



DICHIARAZIONE DI CONFORMITÀ CE

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CIF (VAT number): ESB17419292

Descrizione del prodotto: MASCHERA DI PROTEZIONE AUTOFILTRANTE FFP2

Articolo del produttore: KADI-001

Articolo del distributore: 53946, 537870, 53959, 53960, 53961, 53963

L'oggetto della dichiarazione è conforme al regolamento (UE) 2016/425 sui dispositivi di protezione individuale e alla norma seguente:

Norma	Titolo	Edizione/Data
EN149	Dispositivi di protezione delle vie respiratorie. Filtrare le mezze maschere dispositivi di filtraggio per la protezione dal particolato. Requisiti, test, marcatura.	2001+A1:2009

Certificato di omologazione UE rilasciato da:

CCQS Certification Services Limited

Approvato dal governo irlandese come organismo notificato per la marcatura CE n. 2834.

Block 1 Blanchardstown Corporate Park,

Ballycoolin Road, Blanchardstown, Dublin15, D15 AKK1, Ireland

Tel: + 00 353 1 588 6920

Numero di certificato: CE-PC-200401-179-01-9D, CE-PC200401-179-FPC-C

Numero di test: 2020 (D) – 0778, 2021 (D) - 0073

Firmato:



Eduard Godoy

Responsabile del reparto acquisti

A Girona, 31 maggio 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

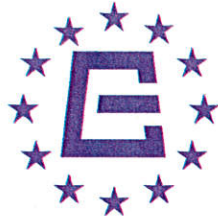


CCQS Certification Services Limited

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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
A	2020-06-12	Initial issue
B	2020-09-11	Certificate validity extended to one year
C	2020-11-19	Addition of mask body colour Black, Grey, Yellow, Dark blue, Purple or Pink variant
D	2021-05-11	Extended expiry date following Module C2 assessment and addition of mask body colour variants - Red, Orange & Army 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., 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 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
To:	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.



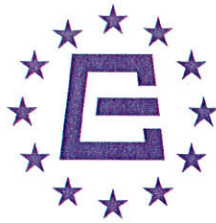
Approved by Ireland Government as a Notified Body for CE Marking No.2834



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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
A	2020-06-12	Initial issue
B	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
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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	Main Components
Manufacturer	FFP2 NR	White folding mask
Manufacturer Address	Hefei Kadi Biological Pharmaceutical Co., Ltd 2 nd Floor, No 3 Building, Workshop 3, Xiwen San Rd, Feidong Economic Development Zone, 231600, Hefei, Anhui, China.	

Signed:

Issued: 2020.6.3

陈倬为 Chen Zhuowei

Authorized Signatory, Lab Director

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Conditions:

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

Test Results

7.3 Visual inspection **Not tested¹**

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 **Pass²**

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 **Pass³**

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 **Pass⁵**

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

Note5: No imperfections.

7.8 Finish of parts **Pass⁶**

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%

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FFP2	≤6%	≤6%
FFP3	≤1%	≤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

Pass¹⁰

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

Pass¹¹

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

Pass¹²

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

Pass¹³

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

Note13: Pass the practical performance tests.

7.15 Exhalation valve

N/A¹⁴

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

Pass¹⁵

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

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

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7.17 CloggingN/A¹⁶**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	≤20%	≤20%
FFP2	≤6%	≤6%
FFP3	≤1%	≤1%

Note16: Single shift use only.

7.18 Demountable partsPass¹⁷

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.

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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

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
All <u>50</u> individual exercise results were not greater than <u>11</u> % <u>8</u> out of <u>10</u> individual wearer arithmetic means were not greater than <u>8</u> %							Pass	

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

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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	0.482	Pass
		12	0.579	
		13	0.414	
	Simulated wearing treatment	14	0.565	
		15	0.682	
		16	0.595	
	Mechanical strength+ Temperature conditioned	17	0.772	
		18	0.841	
		19	0.714	
Paraffin oil test	As received	20	4.61	
		21	4.55	
		22	4.76	
	Simulated wearing treatment	23	4.92	
		24	4.88	
		25	5.19	
	Mechanical strength+ Temperature conditioned	26	5.27	
		27	5.44	
		28	5.31	
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	

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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	0.39%	Mean value 0.4%
	34	0.41%	
	35	0.40%	

Table 7.16 Breathing resistance (mbar)

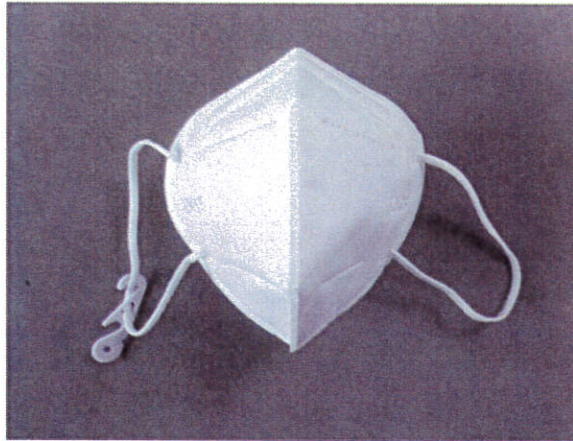
Test specification: EN 149-2001 Clause 8.9

Condition	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	0.5	0.5	0.5	0.6	0.5	0.6	0.4	0.5	0.5	0.6	0.6	0.5	0.4
		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
Simulated wearing treatment	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
		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
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
		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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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	Main Components
Manufacturer	FFP2 NR	Orange folding mask
Manufacturer Address	HEFEI KADI BIOLOGICAL PHARMACEUTICAL CO., LTD No. 3 Building, Workshop 3 Xiwei San Road, Feidong Economic Development Zone, HEFEI, Anhui China	

Signed:

Issued: 2021.05.07

陈倬为 Chen Zhuowei
Authorized Signatory, Lab Director

Page 1 of 5

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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 Results

7.9.1 Total inward leakage

/¹

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

Annex A: Summarization of Test Data

Table 7.9.1-A Inward leakage test data

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

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
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 50 individual exercise results were not greater than 11 % 8 out of the 10 individual wearer arithmetic means were not greater than 8 %							/	

Table 7.9.1-B Facial dimension

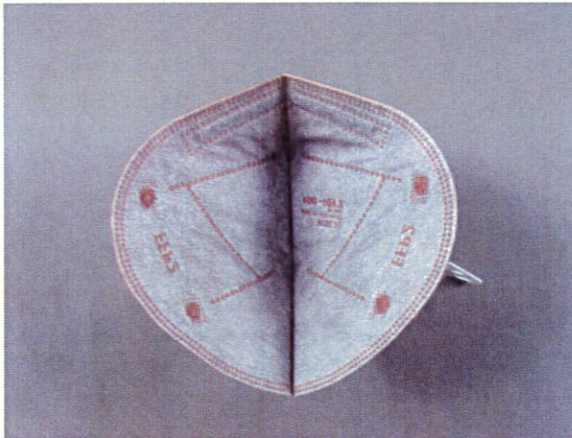
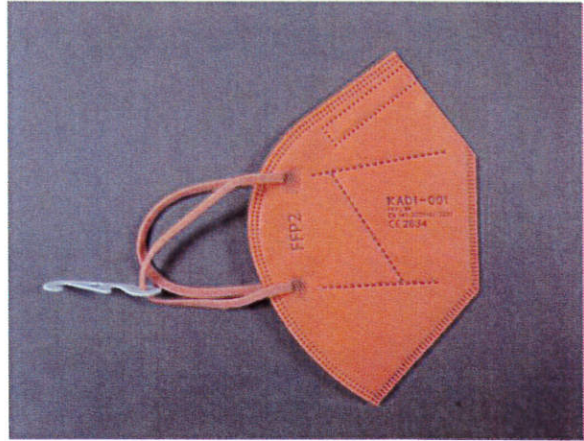
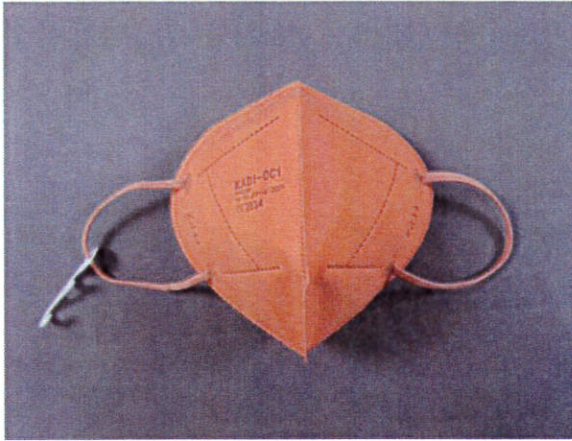
Subject	Face length	Face Width	Face Depth	Mouth Width
Yi	120	130	109	59
Gong	122	140	115	65
Yu	119	160	139	55
Hu	112	122	119	63
Xu	110	130	118	60
Deng	115	119	110	59
Zhang	112	123	113	55
Liu	103	130	100	50
Zhi	118	139	130	63
Fang	115	129	120	50
Chen	116	150	132	56
Lv	110	121	110	53

Test	Uncertainty
Total inward leakage	4.1%

End of Annex A

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ANNEX B PHOTOS OF SAMPLES



End of Annex B

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