

DECLARACIÓN UE DE CONFORMIDAD

Distribuidor: JBM CAMPLLONG, S.L.U.

Dirección: CIM La Selva – Crta. Aeroport Km 1.6 Nave 2.2, 17185 Vilobí d'Onyar, Girona

CIF (VAT number): ESB17419292

Descripción del producto: Mascarilla de protección FFP2

Referencia del fabricante: KADI-001

Referencia del distribuidor: 53946, 537870, 53959, 53960, 53961, 53963

El objeto de la declaración es conforme al reglamento (UE) 2016/425, relativo a los Equipos de

protección individual, y a la siguiente norma:

Norma	Título	Edición/Fecha
EN149	Dispositivos de protección respiratoria. Medias máscaras filtrantes de protección contra partículas. Requisitos, ensayos, marcado.	2001+A1:2009

Certificado de tipo UE realizado por:

CCQS Certification Services Limited

Aprobado por el gobierno irlandés como organismo notificado para el marcado CE No.2834

Block 1 Blanchardstown Corporate Park,

Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland

Tel: + 00 353 1 588 6920

No. Certificado: CE-PC-200401-179-01-9D, CE-PC200401-179-FPC-C

No. Test report: 2020 (D) - 0778, 2021 (D) - 0073

Firmado:



Eduard Godoy

Director departamento de compras

En Girona, a 31 de mayo de 2021



Module B EU Type-Examination Certificate

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200401-179-01-9D

Certificate holder:	Hefei Kadi Biological Pharmaceutical Co., Ltd. 2nd Floor, No.3 Building, Workshop 3, Xiwei San Rd., Feidong Economic Development Zone, 231600, Hefei, Anhui, China
Product:	Particle filtering half mask Detailed product description listed in the Annex
Model(s):	KADI-001
Standard(s):	EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking
Issue date:	2020-06-12
Revision date:	2021-05-11
Expiry date:	2025-06-11

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



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Module B EU Type-Examination Certificate Annex

For the requirements of PPE Regulation 2016/425

Certificate No.: CE-PC-200401-179-01-9D

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		
KADI-001	Folding filtering half mask fitted with ear loops with head harness	
	retaining clip, no valves, internal metal nose clip	
	Mask body variant colours: White, Black, Grey, Yellow, Dark blue,	
	Purple, Pink, Red, Orange or Army Green variant	
	Classification: FFP2 NR	
	Test report No.: 2020(D) - 0778, 2021(D) - 0073	

Certificate Revision	Revision date	Revision details	
Α	2020-06-12	Initial issue	
В	2020-09-11	Certificate validity extended to one year	
С	2020-11-19	Addition of mask body colour Black, Grey,	
		Yellow, Dark blue, Purple or Pink variant	
DS	2021-05-11	Extended expiry date following Module C2	
	CO-	assessment and addition of mask body	
		colour variants - Red, Orange & Army	
	COS II	Green	
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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-200401-179-FPC-C

Certificate holder:	Hefei Kadi Biological Pharmaceutical Co., Ltd. 2nd Floor, No.3 Building, Workshop 3, Xiwei San Rd., Fe Economic Development Zone, 231600, Hefei, Anhui, Ch		Xiwei San Rd., Feidong
Manufacturing location:		Building, Workshop 3, Opment Zone, 231600	Xiwei San Rd., Feidong , Hefei, Anhui, China
The scope of the certification for:	The manufacture of respiratory protective device See annex for articles covered by this certificate		
Valid from:	2020-06-12		
Revision date:	2021-05-11		
то:	2023-06-11		

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.

CE

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



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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-200401-179-FPC-C

Product reference and description			Reference standard	***
Particle Filtering Half Mask	Model: KADI-001	****	EN 149:2001+A1:2009	

Certificate Revision	Revision date	Revision details
	2020-06-12	Initial issue
В	2020-09-11	Certificate validity extended to one year
C	2021-05-11	Extension to validity of certificate following the Module C2 assessment

This schedule has no validity without the accompanying certificate.

This schedule and the accompanying certificate 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



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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) - 0778
Client:	CCQS Certification Services Limited
Model (s):	KADI-001
Date(s) of tests:	2020.05.19-2020.06.03

DESCRIPTION OF SAMPLES

General Information	Classification FFP2 NR	Main Components White folding mask
Manufacturer	Hefei Kadi Biological Pharmaceutical Co., Ltd	
Manufacturer Address	2 nd Floor, No 3 Building, Workshop 3, Xiwen San Rd, Feidong Economic Developm Zone, 231600, Hefei, Anhui, China.	

Signed:

陈倬为 Chen Zhuowei Authorized Signatory, Lab Director Issued: 2020.6.3

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Conditions:

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Test Results

Report No: 2020 (D) - 0778 Page	4 of 10
FFP2 $\leq 6\%$	
FFP3 $\leq 1\%$	
Note8: FFP2 respirator. Test results are shown in Annex A Table 7.9.2.	
7.10 Compatibility with skin Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation of any other adverse effect to health. Note9: No irritation or any other adverse effect to health.	Pass ⁹ r
7.11 Flammability 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. Note10: Test results are shown in Annex A Table 7.11.	Pass ¹⁰
7.12 Carbon dioxide content of the inhalation air The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume) Note11: Test results are shown in Annex A Table 7.12.	Pass ¹¹
7.13 Head harness	Pass ¹²
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 filterin half mask firmly in position and be capable of maintaining total inward leakage requirements for the device. Note12: Head harness can be donned and removed easily, adjustable or self-adjusting and have sufficiently robust to hold the particle filtering half mask firmly.	ıg
7.14 Field of vision The field of vision is acceptable if determined so in practical performance tests. Note13: Pass the practical performance tests.	Pass ¹³
7.15 Exhalation valve A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	N/A ¹⁴
If an exhalation value 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	1

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.

Note14: No exhalation valve.

7.16 Breathing resistance

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

Pass¹⁵

Note15: FFP2 respirator. Test results are shown in Annex A Table 7.16.

7.17 Clogging

7.17.2 Breathing resistance

Valved particle filtering half masks: After clogging the inhalation resistances shall not exceed: FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95L/min continuous flow The exhalation resistance shall not exceed 3 mbar at 160 L/min continuous flow

Valveless particle filtering half masks

After clogging the inhalation and exhalation resistances shall not exceed: FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95L/min continuous flow

7.17.3 Penetration of filter material

Sodium chloride test 95 l/min		Paraffin oil test 95 l/min
FFP1	\leqslant 20%	\leqslant 20%
FFP2	\leqslant 6%	\leqslant 6%
FFP3	\leqslant 1%	\leqslant 1%
Note16: Single shift use only.		

7.18 Demountable parts

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand Note17: In accordance with the requirement.

9 Marking

9.1 Packaging

The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.

9.1.1 The name, trademark or other means of identification of the manufacturer or supplier.

9.1.2 Type-identifying marking.

9.1.3 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

9.1.4 The number and year of publication of this European Standard.

9.1.5 At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month.

9.1.6 The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.

9.1.7 The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.

9.1.8 The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". This letter shall follow the classification marking preceded by a single space.

9.2 Particle filtering half mask

Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:

9.2.1 The name, trademark or other means of identification of the manufacturer or supplier.

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N/A¹⁶

Pass¹⁷

Not tested

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9.2.2 Type-identifying marking.

9.2.3 The number and year of publication of this European Standard.

9.2.4 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

9.2.5 If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space

9.2.6 Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.

End of Test Results

Report No: 2020 (D) - 0778 Annex A: Summarization of Test Data

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Yi	1	A.R.	7.13	7.16	7.14	7.56	7.45	7.3
Gong	2	A.R.	6.89	7.03	6.97	7.17	7.03	7.0
Yu	3	A.R.	7.09	7.67	7.38	7.19	7.47	7.4
Hu	4	A.R.	6.86	6.93	7.23	6.89	7.21	7.0
Xu	5	A.R.	7.18	7.57	7.47	7.39	7.53	7.4
Deng	6	T.C.	9.35	9.48	9.46	9.52	9.74	9.5
Zhang	7	T.C.	6.79	7.04	7.28	6.90	7.01	7.0
Zhi	8	T.C.	7.08	7.51	7.24	7.30	7.41	7.3
Fang	9	T.C.	6.72	6.76	6.89	6.86	7.09	6.9
Lv	10	T.C.	8.37	8.52	8.86	8.68	8.62	8.6
All <u>50</u> inc <u>8</u> out of <u>1</u>	F	Pass						

Table 7.9.1-A Inward leakage test data Test specification: EN 149-2001 Clause 8.5

Table 7.9.1-B Facial dimension

	Indie			
Subject	Face length	Face Width	Face Depth	Mouth Width
Yi	120	130	109	59
Gong	122	140	115	65
Yu	119	160	139	55
Hu	112	122	119	63
Xu	110	130	118	60
Deng	115	119	110	59
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

Aerosol	Condition	ConditionSample No.Penetration (%)				
		11	0.482			
	As received	12	0.579			
		13	0.414			
		14	0.565			
Sodium chloride test	Simulated wearing treatment	15	0.682			
		16	0.595			
		17	0.772			
	Mechanical strength+ Temperature conditioned	18	0.841			
		19	0.714			
		20	4.61	Pass		
	As received	21	4.55			
		22	4.76			
		23	4.92			
Paraffin oil test	Simulated wearing treatment	24	4.88			
		25	5.19			
		26	5.27			
	Mechanical strength+ Temperature conditioned	27	5.44			
		28	5.31			
Flow condition						

Table -7.9.2 Penetration of filter materialTest specification: EN 149-2001 Clause 8.11

Table 7.11 Flammability

Test specification: EN	149-2001 Clause 8.6
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Condition	Sample No.	Result	Assessment
As received	29	Burn for 1 s	
As received	30	Burn for 1 s	Daga
Temperature	31	Burn for 1 s	Pass
conditioned	32	Burn for 1 s	

Pass

0.4%

,	Test specific	ation: EN	V 149-2001 Clause 8.7		
	Condition	Sample No.	Result		Assessment
		33	0.39%		
	As	24	0.410/	Mean value	Daga

0.41%

0.40%

Table 7.12 Carbon dioxide content of the inhalation airspecification: EN 149-2001 Clause 8.7

Table 7.16 Breathing resistance (mbar)

Test specification:	EN 149-2001	Clause 8.9
---------------------	-------------	------------

received

34

35

	Elaw	. noto			36					37					38		
	Flow rate		Α	В	С	D	Е	Α	В	С	D	Е	Α	В	С	D	Е
As received	Inhalation	30 l/min	0.4	0.5	0.5	0.5	0.5	0.6	0.5	0.6	0.4	0.5	0.5	0.6	0.6	0.5	0.4
	minalation	95 l/min	1.6	1.6	1.8	1.6	1.8	1.7	1.7	1.8	1.6	1.6	1.8	1.7	1.6	1.8	1.7
	Exhalation	160 l/min	1.9	2.1	1.9	1.9	2.1	1.9	2.0	2.1	2.0	2.1	2.1	2.0	2.0	2.1	2.1
	Elaw	unto			39					40					41		
Simulated	Flow rate	rate	Α	В	С	D	Е	Α	В	С	D	Е	Α	В	С	D	Е
wearing	Inhalation	30 l/min	0.6	0.6	0.6	0.4	0.5	0.5	0.6	0.4	0.5	0.4	0.6	0.5	0.5	0.5	0.5
treatment		95 l/min	1.8	1.8	1.8	1.8	1.7	1.6	1.7	1.7	1.7	1.8	1.6	1.8	1.7	1.6	1.7
	Exhalation	160 l/min	2.1	2.0	2.0	2.0	2.0	1.9	2.0	2.1	2.0	2.0	2.0	2.0	1.9	2.1	2.0
	Flow	rata			42					43					44		
Townsonstrans	FIOW	Tate	Α	В	С	D	Е	Α	В	С	D	Е	Α	В	С	D	Е
Temperature conditioned	Inhalation	30 l/min	0.6	0.4	0.5	0.5	0.4	0.4	0.4	0.4	0.5	0.4	0.5	0.4	0.6	0.6	0.4
conditioned	maiation	95 l/min	1.7	1.8	1.6	1.7	1.8	1.8	1.7	1.8	1.8	1.8	1.7	1.7	1.7	1.6	1.7
	Exhalation	160 l/min	2.1	1.9	2.0	2.0	2.0	2.1	2.0	2.0	2.0	1.9	1.9	2.1	2.0	2.0	2.0
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

End of Annex A

ANNEX B PHOTOS OF SAMPLES







End of Annex B

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国家劳动保护用品质量监督检验中心(北京)

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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:	2021 (D) - 0073
Client:	CCQS Certification Services Limited
Model (s):	KADI-001
Date(s) of tests:	2021.04.20-2020.05.07

DESCRIPTION OF SAMPLES

General Information	Classification FFP2 NR		Main Components range folding mask	
Manufacturer	HEFEI KADI BIOLOGICAL P		0	
Manufacturer Address	No. 3 Building, Workshop 3 HEFEI, Anhui China	Xiwei San Road,	Feidong Economic	Development Zone,

Signed:

陈倬为 Chen Zhuowei Authorized Signatory, Lab Director Issued: 2021.05.07

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Test Results

7.9.1 Total inward leakage

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 Note1: FFP2 respirator. Test results are shown in Annex A Table 7.9.1-A&B.

End of Test Results

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Report No: 2021 (D) - 0073 Annex A: Summarization of Test Data

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Yi	1	A.R.	5.33	5.73	5.96	5.60	5.78	5.7
Gong	2	A.R.	6.24	6.47	6.61	6.50	6.25	6.4
Yu	3	A.R.	5.96	6.13	6.31	6.10	5.95	6.1
Hu	4	A.R.	6.23	6.37	6.53	6.23	6.68	6.4
Xu	5	A.R.	8.23	8.50	8.67	8.52	8.36	8.5
Deng	6	T.C.	6.93	7.14	7.36	7.16	6.92	7.1
Zhang	7	T.C.	8.19	8.37	8.63	8.47	8.28	8.4
Zhi	8	T.C.	7.42	7.57	7.74	7.50	7.37	7.5
Fang	9	T.C.	6.17	6.35	6.44	6.27	6.10	6.3
Lv	10	T.C.	7.15	7.40	7.63	7.23	7.10	7.3
All <u>50</u> inc <u>8</u> out of t		/						

Table 7.9.1-A Inward leakage test data

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

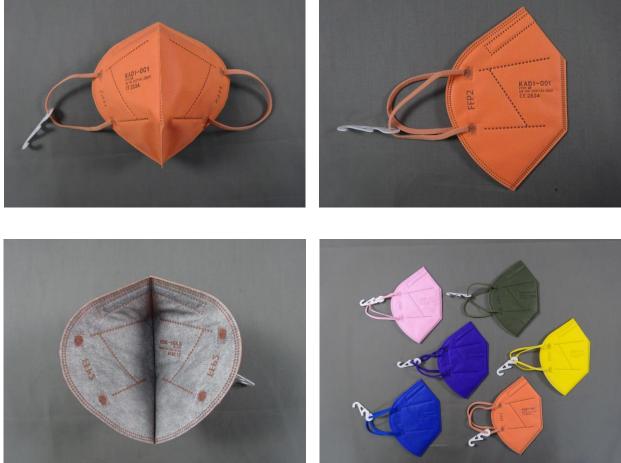
Table 7.9.1-B Facial dimension

Table 7.3.1-D Factal unitension										
Subject	Face length	Face Width	Face Depth	Mouth Width						
Yi	120	130	109	59						
Gong	122	140	115	65						
Yu	119	160	139	55						
Hu	112	122	119	63						
Xu	110	130	118	60						
Deng	115	119	110	59						
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						

Test	Uncertainty
Total inward leakage	4.1%

End of Annex A

Report No: 2021 (D) - 0073 ANNEX B PHOTOS OF SAMPLES



End of Annex B