

TEST REPORT 1:



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 Taoyuanling 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 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 (130*80mm) Date(s) of tests: 2020.05.19-2020.06.03

DESCRIPTION OF SAMPLES

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

Signed: [Signature] Issued: 2020.6.3 Page 1 of 10 Authorized Signatory, Lab Director 陈焯为 Chen Zhuowei



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Conditions:

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Test Results

7.3 Visual inspection

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.

Not tested¹

7.4 Package

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.

Pass²

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.

Pass³

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.

N/A⁴

7.6 Cleaning and disinfecting

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

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

Note5: No imperfections.

Pass⁵

7.8 Finish of parts

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.

Pass⁶

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

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

7.9.2 Penetration of filter material

The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

Sodium chloride test 95 l/min

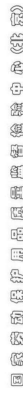
FFP1 ≤20%

Paraffin oil test 95 l/min

≤20%

Pass⁸

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FFP2 ≤6%

FFP3 ≤1%

≤6%

≤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 or any other adverse effect to health.

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

Pass⁹

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.

Pass¹⁰

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.

Pass¹¹

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.

Pass¹²

7.14 Field of vision

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

Note13: Pass the practical performance tests.

Pass¹³

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/A¹⁴

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

Classification	Maximum permitted resistance (mbar)		
	Inhalation	Exhalation	Exhalation
FFP1	30 l/min	95 l/min	160 l/min
FFP2	0.6	2.1	3.0
FFP3	0.7	2.4	3.0
	1.0	3.0	3.0

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

Pass¹⁵

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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: 7 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

FFP1 ≤20%

FFP2 ≤6%

FFP3 ≤1%

Note16: Single shift use only.

Paraffin oil test 95 l/min

≤20%

≤6%

≤1%

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.

Pass¹⁷**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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Report No: 2020 (D) - 0778

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

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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 50 individual exercise results were not greater than 11.1%
8 out of 10 individual wearer arithmetic means were not greater than 8.8%
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

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	
Paraffin oil test	Mechanical strength+ Temperature conditioned	17	0.772	
		18	0.841	
		19	0.714	
	As received	20	4.61	
		21	4.55	
		22	4.76	
Simulated wearing treatment	As received	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	

Table 7.12 Carbon dioxide content of the inhalation air

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

ANNEX B PHOTOS OF SAMPLES



End of Annex B


Table 7.16 Breathing resistance (mbar)

Condition	Flow rate	36					37					38															
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E											
		Inhalation	0.4	0.5	0.5	0.5	0.6	0.4	0.5	0.6	0.4	0.5	0.5	0.6	0.6	0.5	0.4	0.4	0.5	0.5	0.5	0.6	0.4	0.5	0.5	0.6	0.6
As received	95 l/min	1.6	1.6	1.8	1.6	1.8	1.7	1.7	1.8	1.6	1.6	1.6	1.6	1.8	1.7	1.6	1.8	1.7	1.6	1.8	1.7	1.6	1.8	1.7	1.6	1.8	1.7
	Exhalation	1.9	2.1	1.9	1.9	2.1	1.9	2.0	2.1	2.0	2.1	2.1	2.0	2.1	2.1	2.0	2.0	2.1	2.1	2.0	2.1	2.1	2.0	2.1	2.1	2.0	2.1
Simulated wearing treatment	30 l/min	39					40					41															
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E											
	Inhalation	0.6	0.6	0.4	0.5	0.5	0.6	0.4	0.5	0.4	0.5	0.4	0.6	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Temperature conditioned	95 l/min	1.8	1.8	1.8	1.8	1.7	1.6	1.7	1.7	1.7	1.7	1.8	1.6	1.8	1.7	1.6	1.7	1.8	1.8	1.7	1.6	1.7	1.8	1.7	1.6	1.7	1.7
	Exhalation	2.1	2.0	2.0	2.0	2.0	1.9	2.0	2.1	2.0	2.0	2.0	2.0	2.0	2.0	2.0	1.9	2.1	2.0	2.0	2.0	2.0	2.0	1.9	2.1	2.0	2.0
Assessment	Flow rate	42					43					44															
		A	B	C	D	E	A	B	C	D	E	A	B	C	D	E											
	Inhalation	0.6	0.4	0.5	0.4	0.4	0.4	0.4	0.4	0.5	0.4	0.5	0.4	0.5	0.4	0.6	0.6	0.4	0.4	0.5	0.4	0.5	0.4	0.6	0.6	0.4	0.4
Assessment	95 l/min	1.7	1.8	1.6	1.7	1.8	1.8	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.8	1.7	1.7	1.6	1.7	1.6	1.7	1.6	1.7	1.6	1.7	1.6	1.7
	Exhalation	2.1	1.9	2.0	2.0	2.0	2.1	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	1.9	1.9	2.0	2.0	2.0	2.0	2.0	1.9	1.9	2.1	2.0	2.0

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

End of Annex A

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 <i>Huigang Cai</i>
Approved by (name + signature) ..:	: Shumei Cao <i>Shumei Cao</i>
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, Qianrong East Industrial Zone, Jiuwei Community, Xixiang Street, Baoan District, Shenzhen City, Guangdong Province, China.
Applicant's name.....	: Hefei Kadi bio Pharmaceutical Co., Ltd.
Address.....	: Building 003, 3# North of Xiweisan Road, West Outer 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	: KN95 Mask
Model/Type reference	: KN95FFP2, FFP3

Classification.....	: <input type="checkbox"/> FFP1 <input checked="" type="checkbox"/> FFP2 <input type="checkbox"/> FFP3
List of Attachments (including a total number of pages in each attachment):	: This report has total 25 numbers, include annex I, Annex I: Photos documents, 1 page.
Summary of testing: tests performed (name of test and test clause)	: The tested samples comply with the requirements of EN 149:2001+A1:2009.
Summary of compliance with National Differences	: National differences for Europe groups were taken into account.
Copy of marking plate	<div style="border: 1px solid black; padding: 10px; text-align: center;">  <p>KN95 Mask Model: KN95FFP2, FFP3 EN 149:2001+A1:2009 FFP2</p> <p>Manufacturer: Hefei Kadi bio Pharmaceutical Co., Ltd Address: Building 003, 3# North of Xiweisan Road, West Outer Ring, Economic Development Zone, Feidong County, Hefei, China</p> </div> <p>Note: - The Markings are attached on external enclosure and visible during normal use. - The height of CE mark should be minimum 5,0mm. - The importer name and address were marked on the product.</p>

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

Date of receipt of test item : 2020-03-16
 Date (s) of performance of tests : 2020 03-16 to 2020-03-26

General remarks:

The test results presented in this report relate only to the object tested.
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 "(See Enclosure #)" refers to additional information appended to the report.
 "(See appended table)" refers to a table appended to the report.

Throughout this report a comma / point is used as the decimal separator.

General product information:

1. This production, named KN95 Mask
2. All models have similar construction and performance, only different with appearance.

Clause	Requirement + Test	Result - Remark	Verdict
4	Description		—
	A particle filtering half mask covers the nose and mouth and the chin and may have inhalation and/or exhalation valve(s).		P
	The half mask consists entirely or substantially of filter material or facepiece in which the main filter(s) form an inseparable part of the device.		P
	It is intended to provide adequate sealing on the face of the wearer against the ambient atmosphere, when the skin is dry or moist and when the head is moved.		P
	Air enters the particle filtering half mask and passes directly to the nose and mouth area of the facepiece or, via an inhalation valve(s) if fitted.		P
5	The exhaled air flows through the filter material and/or an exhalation valve (if fitted) directly to the ambient atmosphere.		P
	These devices are designed to protect against both solid and liquid aerosols.		P
	Classification		—
	Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage.		P
	There are three classes of devices: FFP1, FFP2 and FFP3	FFP2	P
6	The protection provided by an FFP2 - or FFP3 - device includes that provided by the device of lower class or classes.		P
	In addition, particle filtering half masks are classified as single shift use only or as re-usable (more than one shift)."		P
	Designation		—
	Particle filtering half masks meeting the requirements of this European Standard shall be designated in the following manner:		P
	Particle filtering half mask EN 149, year of publication, classification, option (where "D" is an option for a non re-usable particle filtering half mask and mandatory for re-usable particle filtering half mask).		P
7	Requirements		—
	General		P
	In all tests all test samples shall meet the requirements.		P
	7.2 Nominal values and tolerances		P
	Unless otherwise specified, the values stated in this European Standard are expressed as nominal values.		P
Except for temperature limits, values which are not stated as maxima or minima shall be subject to a		P	

Clause	Requirement + Test	Result - Remark	Verdict
EN 149			
	-3 samples after the simulated wearing treatment described in 8.3.1. Testing in accordance with 8.11 using the Exposure test with a specified mass of test aerosol of 120 mg, and for particle filtering devices claimed to be re-usable additionally the Storage test, according to EN 13274-7, shall be performed. -for non-re-usable devices on:		P
	-3 samples after the test for mechanical strength in accordance with 8.3.3 followed by temperature conditioning in accordance with 8.3.2.		P
	-for re-usable devices on:		N/A
	-3 samples after the test for mechanical strength in accordance with 8.3.3 followed by temperature conditioning in accordance with 8.3.2 and followed by one cleaning and disinfecting cycle according to the manufacturer's instruction.		N/A
	Compatibility with skin		P
	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.		P
	Testing shall be done in accordance with 8.4 and 8.5.		P
7.11	Flammability The material used shall not present a danger for the wearer and shall not be of highly flammable nature. When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5s after removal from the flame. The particle filtering half mask does not have to be usable after the test.		P
	Testing shall be done in accordance with 8.6.		P
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). Testing shall be done in accordance with 8.7.		P
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.		P

Clause	Requirement + Test	Result - Remark	Verdict
EN 149			
	Testing shall be done in accordance with 8.4 and 8.5.		P
7.14	Field of vision The field of vision is acceptable if determined so in practical performance tests. Testing shall be done in accordance with 8.4.		P
7.15	Exhalation valve(s) A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations. Testing shall be done in accordance with 8.2 and 8.9.1. 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. Testing shall be done in accordance with 8.2.		N/A
	Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30s.		N/A
	Testing shall be done in accordance with 8.3.4.		N/A
	When the exhalation valve housing is attached to the faceplate, it shall withstand axially a tensile force of 10 N applied for 10s.		N/A
	Testing shall be done in accordance with 8.8.		N/A
7.16	Breathing resistance The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 2. Testing shall be done in accordance with 8.9.		P
7.17	Clogging		P
7.17.1	General For single shift use devices, the clogging test is an optional test. For re-usable devices the test is mandatory.		N/A
	Devices designed to be resistant to clogging, shown by a slow increase of breathing resistance when loaded with dust, shall be subjected to the treatment described in 8.10.		P
	The specified breathing resistances shall not be exceeded before the required dust load of 833 mg/m ³ is reached.		P

Clause	Requirement + Test	Result - Remark	Verdict
EN 149			
7.17.2	Breathing resistance		P
7.17.2.1	Valved particle filtering half masks After clogging the inhalation resistances shall not exceed - FFP1: 4 mbar - FFP2: 5 mbar - FFP3: 7 mbar at 95 l/min continuous flow, The exhalation resistance shall not exceed 3 mbar at 160 l/min continuous flow. Testing shall be done in accordance with 8.9.		N/A
7.17.2.2	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 95 l/min continuous flow. Testing shall be done in accordance with 8.9.		N/A
7.17.3	Penetration of filter material All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements given in 7.9.2, for the Penetration test according to EN 13274-7, after the clogging treatment. Testing shall be done in accordance with 8.11 using EN 13274-7		P
7.18	Demountable parts All demountable parts (if fitted) shall be readily connected and secured, where possible by hand. Testing shall be done in accordance with 8.2.		P
8	Testing		-
8.1	General If no special measuring devices and methods are specified, commonly used devices and methods shall be used. Before performing tests involving human subjects account should be taken of any national regulations concerning the medical history, examination or supervision of the test subjects.		P

Clause	Requirement + Test	Result - Remark	Verdict
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8.2	Visual inspection		P
	The visual inspection is carried out where appropriate by the test house prior to laboratory or practical performance tests.		P
8.3	Conditioning		P
8.3.1	Simulated wearing treatment Conditioning by simulated wearing treatment shall be carried out by the following process. A breathing machine is adjusted to 25 cycles/min and 2.0 l/stroke. The particle filtering half mask is mounted on a sheffield dummy head. For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head, the saturator being set at a temperature in excess of 37 °C to allow for the cooling of the air before it reaches the mouth of the dummy head. The air shall be saturated at (37 ±2) °C at the mouth of the dummy head. In order to prevent excess water spilling out of the dummy's mouth and contaminating the particle filtering half mask the head shall be inclined so that the water runs away from the mouth and is collected in a trap. The breathing machine is brought into operation, the saturator switched on and the apparatus allowed to stabilize. The particle filtering half mask under test shall then be mounted on the dummy head. During the test time at approximately 20 min intervals the particle filtering half mask shall be completely removed from the dummy head and refitted such that during the test period it is fitted ten times to the dummy head.		P
8.3.2	Temperature conditioning Expose the particle filtering half masks to the following thermal cycle: a) for 24 h to a dry atmosphere of (70 ±3) °C; b) for 24 h to a temperature of (-30 ±3) °C; and allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing. The conditioning shall be carried out in a manner which ensures that no thermal shock occurs. Mechanical strength		P
8.3.3			P

Conditioning shall be done in accordance with EN 143.	P
Flow conditioning	N/A

Clause	Requirement + Test	Result - Remark	Verdict
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8.4	A total of 3 valved particle filtering half masks shall be tested, one as received and two temperature conditioned in accordance with 8.3.2.		N/A
8.4.1	Practical performance		P
8.4.1	General		P
8.4.1.1	A total of 2 particle filtering half masks shall be tested, both as received.		P
8.4.1.1.1	All tests shall be carried out by two test subjects at ambient temperature and the test temperature and humidity shall be recorded.		P
8.4.1.1.2	Prior to the test there shall be an examination to assure that the particle filtering half mask is in good working condition and that it can be used without hazard.		P
8.4.1.1.3	Examination shall be done in accordance with 8.2.		P
8.4.1.1.4	For the test, persons shall be selected who are familiar with using such or similar equipment.		P
8.4.1.1.5	During the tests the particle filtering half mask shall be subjectively assessed by the wearer and after the test, comments on the following shall be recorded:		P
8.4.1.1.5.1	a) head harness comfort;		P
8.4.1.1.5.2	b) security of fastenings;		P
8.4.1.1.5.3	c) field of vision;		P
8.4.1.1.5.4	d) any other comments reported by the wearer on request.		P
8.4.2	Walking test		P
8.4.2.1	The subjects wearing normal working clothes and wearing the particle filtering half mask shall walk at a regular rate of 6 km/h on a level course.		P
8.4.2.1.1	The test shall be continuous, without removal of the particle filtering half mask, for a period of 10 min.		P
8.4.3	Work simulation test		P
8.4.3.1	The particle filtering half mask shall be tested under conditions which can be expected during normal use.		P
8.4.3.1.1	During this test the following activities shall be carried out in simulation of the practical use of the particle filtering half mask.		P
8.4.3.1.2	The test shall be completed within a total working time of 20 min.		P
8.4.3.1.3	The sequence of activities is at the discretion of the test house.		P

The individual activities shall be arranged so that sufficient time is left for the comments prescribed.	P
a) walking on the level with headroom of (1.3 ± 0.2) m for 5 min;	P

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b) crawling on the level with headroom of (0.70 ± 0.05) m for 5 min;			P
c) filling a small basket (see Figure 1, approximate volume = 8 l) with chippings or other suitable material from a hopper which stands 1.5 m high and has an opening at the bottom to allow the contents to be shovelled out and a further opening at the top where the basket full of chippings is returned.			P
The subject shall stoop or kneel as he wishes and fill the basket with chippings.			P
He shall then lift the basket and empty the contents back into the hopper.			P
This shall be done 20 times in 10 min.			P
8.5	Leakage		P
8.5.1	General test procedure		P
8.5.1.1	Total inward leakage		P
8.5.1.1.1	A total of 10 test specimens shall be tested: 5 as received and 5 after temperature conditioning in accordance with 8.3.2.		P
8.5.1.1.2	The total inward leakage shall be tested using sodium chloride aerosol.		P
8.5.1.1.3	Prior to the test there shall be an examination to ensure that the particle filtering half mask is in good working condition and that it can be used without hazard.		P
8.5.1.1.4	Examination shall be done in accordance with 8.2.		P
8.5.1.1.5	For the test, persons shall be selected who are familiar with using such or similar equipment.		P
8.5.1.1.5.1	A panel of ten clean-shaven persons (without beards or sideburns) shall be selected covering the spectrum of facial characteristics of typical users (excluding significant abnormalities).		P
8.5.1.1.5.2	It is to be expected that exceptionally some persons cannot be satisfactorily fitted with a particle filtering half mask.		P
8.5.1.1.5.3	Such exceptional subjects shall not be used for testing particle filtering half masks.		P
8.5.1.1.5.4	In the test report the faces of the ten test subjects shall be described (for information only) by the four facial dimensions (in mm) illustrated in Figure 2.		P
8.5.1.2	Test equipment		P
8.5.1.2.1	The test atmosphere shall preferably enter the top of the enclosure through a flow distributor, and be		P

Clause	Requirement + Test	Result - Remark	Verdict
	directed downwards over the head of the test subject at a minimum flow rate of 0,12 m/s. The concentration of the test agent inside the effective working volume shall be checked to be homogeneous.		P
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Clause	Requirement + Test	Result - Remark	Verdict
	The flow rate should be measured close to the subject's head. A level treadmill is required capable of working at 6 km/h.		P
8.5.1.3	Test procedure Ask the test subjects to read the manufacturer's fitting information and if more than one size of particle filtering half mask is manufactured, ask the test subject to select the size deemed by him to be the most appropriate. If necessary the test supervisor shall show the test subjects how to fit the particle filtering half mask correctly in accordance with the fitting information. Inform the test subjects that if they wish to adjust the particle filtering half mask during the test they may do so. However if this is done, repeat the relevant section of the test, having allowed the system to resettle. The test subjects shall have no indication of the results as the test proceeds. After fitting the particle filtering half mask, ask each test subject 'Does the mask fit'. If the answer is 'Yes', continue the test. If the answer is 'No', take the test subject off the panel, report the fact and replace with another test subject. The test sequence shall be as follows:		P
	a) Ensure the test atmosphere is OFF.		P
	b) Place the test subject in the enclosure. Connect up the facepiece sampling probe. Have the test subject walk at 6 km/h for 2 min. Measure the test agent concentration inside the particle filtering half mask to establish the background level.		P
	c) Obtain a stable reading.		P
	d) Turn the test atmosphere ON.		P
	e) The subject shall continue to walk for a further 2 min or until the test atmosphere has stabilized.		P
	f) Whilst still walking the subject shall perform the following exercises: 1) walking for 2 min without head movement or talking. 2) turning head from side to side (approx. 15		P

Clause	Requirement + Test	Result - Remark	Verdict
	times), as if inspecting the walls of a tunnel for 2 min. 3) moving the head up and down (approx. 15 times), as if inspecting the roof and floor for 2 min. 4) reciting the alphabet or an agreed text out loud as if communicating with a colleague for 2 min;		P
	5) walking for 2 min without head movement or talking.		P
	g) Record		P
	1) enclosure concentration;		P
	2) the leakage over each exercise period.		P
	h) Turn off the test atmosphere and when the test agent has cleared from the enclosure remove the subject.		P
	After each test, replace the particle filtering half mask by a new sample.		P
8.5.2	Method		P
8.5.2.1	Principle The subject wearing the particle filtering half mask under test walks on a treadmill over which is an enclosure. Through this enclosure flows a constant concentration of NaCl aerosol. The air inside the particle filtering half mask is sampled and analysed during the inhalation phase of the respiratory cycle to determine the NaCl content. The sample is extracted by punching a hole in the particle filtering half mask and inserting a probe through which the sample is drawn. The pressure variation inside the particle filtering half mask is used to actuate a change-over valve so that inhaled air only is sampled. A second probe is inserted for this purpose.		P
8.5.2.2	Test equipment (see Figure 3)		P
8.5.2.2.1	Aerosol generator The NaCl aerosol shall be generated from a 2% solution of reagent grade NaCl in distilled water. An atomizer equivalent to the type described should be used (see Figure 4). This requires an air flow rate of 100 l/min at a pressure of 7 bar. The atomizer and its housing shall be fitted into a duct through which a constant flow of air is maintained. It may be necessary to heat or dehumidify the air in order to obtain complete drying of the aerosol particles.		P

	The leakage P shall be calculated from measurements made over the last 100 s of each of the exercise periods to avoid carry over of results from one exercise to the other.		P
	$P(\%) = \frac{C_2}{C_1} \times \left(\frac{t_{IN} + t_{EX}}{t_{IN}} \right) \times 100$		P

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Clause	Requirement + Test	Result - Remark	Verdict
8.6	Measurement of C ₂ is preferably made using an integrating recorder.		P
	Flammability		P
	A total of four particle filtering half masks shall be tested: two in the state as received and two after temperature conditioning in accordance with 8.3.2		P
	The single burner test is carried out according to the following procedure.		P
	The facepiece is put on a metallic dummy head which is motorized such that it describes a horizontal circle with a linear speed, measured at the tip of the nose, of (60 ±5) mm/s.		P
	The head is arranged to pass over a propane burner the position of which can be adjusted.		P
	By means of a suitable gauge, the distance between the top of the burner, and the lowest part of the facepiece (when positioned directly over the burner) shall be set to (20 ±2) mm.		P
	A burner described in ISO 6947 has been found suitable.		P
	With the head turned away from the area adjacent to the burner, the propane gas is turned on, the pressure adjusted to between 0.2 bar and 0.3 bar and the gas ignited.		P
	By means of a needle valve and fine adjustments to the supply pressure, the flame height shall be set to (40 ±4) mm.		P
	This is measured with a suitable gauge.		P
	The temperature of the flame measured at a height of (20 ±2) mm above the burner tip by means of a 1.5 mm diameter mineral insulated thermocouple probe, shall be (800 ±50) °C.		P
	Failure to meet the temperature requirement indicates that a fault such as a partially blocked burner exists.		P
	This shall be rectified before testing.		P
	The head is set in motion and the effect of passing the facepiece once through the flame shall be noted.		P
	The test shall be repeated to enable an assessment to be made of all materials on the exterior of the device.		P

	Any one component shall be passed through the flame once only.		P
8.7	Carbon dioxide content of the inhalation air		P
	A total of 3 particle filtering half masks shall be tested: all 3 as received.		P
	The apparatus consists essentially of a breathing machine with solenoid valves controlled by the breathing machine, a connector, a CO ₂ flowmeter and a CO ₂ analyser.		P

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Clause	Requirement + Test	Result - Remark	Verdict
	The apparatus subjects the particle filtering half mask to a respiration cycle by the breathing machine.		P
	For this test the particle filtering half mask shall be fitted securely in a leak-tight manner, but without deformation to a Sheffield dummy head (see Figure 6).		P
	Air shall be supplied to it from a breathing machine adjusted to 25 cycles/min and 2.0 l/stroke and the exhaled air shall have a carbon dioxide content of 5 % by volume.		P
	A typical test arrangement is shown in Figure 7.		P
	If the design of the test equipment causes a CO ₂ build-up a CO ₂ absorber shall be used in the inhalation branch between solenoid valve and breathing machine.		P
	The CO ₂ is fed into the breathing machine via a control valve, a flowmeter, a compensating bag and two non-return valves.		P
	Immediately before the solenoid valve a small quantity of exhaled air is preferably continuously withdrawn through a sampling line and then fed into the exhaled air via a CO ₂ analyser.		P
	To measure the CO ₂ content of the inhaled air, 5 % of the stroke volume of the inhalation phase of the breathing machine is drawn off at the marked place by an auxiliary lung and fed to a CO ₂ analyser.		P
	The total dead space of the gas path (excluding the breathing machine) of the test installation should not exceed 2000 ml.		P
	Measure the carbon dioxide content of the inhaled air and record continuously.		P
	Test conditions are ambient atmospheric conditions.		P
	The ambient carbon dioxide level is measured 1 m in front of and level with the tips of the nose of the dummy head.		P
	The ambient level is measured once a stabilized level for carbon dioxide in the inhalation air has been attained.		P
	Alternatively, the ambient level of carbon dioxide may be measured at the sampling tube with the carbon dioxide supply turned off.		P

	Results are deemed acceptable only if the measured value of the ambient level of carbon dioxide is less than 0.1 %.	P
	The laboratory ambient carbon dioxide level shall be subtracted from the measured value.	P
	The air flow from the front shall be 0.5 m/s.	P
	For test arrangement see Figure 8.	P
	The test shall be performed until a constant carbon dioxide content in the inhalation air is achieved.	P

Clause	Requirement + Test	Result - Remark	Verdict
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8.8	Strength of attachment of exhalation valve housing		P
	A total of three particle filtering half masks shall be tested: one as received, one temperature conditioned in accordance with 8.3.2 and one after the test described for mechanical strength in EN 143.		P
	Mount the particle filtering half mask securely to a fixture as shown in Figure 9. Apply an axial tensile force of 10 N to the valve (housing) for 10 s, and note the results.		P
8.9	Breathing Resistance		P
8.9.1	Test samples and fixture		P
8.9.1.1	Valveless particle filtering half masks		P
	A total of 9 valveless particle filtering half masks shall be tested: 3 as received, 3 after temperature conditioning in accordance with 8.3.2 and 3 after the test for simulated wearing in accordance with 8.3.1		P
8.9.1.2	Valved particle filtering half masks		N/A
	A total of 12 valved particle filtering half masks shall be tested: 3 as received, 3 after temperature conditioning in accordance with 8.3.2, 3 after the test for simulated wearing in accordance with 8.3.1 and 3 after the flow conditioning in accordance with 8.3.4.		N/A
	The particle filtering half mask shall be fitted securely in a leaktight manner but without deformation on the Sheffield dummy head.		N/A
	The flow rate at which the resistance is measured shall be corrected to 23 °C and 1 bar absolute.		N/A
8.9.2	Exhalation resistance		P
	Seal the particle filtering half mask on the Sheffield dummy head.		P
	Measure the exhalation resistance at the opening for mouth of the dummy head using the adapter shown in Figure 6 and a breathing machine adjusted to 25 cycles/min and 2.0 l/stroke or a continuous flow 160 l/min.		P

	Use a suitable pressure transducer.	P
	Measure the exhalation resistance with the dummy head successively placed in 5 defined positions: -facing directly ahead	P
	-facing vertically upwards	P
	-facing vertically downwards	P
	-lying on the left side	P

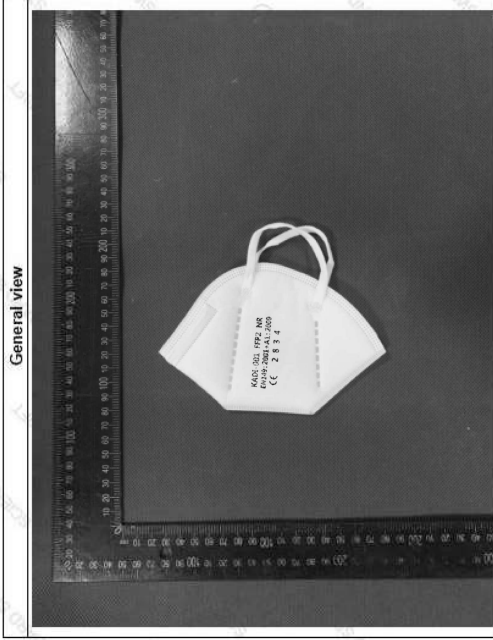
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	-lying on the right side		P
8.9.3	Inhalation resistance		P
	Test the inhalation resistance at 30 l/min and 95 l/min continuous flow.		P
8.10	Clogging		P
8.10.1	Principle		P
	The test aerosol shall be dolomite. A total of 3 particle filtering half masks shall be tested: 1 as received and 2 after temperature conditioning in accordance with 8.3.2.		P
	The test consists of subjecting the particle filtering half mask to a sinusoidal breathing simulation, whilst the sample is surrounded by a known concentration of dolomite dust in air.		P
	Following the exposure, the breathing resistance and the filter penetration of the sample particle filtering half mask are measured.		P
8.10.2	Test equipment		P
	A scheme of a typical apparatus is given in Figure 10.		P
	The working area of the test chamber has a suggested square section of 650 mm x 650 mm.		P
	The breathing machine has a displacement of 2.0 l/stroke.		P
	The exhaled air shall pass a humidifier in the exhaled air circuit, such that the exhaled air temperature, measured at the position of the sample particle filtering half mask is (37 ±2) °C and 95 % R.H. minimum.		P
8.10.3	Test conditions		P
	-Dust: DRB 4/15 dolomite		P
	The size distribution of dolomite dust is given in Table 3.		P
	The particle size distribution of the airborne dust at the working area of the dust chamber is given in Figure 11.		P

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	This characteristic is an essential parameter, which shall be verified especially if the geometry of the test chamber is somewhat different from the model described as follows: -Continuous flow through the dust chamber: 60 m ³ /h, linear velocity 4 cm/s. -Sinusoidal flow through the particle filtering half mask is delivered by a breathing machine adjusted to 15 cycles/min and 2.0 l/stroke, the exhaled air shall be saturated in humidity. -Concentration of the dust: (400 ± 100) mg/m ³ . -Temperature of the air: (23 ± 2) °C.		P
	-Relative humidity of the air: (45 ± 15) %; -Testing time: Until the product of measured dust concentration and exposure time is 833 mg·h/m ³ or until: 1) for valved particle filtering half masks the peak inhalation resistance (corresponding to a continuous flow of 95 l/min) has reached 4 mbar for class FFP1 or 5 mbar for class FFP2 or 7 mbar for class FFP3, or until the peak exhalation resistance has reached a 1.8 mbar (corresponding to 3 mbar at a continuous flow of 160 l/min). 2) for valveless particle filtering half masks the peak inhalation or the peak exhalation resistance has reached 3 mbar for class FFP1 or 4 mbar for class FFP2 or 5 mbar for class FFP3.		P
	Test procedure Convey dust from the distributor to the dust chamber where it is dispersed into the air stream of 60 m ³ /h. Fit the sample particle filtering half mask in a leaktight manner to a dummy head or a suitable filter holder located in the dust chamber. Connect the breathing machine and humidifier to the sample and operate for the specified testing time. The concentration of dust in the test chamber may be measured by drawing air at 2 l/min through a sampling probe equipped with a pre-weighed, high efficiency filter (open face, diameter 37 mm) located near the test sample, as shown in Figure 10. Calculate the dust concentration from the weight of dust collected, the flow rate through the filter and the time of collection. Other suitable means may be used.		N/A
8.10.4	Assessment of clogging Following the exposure, measure the breathing resistance of the particle filtering half mask using		P

Clause	Requirement + Test	Result - Remark	Verdict
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9	Clean air. Then measure the filter penetration in accordance with 8.11.		P
9.1	8.11 Penetration of filter material The device shall be mounted in a leaktight manner on a suitable adaptor and subjected to the test(s), ensuring that components of the device that could affect filter penetration values such as valves and harness attachment points are exposed to the challenge aerosol. Testing of penetration, exposure and storage shall be done in accordance with EN 13274-7.		P
9.1.1	Marking 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. The name, trademark or other means of identification of the manufacturer or supplier.		P
9.1.2	Type-identifying marking		P
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. "R", if the particle filtering half mask is re-usable.		P
9.1.4	The number and year of publication of this European Standard.	EN 149:2001+A1:2009	P
9.1.5	At least the year of end of shelf life.	2023/02	P
9.1.6	The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month. 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. The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.		P
9.1.7	The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter 'D'.	-20~38°C; 80%RH	P
9.1.8	This letter shall follow the classification marking preceded by a single space. Particle filtering half mask		P

Photos document



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