

CERTIFICATE OF CONFORMITY

Registration No.: QTC20N030015R

Technical Construction File No.: QTC20N030015-1RR

Certificate's Holder: GUANGDONG CHUNXIA NEW MATERIALS TECH CO.,LTD

No.1 Makeng New District Xinmalian Dalang Town.
Dongguan

Manufactured: GUANGDONG CHUNXIA NEW MATERIALS TECH CO.,LTD

No.1 Makeng New District Xinmalian Dalang Town.
Dongguan

Product: Kn95 Protective Mask

Model (S): Z40086

Trade Mark: N/A

Directives: R (EU)2016/425

Standard(s): EN 149:2001 + A1:2009

Remark: This Certificate of Compliance has been issued on a voluntary basis. QTC confirms that a Technical Construction File (TCF) is existent for the above listed product(s). The TCF satisfactorily covers the essential requirements of the above listed Directive(s).

Other relevant Directives have to be observed in case they are applicable.

This Document is only valid for the equipment and configuration described and in conjunction with the TCF detailed above. Whereas the Manufacturer is responsible of the certification of the product(s) and not exempted to perform all the necessary activities before placing the product(s) on the market.

The Manufacturer is also responsible of the internal production control to ensure the product(s) are in compliance with the essential requirements of the above mentioned Directive(s).

This certificate can be checked for validity at service@qtcclab.com



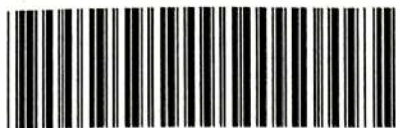
Certification Manager

Date of issue: Mar.12, 2020

QTC Certification & Testing Co., Ltd.

Address: 85 Guangshen Road, Baocheng 11st Zone, Xin'an Street, Bao'an, Shenzhen, Guangdong, China

TEST REPORT



No: 200094939

VERIFICATION WEBSITE: www.gtgc.net.cn

VERIFICATION CODE: XKCA-6843-54

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ISSUE DATE: 2020-04-29

APPLICANT: GUANGDONG CHUNXIA NEW MATERIALS TECH CO., LTD.

ADDRESS: NO. 1 MAKENG NEW DISTRICT, XINMALIAN, DALANG TOWN DONGGUAN GUANGDONG, CNINA

INFORMATION CONFIRMED BY APPLICANT:

KN95 PROTECTIVE MASK

QUANTITY: EIGHTY PIECES

STYLE NO. : 20200328

COLOUR: WHITE

SIZE: Z40086/FOLDING TYPE

DATE RECEIVED/DATE TEST STARTED: 2020-04-28

CONCLUSION:

VISUAL FIELD

M

FILTRATION EFFICIENCY TO NaCl PARTICULATE MATTER

M

INSPIRATORY RESISTANCE

M

EXPIRATORY RESISTANCE

M

FLAMMABILITY

M

HEAD BAND

M

APPEARANCE INSPECTION[2 PIECES]

M

NOTE: "M" -MEET THE STANDARD'S REQUIREMENT "F" -FAIL TO MEET THE STANDARD'S REQUIREMENT
"___" -NO COMMENT

REMARK:

THIS REPORT IS THE ENGLISH TRANSLATION VERSION OF THE REPORT 200056004.

THE AUTHORIZATION OF APPEARANCE INSPECTION IS NOT RECEIVED FROM CNAS.

ALL THE TESTED ITEMS ARE TESTED UNDER THE STANDARD CONDITION (EXCEPT FOR INDICATION).

COPIES OF THE REPORT ARE VALID ONLY RE-STAMPED.

THE EXPERIMENT WAS CARRIED OUT AT No.1, ZHUJIANG ROAD, PANYU DISTRICT, GUANGZHOU, GUANGDONG, P. R. CHINA.



APPROVED BY:

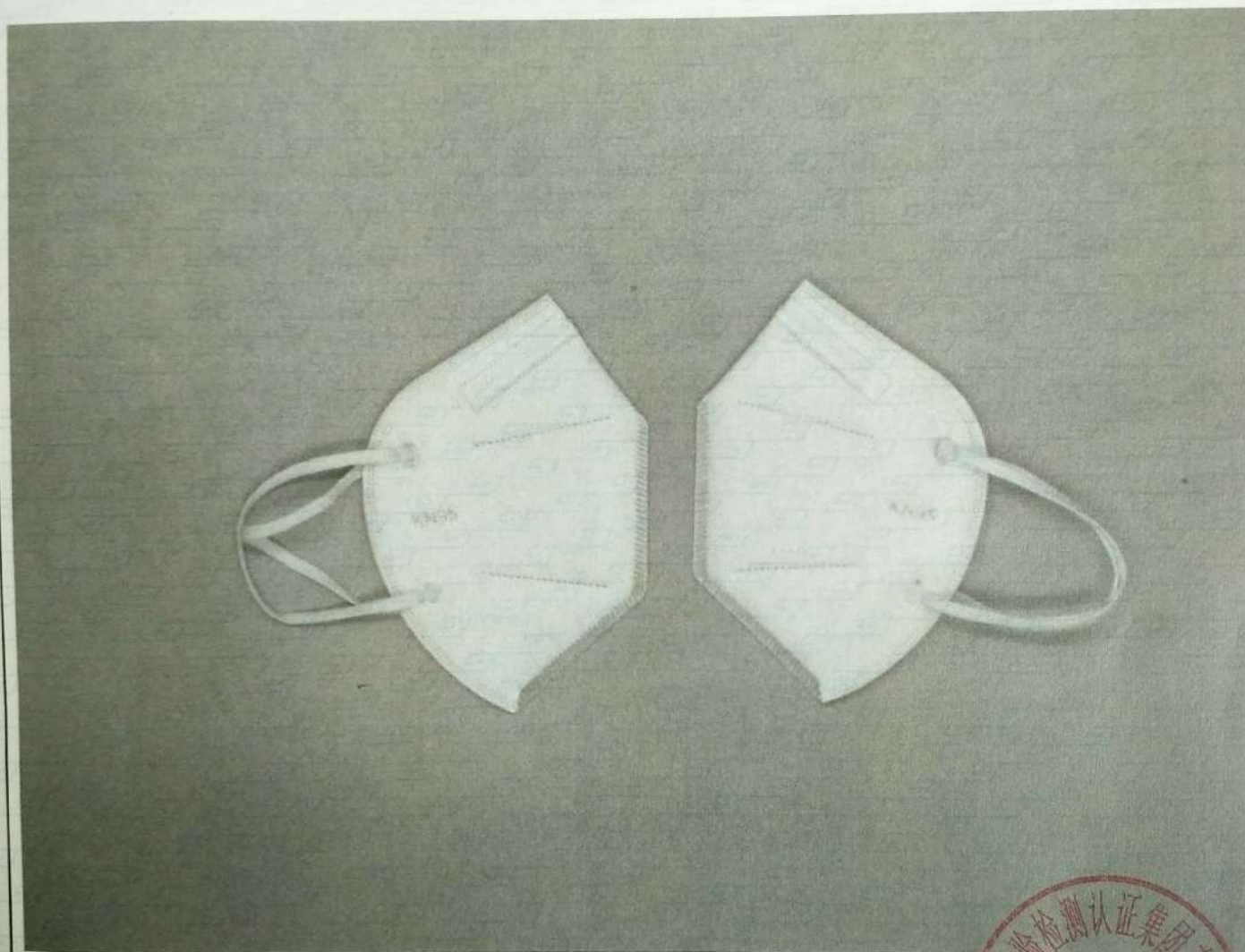
ZiShan Guo SENIOR ENGINEER

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VISUAL FIELD(°)

(GB 2890-2009 6.8)

70

REQUIREMENT

≥60

(GB 2626-2006)

FILTRATION EFFICIENCY TO NaCl PARTICULATE MATTER

(GB 2626-2006 6.3, AIR FLOW: 85L/min, AEROSOL: NaCl, AEROSOL CONCENTRATION: 15mg/m³,
TEMP: 23.1°C, RH: 36.0%)

FILTRATION EFFICIENCY(%) :

UNTREATED SAMPLE

1# 99.080

2# 99.270

3# 99.145

4# 99.362

5# 99.075

6# 99.158

7# 98.95

8# 99.075

9# 98.89

10# 99.172

CONDITIONING TREATED

1# 98.72

2# 97.48

3# 98.81

4# 98.36

5# 98.90

REQUIREMENT

FILTRATION EFFICIENCY(%) :

≥95.0

(KN95)

(GB 2626-2006)

INSPIRATORY RESISTANCE(Pa)

(GB 2626-2006 6.5, HEAD SIZE: MEDIUM)

UNTREATED SAMPLE:

1# 104.4

2# 107.9

PRETREATMENT SAMPLE:

1# 102.4

2# 104.7

REQUIREMENT

≤350

(GB 2626-2006)

EXPIRATORY RESISTANCE(Pa)

(GB 2626-2006 6.6, HEAD SIZE: MEDIUM)

UNTREATED SAMPLE:

1# 94.1

2# 95.8

PRETREATMENT SAMPLE:

1# 106.0

2# 101.3

REQUIREMENT

≤250

(GB 2626-2006)



TEST REPORT

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FLAMMABILITY(s)

(GB 2626-2006 6.15)

AFTERFLAME TIME
UNTREATED SAMPLE

1# 0.0

2# 0.0

CONDITIONING TREATED

3# 0.0

4# 0.0

REQUIREMENT

AFTERFLAME TIME

≤5

(GB 2626-2006)

HEAD BAND

(GB 2626-2006 6.11)

UNTREATED SAMPLE:

1# PASS

CONDITIONING TREATED:

1# PASS

REQUIREMENT

EACH HEAD BAND, BUCKLE AND OTHER ADJUST
PARTS OF MASK SHOULD NOT SLIP OR BREAK
UNDER 10N TENSION FOR 10S.

(GB 2626-2006)

APPEARANCE INSPECTION[2 PIECES]

(GB 2626-2006 6.1)

PASS

REQUIREMENT

ACCORDING TO THE CLAUSE 5.2 OF THE
PRODUCT STANDARD

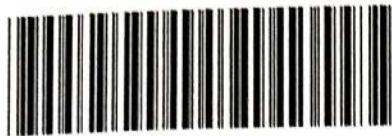
(GB 2626-2006)



—End of Report—

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TEST REPORT



No:200117138

VERIFICATION WEBSITE: www.gttc.net.cn

VERIFICATION CODE: CDLK-3313-24

ISSUE DATE:2020-05-11

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APPLICANT: GUANGDONG CHUNXIA NEW MATERIALS TECH CO., LTD.
ADDRESS: NO. 1 MAKENG NEW DISTRICT, XINMALIAN, DALANG TOWN DONGGUAN GUANGDONG, CNINA

INFORMATION CONFIRMED BY APPLICANT:

KN95 PROTECTIVE MASK

QUANTITY: TWENTY PIECES

STYLE NO. : 20200328

COLOUR: WHITE

SIZE: Z40086/FOLDING TYPE

DATE RECEIVED/DATE TEST STARTED: 2020-05-09

CONCLUSION:

DEAD SPACE

M

TOTAL INWARD LEAKAGE (TIL)

M

NOTE: "M" -MEET THE STANDARD'S REQUIREMENT "F" -FAIL TO MEET THE STANDARD'S REQUIREMENT
"----" -NO COMMENT

REMARK:

ALL THE ITEMS ARE SUBCONTRACTED AND TESTED BY Jiangsu Quality Supervision and Inspection Center for Special
Safety Protection Products(CMA No.: 171021110579).

THIS REPORT IS THE ENGLISH TRANSLATION VERSION OF THE REPORT 200056691.

ALL THE TESTED ITEMS ARE TESTED UNDER THE STANDARD CONDITION (EXCEPT FOR INDICATION).

COPIES OF THE REPORT ARE VALID ONLY RE-STAMPED.

THE EXPERIMENT WAS CARRIED OUT AT No.1, ZHUJIANG ROAD, PANYU DISTRICT, GUANGZHOU, GUANGDONG, P.R.CHINA.

APPROVED BY:

ZiShan Guo SENIOR ENGINEER

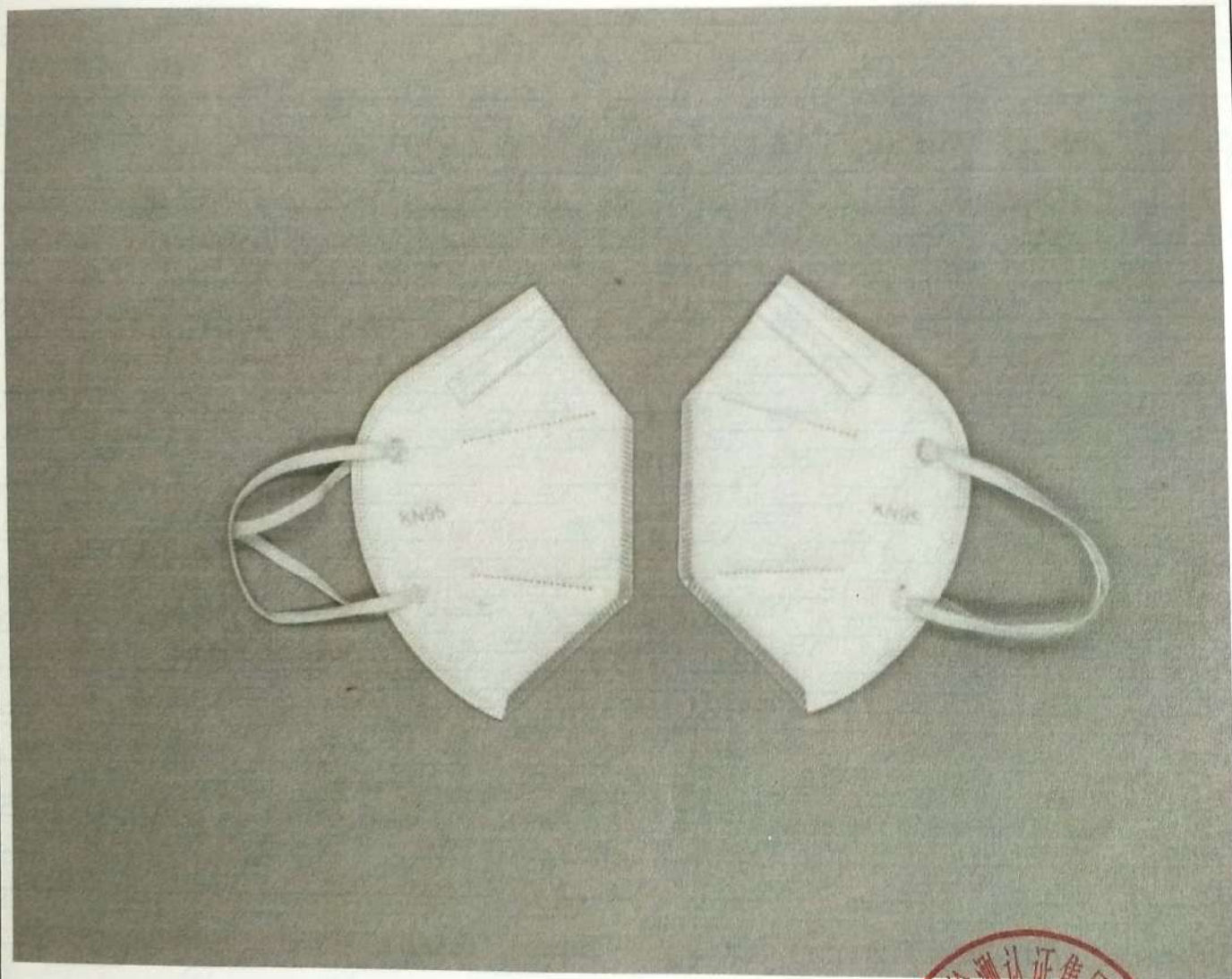
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DEAD SPACE

(GB 2626-2006 6.9)

CARBON DIOXIDE VOLUME FRACTION:0.5%

REQUIRMENT

CARBON DIOXIDE VOLUME FRACTION SHOULD NOT
BE MORE THAN 1%

(GB 2626-2006)



TEST REPORT

No: 200117138

TOTAL INWARD LEAKAGE (TIL)

 STANDARD ADOPTED: GB 2626-2006

REQUIREMENT	RESULT		JUDGEMENT
Based on the TIL of each action (i.e. 10 persons × 5 actions), the TIL of at least 46 actions out of 50 actions is less than 11% (KN95 Disposable facepiece)	UNTREATED SAMPLE		PASS
	1#	TIL of 47 actions is less than 11%	
	2#	TIL of 47 actions is less than 11%	
	3#	TIL of 47 actions is less than 11%	
	4#	TIL of 47 actions is less than 11%	
	5#	TIL of 47 actions is less than 11%	
	CONDITIONING TREATED		
	1#	TIL of 47 actions is less than 11%	
	2#	TIL of 47 actions is less than 11%	
	3#	TIL of 47 actions is less than 11%	
	4#	TIL of 47 actions is less than 11%	
	5#	TIL of 47 actions is less than 11%	
The total TIL of at least 8 out of 10 subjects is less than 8% based on the overall TIL of the subjects (KN95 Disposable facepiece)	UNTREATED SAMPLE		
	1#	TIL of 9 subjects is less than 8%	
	2#	TIL of 9 subjects is less than 8%	
	3#	TIL of 9 subjects is less than 8%	
	4#	TIL of 9 subjects is less than 8%	
	5#	TIL of 9 subjects is less than 8%	
	CONDITIONING TREATED		
	1#	TIL of 9 subjects is less than 8%	
	2#	TIL of 9 subjects is less than 8%	
	3#	TIL of 9 subjects is less than 8%	
	4#	TIL of 9 subjects is less than 8%	
	5#	TIL of 9 subjects is less than 8%	
REMARK	---		





Fiscal Year 2020 USA FDA CERTIFICATION OF REGISTRATION

This certifies that:

GUANGDONG CHUNXIA NEW MATERIALS TECH CO., LTD.
No. 1 Makeng New District, Xinmalian, Dalang Town, Dongguan,
Guangdong, 523797, China

has completed the FDA Establishment Registration (as manufacturer and foreign exporter) and Device Listing with the US Food & Drug Administration, through

MicroKy Services, LLC.

Owner/Operator Number: 10064803

Device Listings:

Listing Number	Product Code	Device Name ➤ Proprietary Name	Premarket Submission Type
D380086	KHA	MASK, SCAVENGING ➤ KN95 Protective Mask: Z40086	510(k) Exempt

MicroKy Services, LLC will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. MicroKy Services, LLC makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. MicroKy Services, LLC assumes no liability to any person or entity in connection with the foregoing.

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MicroKy Services, LLC



Executive Director
Issued: Mar. 27, 2020
Cert. No.: 2020032703
Expiration Date: Dec. 31, 2020

Test Report

EN 149:2001 + A1:2009	
Respiratory protective devices — Filtering half masks to protect against particles — Requirements, testing, marking	
Applicant's Name	GUANGDONG CHUNXIA NEW MATERIALS TECH CO.,LTD
Address	No.1 Makeng New District Xinmalian Dalang Town.Dongguan
Manufacturer	GUANGDONG CHUNXIA NEW MATERIALS TECH CO.,LTD
Address	No.1 Makeng New District Xinmalian Dalang Town.Dongguan
Testing Laboratory Name	QTC Certification & Testing Co., Ltd.
Address	85 Guangshen Road, Baocheng 11st Zone, Xin'an Street, Bao'an, Shenzhen, Guangdong
Test specification	
Standard :	EN 149:2001 + A1:2009
Test item description :	Kn95 Protective Mask
Model and/or type reference :	Z40086
Trade Mark	N/A
Rating(s) :	Folding type (Non sterile)
Test Date:	Feb.27, 2020 To Mar.12, 2020
Date of Report :	Mar.12, 2020
Report No.:	QTC20N030015-1RR
Test case verdicts	
Test case does not apply to the test object	N/A
Test item does meet the requirement	P(pass)
Test item does not meet the requirement	F(Fail)

Checked By:



(Nana Lin)

Approved By:



(Coco Tang)



EN 149			
Clause	Requirement + Test	Result - Remark	Verdict
4	<p>Description A particle filtering half mask covers the nose and mouth and the chin and may have inhalation and/or exhalation valve(s). The half mask consists entirely or substantially of filter material or comprises a facepiece in which the main filter(s) form an inseparable part of the device. 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. 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. The exhaled air flows through the filter material and/or an exhalation valve (if fitted) directly to the ambient atmosphere. These devices are designed to protect against both solid and liquid aerosols.</p>	No valve	P
5	<p>Classification Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage. There are three classes of devices: FFP1 FFP2 and FFP3</p>	FFP2	P
6	<p>Designation Particle filtering half masks meeting the requirements of this European Standard shall be designated in the following manner: Particle filtering half mask EN 149, year of publication, classification, option (where "D" is an option for a non re-useable particle filtering half mask and mandatory for re-useable particle filtering half mask)." EXAMPLE Particle filtering half mask EN 149:2001 FFP1 NR D</p>	FFP2 NR D	P
7	Requirements		P
7.1	<p>General In all tests all test samples shall meet the requirements.</p>		P
7.2	<p>Nominal values and tolerances Unless otherwise specified, the values stated in this European Standard are expressed as nominal values. Except for temperature limits, values which are not stated as maxima or minima shall be subject to a tolerance of $\pm 5\%$. Unless otherwise specified, the ambient temperature for testing shall be $(16-32)^{\circ}\text{C}$, and the temperature limits shall be subject to an accuracy of $\pm 1^{\circ}\text{C}$</p>	26°C	P
7.3	<p>Visual inspection The visual inspection shall also include the marking and the information supplied by the manufacturer.</p>		P
7.4	<p>Packaging 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. Testing shall be done in accordance with 8.2.</p>		P
7.5	<p>Material Materials used shall be suitable to withstand handling and wear over the period for which the particlfiltering half mask</p>		P

EN 149			
Clause	Requirement + Test	Result - Remark	Verdict
	is designed to be usedAfter undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or strapsThree particle filtering half masks shall be testedWhen conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapseAny material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearerTesting shall be done in accordance with 8.2		
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. Testing shall be done in accordance with 8.4 and 8.5. With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class. Testing shall be done in accordance with 8.11.	NR D	P
7.7	Practical performance The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections. Testing shall be done in accordance with 8.4.		P
7.8	Finish of parts Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs. Testing shall be done in accordance with 8.2.		P
7.9	Leakage		P
7.9.1	Total inward leakage The laboratory tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected.		P
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		P
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. 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 5 s after removal		P

EN 149			
Clause	Requirement + Test	Result - Remark	Verdict
	from the flame. The particle filtering half mask does not have to be usable after the test. Testing shall be done in accordance with 8.6.		
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. 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. 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. Testing shall be done in accordance with 8.3.4. When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s. Testing shall be done in accordance with 8.8.		N/A
7.16	Breathing resistance 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." 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. The specified breathing resistances shall not be exceeded before the required dust load of 833 mg•h/m ³ is reached.		P
7.17.2	Breathing resistance		P
7.17.2.1	Valved particle filtering half masks		N/A

EN 149			
Clause	Requirement + Test	Result - Remark	Verdict
	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 160l/min continuous flow. Testing shall be done in accordance with 8.9.		
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		P
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		P
8.1	General If no special measuring devices and methods are specified, commonly used devices and methods shall be used.		P
8.2	Visual inspection 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 cycle/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		P

EN 149			
Clause	Requirement + Test	Result - Remark	Verdict
	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		
8.3.2	<p>Temperature conditioning</p> <p>Expose the particle filtering half masks to the following thermal cycle:</p> <p>a) for 24 h to a dry atmosphere of $(70 \pm 3) ^\circ\text{C}$;</p> <p>b) for 24 h to a temperature of $(-30 \pm 3) ^\circ\text{C}$;</p> <p>and allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing.</p> <p>The conditioning shall be carried out in a manner which ensures that no thermal shock occurs.</p>		P
8.3.3	<p>Mechanical strength</p> <p>Conditioning shall be done in accordance with EN 143.</p>		P
8.3.4	<p>Flow conditioning</p> <p>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.</p>		N/A
8.4	Practical performance		P
8.4.1	<p>General</p> <p>A total of 2 particle filtering half masks shall be tested: both as received. All tests shall be carried out by two test subjects at ambient temperature and the test temperature and humidity shall be recorded. 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. Examination shall be done in accordance with 8.2. For the test, persons shall be selected who are familiar with using such or similar equipment.</p> <p>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> <p>a) head harness comfort</p> <p>b) security of fastenings,</p> <p>c) field of vision,</p> <p>d) any other comments reported by the wearer on request</p>		P
8.4.2	<p>Walking test</p> <p>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. The test shall be continuous, without removal of the particle filtering half mask, for a period of 10 min.</p>		P
8.4.3	<p>Work simulation test</p> <p>The particle filtering half mask shall be tested under conditions which can be expected during normal use. During this test the following activities shall be carried out in simulation of the practical use of the particle filtering half mask. The test shall be completed within a total working time of 20 min.</p> <p>The sequence of activities is at the discretion of the test house. The individual activities shall be arranged so that</p>		

EN 149			
Clause	Requirement + Test	Result - Remark	Verdict
	<p>sufficient time is left for the comments prescribed.</p> <p>a)walking on the level with headroom of(1, 3 \pm 0, 2)m for 5 min;</p> <p>b)crawling on the level with headroom of(0, 70 \pm 0,05)m for 5 min</p> <p>c)filling a small basket(see Figure 1, approximate volume=8)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> <p>The subject shall stoop or kneel as he wishes and fill the basket with chippings. He shall then lift the basket and empty the contents back into the hopper. 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	<p>Total inward leakage</p> <p>A total of 10 test specimens shall be tested: 5 as received and 5 after temperature conditioning in accordance with 8.3.2.</p> <p>The total inward leakage shall be tested using sodium chloride aerosol.</p> <p>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> <p>Examination shall be done in accordance with 8.2.</p> <p>For the test, persons shall be selected who are familiar with using such or similar equipment.</p> <p>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). It is to be expected that exceptionally some persons cannot be satisfactorily fitted with a particle filtering half mask. Such exceptional subjects shall not be used for testing particle filtering half masks.</p> <p>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>		P
8.5.1.2	<p>Test equipment</p> <p>The test atmosphere shall preferably enter the top of the enclosure through a flow distributor, and be 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. The flow rate should be measured close to the subject's head.</p> <p>A level treadmill is required capable of working at 6 km/h.</p>		P
8.5.1.3	<p>Test procedure</p> <p>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</p>		P

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Clause	Requirement + Test	Result - Remark	Verdict
	<p>supervisor shall show the test subjects how to fit the particle filtering half mask correctly in accordance with the fitting information.</p> <p>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 re settle.</p> <p>The test subjects shall have no indication of the results as the test proceeds.</p> <p>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.</p> <p>The test sequence shall be as follows:</p> <ol style="list-style-type: none"> Ensure the test atmosphere is OFF. 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. Obtain a stable reading. Turn the test atmosphere ON. The subject shall continue to walk for a further 2 min or until the test atmosphere has stabilized. Whilst still walking the subject shall perform the following exercises: <ol style="list-style-type: none"> walking for 2 min without head movement or talking; turning head from side to side (approx. 15 times), as if inspecting the walls of a tunnel for 2 min; moving the head up and down (approx. 15 times), as if inspecting the roof and floor for 2 min; reciting the alphabet or an agreed text out loud as if communicating with a colleague for 2 min; walking for 2 min without head movement or talking. Record <ol style="list-style-type: none"> enclosure concentration; the leakage over each exercise period. 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	<p>Principle</p> <p>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</p>		P

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	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.		
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
8.5.2.2.2	Test agent The mean NaCl concentration within the enclosure shall be (8 ± 4) mg/m ³ and the variation throughout the effective working volume shall be not more than 10 %. The particle size distribution shall be 0,02 µm to 2 µm equivalent aerodynamic diameter with a mass median diameter of 0,6 µm.		P
8.5.2.2.3	Flame photometer A flame photometer shall be used to measure the concentration of NaCl inside the particle filtering half mask. Essential performance characteristics for a suitable instrument are: a) It should be a flame photometer specifically designed for the direct analysis of NaCl aerosol; b) It should be capable of measuring concentrations of NaCl aerosol between 15 mg/ m ³ and 5 ng/ m ³ c) The total aerosol sample required by the photometer should not be greater than 15 /min, d) The response time of the photometer, excluding the sampling system, should not be greater than 500ms; e) It is necessary to reduce the response to other elements, particularly carbon, the concentration of which will vary during the breathing cycle. This will be achieved by ensuring that the band pass width of the interference filter is no greater than 3 nm and that all necessary side-band filters are included.		P
8.5.2.2.4	Sample selector A system is required which will switch the sample to the photometer only during the inhalation phase of the respiratory cycle. During the exhalation phase clean air shall be fed to the photometer. The essential elements of such a system are: a) An electrically operated valve with a response time of the order of 100 ms. The valve should have the minimum possible dead space compatible with straight-through, unrestricted flow when open; b) A pressure sensor which is capable of detecting a minimum pressure change of approx 0,05 mbar and which		P

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	<p>can be connected to a probe inserted in the cavity of the particle filtering half mask. The sensor shall have an adjustable threshold and be capable of differential signalling when the threshold is crossed in either direction. The sensor shall work reliably when subjected to the accelerations produced by the head movements of the subject;</p> <p>c) An interfacing system to actuate the valve in response to a signal from the pressure sensor;</p> <p>d) timing device to record the proportion of the total respiratory cycle during which sampling took place;</p>		
8.5.2.2.5	<p>Sampling probe The probe shall be fitted securely in an airtight manner to the particle filtering half mask as near as possible to the centre line of the particle filtering half mask. A multiple hole sampling probe is strongly recommended. Measures shall be taken to prevent the influence of condensation in the sampling probe on the measurement (by supplying dry air). Figure 5 shows a design that has been found suitable. The probe is adjusted so that it just touches the wearer's lips. Care shall be taken to ensure that the probe does not disturb the normal fit or shape of the mask.</p>		P
8.5.2.2.6	<p>Sample pump If no pump is incorporated into the photometer an adjustable flow pump is used to withdraw an air sample from the particle filtering half mask under test. This pump is so adjusted as to withdraw a constant flow of 1 l/min from the sample probe. Dependent on the type of photometer it may be necessary to dilute the sample with clean air.</p>		P
8.5.2.2.7	<p>Sampling of enclosure concentration The enclosure aerosol concentration is monitored during the tests using a separate sampling system, to avoid contamination of the particle filtering half mask sampling lines. It is preferable to use a separate flame photometer for this purpose. If a second photometer is not available, sampling of the enclosure concentration using a separate sampling system and the same photometer may be made. However, time will then be required to allow the photometer to return to a clean background.</p>		P
8.5.2.2.8	<p>Pressure detection probe A second probe is fitted near to the sample probe and is connected to the pressure sensor.</p>		P
8.5.2.3	<p>Expression of results 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
8.6	<p>Flammability 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. The single burner test is carried out according to the</p>		P

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	<p>following procedure. 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> <p>The head is arranged to pass over a propane burner the position of which can be adjusted. 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> <p>A burner described in ISO 6941 has been found suitable. 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. By means of a needle valve and fine adjustments to the supply pressure, the flame height shall be set to (40 ± 4) mm. This is measured with a suitable gauge. 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> <p>Failure to meet the temperature requirement indicates that a fault such as a partially blocked burner exists. This shall be rectified before testing. The head is set in motion and the effect of passing the facepiece once through the flame shall be noted. The test shall be repeated to enable an assessment to be made of all materials on the exterior of the device. Any one component shall be passed through the flame once only.</p>		
8.7	<p>Carbon dioxide content of the inhalation air</p> <p>A total of 3 particle filtering half masks shall be tested: all 3 as received. The apparatus consists essentially of a breathing machine with solenoid valves controlled by the breathing machine, a connector, a CO₂ flowmeter and a CO₂ analyser. The apparatus subjects the particle filtering half mask to a respiration cycle by the breathing machine. 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> <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. A typical test arrangement is shown in Figure 7. If the design of the test equipment causes a CO₂ build-up a CO₂ absorber shall be used in the inhalation branch between solenoid valve and breathing machine. The CO₂ is fed into the breathing machine via a control valve, a flowmeter, a compensating bag and two non-return valves.</p> <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 CO₂ analyser. To measure the CO₂ 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</p>		P

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	<p>auxiliary lung and fed to a CO₂ analyser. The total dead space of the gas path(excluding the breathing machine)of the test installation should not exceed 2000 ml.Measure the carbon dioxide content of the inhaled air and record continuously.Test conditions are ambient atmospheric conditions.</p> <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. The ambient level is measured once a stabilized level for carbon dioxide in the inhalation air has been attained. Alternatively, the ambient level of carbon dioxide may be measured at the measured value of the ambient level of carbon dioxide is less than 0,1%. The laboratory ambient carbon dioxide level shall be subtracted from the measured value.The air flow from the front shall be 0.5 m/s.For test arrangement see Figure 8.The test shall be performed until a constant carbon dioxide content in the inhalation air is achieved.</p>		
8.8	<p>Strength of attachment of exhalation valve housing</p> <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> <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>		N/A
8.9	Breathing Resistance		P
8.9.1	Test samples and fixture		P
8.9.1.1	<p>Valveless particle filtering half masks</p> <p>A total of 9 valveless particle filtering™ half masks shall be tested:</p> <p>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>		P
8.9.1.2	<p>Valved particle filtering half masks</p> <p>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 8.3.1and 3 after the flow conditioning in accordance with 8.3.4.</p> <p>The particle filtering half mask shall be fitted securely in a leaktight manner but without deformation on the Sheffield dummy head.</p> <p>The flow rate at which the resistance is measured shall be corrected to 23°C and 1 bar absolute.</p>		N/A
8.9.2	<p>Exhalation resistance</p> <p>Seal the particle filtering half mask on the Sheffield dummy head. 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 2.0l/ stroke or a continuous flow 160 l/min. Use a suitable pressure transducer.Measure the exhalation resistance with the dummy head successively placed in 5 defined positions;facing directly ahead facing vertically</p>		P

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	upwards facing vertically downwards lying on the left side ying on the right side		
8.9.3	Inhalation resistance Test the inhalation resistance at 30 l/min and 95 l/min continuous flow.		P
8.10	Clogging		P
8.10.1	Principle 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. 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. 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 A scheme of a typical apparatus is given in Figure 10. The working area of the test chamber has a suggested square section of 650 mm × 650 mm. The breathing machine has a displacement of 2,0 l/stroke. 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 Dust: DRB 4/15 dolomite The size distribution of dolomite dust is given in Table 3		P
8.10.4	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 2l /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.		P
8.10.5	Assessment of clogging Following the exposure, measure the breathing resistance of the particle filtering half mask using clean air. Then measure the filter penetration in accordance with 8.11.		P
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		P

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	be done in accordance with EN 13274-7.		
9	Marking		P
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.		P

Table 1 — Penetration of filter material

Classification	A ₁ Maximum penetration of test aerosol A ₁	
	Sodium chloride test 95 l/min % max.	Paraffin oil test 95 l/min % max.
FFP1	20	20
FFP2	6	6
FFP3	1	1

Table 2 — Breathing resistance

Classification	Maximum permitted resistance (mbar)		
	inhalation		exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0,6	2,1	3,0
FFP2	0,7	2,4	3,0
FFP3	1,0	3,0	3,0

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Table 3 — Size distribution of dolomite dust

Coulter counter		Sedimentation analysis	
Size (equivalent spherical diameter) μm	% Number particles oversize	Size (Stokes diameter) μm	% weight oversize
0,7	100	1	99,5
1	80	2	97,5
2	30	3	95
3	17	5	85
5	7	8	70
		10	50
9	2	12	26
		14	10
12	1	18	1

ANNEX A:

Photo-documentation



---The end of report---