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

This EU Declaration of conformity refers to the following products:

1. Product info

Name: Particle filtering half mask

Model: KADI-001 Classification: FFP2

Serial No .: ---

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

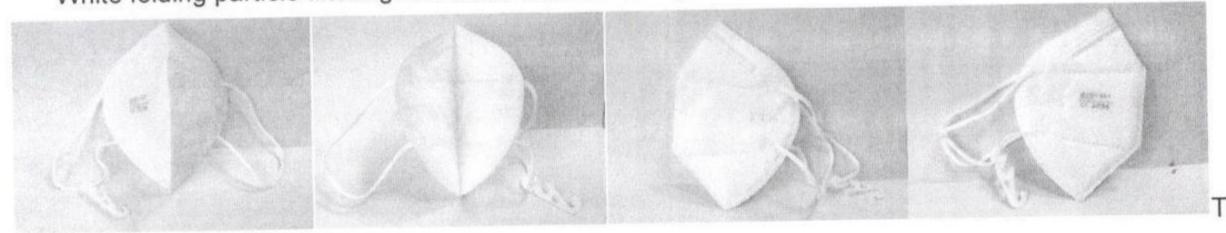
Name: Hefei Kadi Biological Pharmaceutical Co., Ltd.

Address: 2<sup>nd</sup> Floor, No.3 Building, Workshop 3, Xiwei San Rd., Feidong Economic Development Zone, 231600, Hefei, Anhui, 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.

KADI-001

White folding particle filtering half mask without valve, internal metal nose clip



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

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:

EN 149:2001+A1:2009

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

No.	EU Type Examination (Module B) Certificate Number
1	We will fill this sheet when the certificate is issued

Product Category:

□ 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:

Company stamp and/or legal signature:

320118489

Date: 22.6.18

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

This EU Declaration of conformity refers to the following products:

1. Product info

Name: Particle filtering half mask

Model: KADI-001 Classification: FFP2

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

Name: Hefei Kadi Biological Pharmaceutical Co., Ltd.

Address: 2<sup>nd</sup> Floor, No.3 Building, Workshop 3, Xiwei San Rd., Feidong Economic Development Zone, 231600, Hefei, Anhui, 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.

**KADI-001** 

Black folding particle filtering half mask without valve, internal metal nose clip



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

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:

EN 149:2001+A1:2009

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

No.	EU Type Examination (Module B) Certificate Number	
1	CE-PC-200401-179-01-9B	

#### **Product Category:**

 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: Date: 2020.9.15
Company stamp and/or legal signature:



Manufacturer's name: Hefei Kadi Biological Pharmaceutical Co., Ltd.

Address: 2<sup>nd</sup> Floor, No. 3 Building, Workshop 3, Xiwei San Rd.,

Feidong Economic Development Zone, 231600, Hefei,

Anhui, China

Date: 07.04.2020

CCQS Project Reference: CE-PC-200401-179

# **Confirmation Letter**

To whom it may concern:

This is to confirm that Hefei Kadi Biological Pharmaceutical Co., Ltd., Address: 2<sup>nd</sup> Floor, No. 3 Building, Workshop 3, Xiwei San Rd., Feidong Economic Development Zone, 231600, Hefei, Anhui, China has entered into the service agreement CE-PC-200401-179 with CCQS Certification Services Limited, with regards to the application of Module B EU Type Examination Certification and Module D Production Monitoring for Particle filtering half mask, Model: KADI-001, KADI-002, KADI-003 within the scope of Personal Protective Equipment Regulation (EU) 2016/425 Category III.

Please note this document does not provide the function of a EU Type Examination Certificate. This document merely confirms that the project referenced above is currently under our assessment.

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





#### **CCQS Certification Services Limited**

Block1, Blanchardstown Corporate Park, Ballycoolin Rd., Blanchardstown, Dublin 15, D15 AKK1 Ireland Tel: +353 (0) 1 588 6920 Email info@ccqs.ie

Registered in Ireland as a Limited Company No.623897

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



# Module B EU Type-Examination Certificate

# For the requirements of PPE Regulation 2016/425

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

Certificate Hefei Kadi Biological Pharmaceutical Co., Ltd.

holder: 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:** 2020-09-11

**Expiry date:** 2021-06-11

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





## **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 PPE Regulation 2016/425

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

# 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
KADI-001	Folding filtering half mask fitted with ear loops, no valves Classification: FFP2 NR

Certificate Revision	Revision date	Revision details
Α	2020-06-12	Initial issue
В	2020-09-11	



# **CCQS Certification Services Limited**

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



# 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-B

Certificate Hefei Kadi Biological Pharmaceutical Co., Ltd.

holder: 2nd Floor, No.3 Building, Workshop 3, Xiwei San Rd., Feidong

Economic Development Zone, 231600, Hefei, Anhui, China

Manufacturing

Location:

2nd Floor, No.3 Building, Workshop 3, Xiwei San Rd., Feidong Economic Development Zone, 231600, Hefei, Anhui, China

The scope of the 
The manufacture of respiratory protective device

certification for: See annex for articles covered by this certificate

**Validity from:** 2020-06-12

**Revision date:** 2020-09-11

**To:** 2021-06-11

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.



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.



# 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-B

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

Certificate Revision	Revision date	Revision details	
S A S	2020-06-12	Initial issue	
В	2020-09-11	Certificate validity extended to one year	

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 edition is no longer in conformity with the requirements of the Regulation.



### **CCQS Certification Services Limited**





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) - 0778

**Client: CCQS Certification Services Limited** 

KADI-001 (130\*80mm) Model (s):

2020.05.19-2020.06.03 Date(s) of tests:

#### DESCRIPTION OF SAMPLES

Classification **Main Components General Information** FFP2 NR White folding mask

Hefei Kadi Biological Pharmaceutical Co., Ltd Manufacturer

2<sup>nd</sup> Floor, No 3 Building, Workshop 3, Xiwen San Rd, Feidong Economic Development **Manufacturer Address** 

Zone, 231600, Hefei, Anhui, China.

Signed:

Issued: 2020.6.3

陈倬为 Chen Zhuowei Authorized Signatory, Lab Director

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This report may not be published except in full unless per sion for the publication of an approved extract has been obtained in writing.

原 印 命 (组 京) 国家劳动保护 ... 品

### **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** 

7.3 Visual inspection

Not tested<sup>1</sup>

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

Note1: As requested by the client, marking and information supplied by the manufacturer was not inspected.

7.4 Package Pass<sup>2</sup>

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.

Note2: In accordance with the requirement.

7.5 Material

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.

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

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.

Note3: No mechanical failure after undergoing the conditioning described in 8.3.1. No collapse when conditioned in accordance with 8.3.1 and 8.3.2.

#### 7.6 Cleaning and disinfecting

N/A4

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.

Note4: Single shift use only.

#### 7.7 Practical performance

Pass<sup>5</sup>

The particle filtering half mask shall undergo practical performance tests under realistic conditions. Note5: No imperfections.

#### 7.8 Finish of parts

Pass<sup>6</sup>

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

Note6: No sharp edges or burrs.

#### 7.9.1 Total inward leakage

Pass7

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

Note7: FFP2 respirator. Test results are shown in Annex A Table 7.9.1-A&B.

#### 7.9.2 Penetration of filter material

Pass8

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%

Note8: FFP2 respirator. Test results are shown in Annex A Table 7.9.2.

#### 7.10 Compatibility with skin

Pass9

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.

Note9: No irritation or any other adverse effect to health.

7.11 Flammability
Pass<sup>10</sup>

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.

#### 7.12 Carbon dioxide content of the inhalation air

Pass<sup>11</sup>

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.

7.13 Head harness

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.

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.

7.14 Field of vision
Pass<sup>13</sup>

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

Note13: Pass the practical performance tests.

7.15 Exhalation valve

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.

Note14: No exhalation valve.

#### 7.16 Breathing resistance

Pass<sup>15</sup>

Classification	Ma	aximum permitted resistance (mba	ar)
	Inhalati	Exhalation	
	30 1/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

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

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N/A16 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

Soc	dium chloride test 95 l/min	Paraffin oil test 95 1/min
FFP1	≤20%	≤20%
FFP2	≤6%	≤6%
FFP3	≤1%	≤1%
Note16: Single	shift use only.	

7.18 Demountable parts Pass<sup>17</sup>

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

9 Marking Not tested

#### 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.

- 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

# Annex A: Summarization of Test Data

Table 7.9.1-A Inward leakage test data

Test specification: EN 149-2001 Clause 8.5

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
				ater than 11 % were not greate	er than <u>8</u> %		P	ass

Table 7.9.1-B Facial dimension

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

Table -7.9.2 Penetration of filter material

Test specification: EN 149-2001 Clause 8.11

Aerosol	Condition	Sample No.	Penetration (%)	Assessment
		11	0.482	
	As received	12	0.579	1
		13	0.414	1
		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	
312.2.3		25	5.19	
		26	5.27	
	Mechanical strength+ Temperature conditioned	27	5.44	]
		28	5.31	

# **Table 7.11 Flammability**

Test specification: EN 149-2001 Clause 8.6

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

Table 7.12 Carbon dioxide content of the inhalation air

Test specification: EN 149-2001 Clause 8.7

Condition	Sample No.	Result		Assessment
	33	0.39%		
As received	34	0.41%	Mean value 0.4%	Pass
	35	0.40%		

**Table 7.16 Breathing resistance (mbar)** 

Test specification: EN 149-2001 Clause 8.9

192	Flow	rata			36					37					38		
	Flow	rate	A	В	C	D	E	A	В	C	D	E	A	В	C	D	E
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
	innaiation	95 1/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
	Elem				39					40					41		
Simulated	Flow	rate	Α	В	C	D	Е	A	В	C	D	Е	Α	В	C	D	Е
wearing	Inhalatian	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	Inhalation	95 1/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
	El.				42					43					44		
Т.	Flow	rate	A	В	С	D	Е	A	В	С	D	Е	Α	В	C	D	Е
Temperature conditioned	To be detired	30 1/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	Inhalation	95 1/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							Pas	s									

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



# ANNEX B PHOTOS OF SAMPLES







**End of Annex B** 



Documen No.: XKS202003160104PPE Page 1 of 25

# TECHNICAL DOCUMENT

#### EN 149

Respiratory protective devices —
Filtering half masks to protect against particles —
Requirements, testing, marking

Report Reference No.....: XKS202003160104PPE

Tested by (name + signature).....: Huigang.Cai

Approved by (name + signature) .: Shuimei.Cao

Date of issue.....: 2020-03-26

Total number of pages.....: 25

Testing Laboratory.....: Shenzhen Xunke Standards Technical Services Co., LTD

Address...... 2nd Floor, Building E2, Qiangrong East Industrial Zone, Jiuwei

Community, Xixiang Street, Baoan District, Shenzhen City,

Guangdong Province, China.

Applicant's name...... Hefei Kadi bio Pharmaceutical Co., Ltd.

Building 003,3# North of Xiweisan Road, West Outer

Address...... Ring, Economic Development Zone, Feidong County, Hefei, China.

Test specification:

Standard.....: EN 149:2001+A1:2009

Test procedure .....: CE-PPE

Non-standard test method.....: N/A

Test Report Form No.....: EN 149-104PPE

Master TRF.....: Dated 2020-03

Trade Mark .....: None

Manufacturer ...... Hefei Kadi bio Pharmaceutical Co., Ltd.

Building 003,3# North of Xiweisan Road, West Outer

Ring, Economic Development Zone, Feidong County, Hefei, China.

Test item description ...... FFP2 Mask

Model/Type reference .....: FFP2,FFP3



-DECIALTY SWIFT

Page 2 of 25 Documen No.: XKS202003160104PPE

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Possible test case verdicts:	
- test case does not apply to the test object:	: N/A
- test object does meet the requirement	P (Pass)
- test object does not meet the requirement:	: F (Fail)
Testing	CARLON CONTRACTOR
Date of receipt of test item	: 2020-03-16
Date (s) of performance of tests	2020 03-16 to 2020-03-26
General remarks:	Co (45)
This report shall not be reproduced, except in full, with "(See Enclosure #)" refers to additional information a "(See appended table)" refers to a table appended to Throughout this report a   comma /   point is	appended to the report. the report.
General product information:	NAD SCIENTIFIC TOURS
OREN TANK	
1. This production, named FFP2 Mask	
2. All models have similar construction and performa	ance, only different with appearance.
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# Photos document



