.5	0.5	0.6	0.6	0.5	0.6	0.5	0.5	0.4	0.5	0.6	0.5	0.4	0.4	0.5
		95 l/min	1.6	1.4	1.4	1.5	1.6	1.4	1.4	1.4	1.4	1.5	1.5	1.4	1.4	1.5	1.6
	Exhalation	160 l/min	1.9	1.8	1.8	1.9	1.9	1.7	1.7	1.7	1.7	1.8	1.9	1.8	1.7	1.9	1.9
Temperature conditioned	Inhalation	30 l/min	0.5	0.5	0.6	0.6	0.4	0.4	0.4	0.5	0.4	0.4	0.4	0.6	0.6	0.6	0.4
		95 l/min	1.5	1.5	1.6	1.4	1.6	1.4	1.6	1.5	1.5	1.5	1.6	1.4	1.5	1.6	1.6
	Exhalation	160 l/min	1.9	1.8	1.9	1.7	1.9	1.8	1.9	1.9	1.8	1.8	1.9	1.8	1.8	1.9	1.9
Assessment		Pass															

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