Review Report – 审查报告 – 검토 보고서 – Rapport d'Evaluation

CE Documentation Review

No. 0P200319T.HBA0058

Holder:	**Hunan Bei'er An'qin Medical Technology Co., Ltd.** No. 502 Juxing Chuangye Jidi, No.8 Lujing Road, Changsha High-tech development Zone, Changsha City, Hunan Province, China
Review goal:	Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Annex VII
Product:	Disposable Medical masks (no sterile)
Model(s):	\
Classification:	Class I (no sterile) (accordingly to the Manufacturer's declaration)
Review output:	We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process. Technical File identified with the no. TMHN20031322435. The manufacturer is responsible for the CE Marking process and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 19 March 2020

Expiry date: 18 March 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Bedonni

Certificate of Compliance

No. 0P200319T.HBA0059

Technical Construction File no. TPHN20031322436

Certificate's Holder:	Hunan Bei'er An'qin Medical Technology Co., Ltd. No. 502 Juxing Chuangye Jidi, No.8 Lujing Road, Changsha High-tech development Zone, Changsha City, Hunan Province, China
Certification ECM Mark:	ENTE CERTIFICAZIONE MACCHINE – European Conformity – SAFETY COMPLIANCE MARK – Type Approved
Product:	Disposable protective masks
Model(s):	\
Verification to:	Standard: EN 149: 2001+A1:2009 related to CE Directive(s): R2016/425 (Personal Protective Equipment)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:

CE

The manufacturer is responsible for the CE Marking process. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 19 March 2020

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Technical Construction File
EN 14683: 2019
Medical face masks - Requirements and test methods

Report reference No.	TMHN20031222435
Compiled by (+ signature)	Stephen Zhang / Test Engineer
Approved by (+ signature)	Kosco Vent / Project Manager
Date of issue	March 19,2020
Reviewing laboratory	Shanghai Global Testing Services Co., Ltd.
Reviewing location	Floor 2nd, Building D-1, No. 128, Shenfu Road, Minhang District, Shanghai, China.
Applicant	Hunan Bei’er An’qin Medical Technology Co., Ltd.
Address	No. 502 Juxing Chuangye Jidi, No.8 Lujing Road, Changsha High-tech development Zone, Changsha City, China
Manufacturer	Hunan Bei’er An’qin Medical Technology Co., Ltd.
Address	No. 502 Juxing Chuangye Jidi, No.8 Lujing Road, Changsha High-tech development Zone, Changsha City, China
Factory	The same as applicant
Address	
Standard	☒ EN 14683: 2019
Review Report Form No.	14683
TRF originator	GTS
Master TRF	Reference No. EN 14683: 2019
Review procedure	GTS
Type of Review object	Disposable Medical masks
Trademark	-
Main Model	-
Rating	/

Possible review case verdicts:

- review case does not apply to the test object: N(.A.)
- review object does meet the requirement: P(ass)
- review object does not meet the requirement: F(ail)

General remarks:

"(see remark #)" refers to a remark appended to the report.

"(see appended table)" refers to a table appended to the report.

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

The review results presented in this report relate only to the object reviewed.

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Testing:	
Date of receipt of review item:	March 16,2020
Date(s) of performance of review:	March 16,2020 to March 19,2020

General product information:
Disposable Medical masks

Summary of reviewing:

This review report includes:

Annex I: 1 page(s) of photo documentation.

Copy of marking plate

Disposable Medical masks Hunan Bei’er An’qin Medical Technology Co., Ltd.	Marking 

4	Classification		--
	Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant. The 'R' signifies splash resistance.	Type II	P
5	Requirements		--
5.1	General		--
5.1.1	Materials and construction		--
	The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric. The medical face mask shall not disintegrate, split or tear during intended use. In the selection of the filter and layer materials, attention shall be paid to cleanliness.		P
5.1.2	Design		--
	The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides. Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).		P
5.2	Performance requirements		--
5.2.1	General		--
	All tests shall be carried out on finished products or samples cut from finished products.		P
5.2.2	Bacterial filtration efficiency (BFE)		--
	When tested in accordance with Annex B, the BFE of the medical face mask shall conform to the minimum value given for the relevant type in Table 1. For thick and rigid masks such as rigid duckbill or cup masks the test method may not be suitable as a proper seal cannot be maintained in the cascade impactor. In these cases, another valid equivalent method shall be used to determine the BFE. When a mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually. The lowest performing panel or area shall determine the BFE value of the complete mask.		P
5.2.3	Breathability		--
	When tested in accordance with Annex C, the		P

	differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1. If the use of a respiratory protective device as face mask is required in an operating theatre and/or other medical settings, it might not fulfil the performance requirements with regard to differential pressure as defined in this European Standard. In such case, the device should fulfil the requirement as specified in the relevant Personal Protective Equipment (PPE) standard(s).		
5.2.4	Splash resistance		--
	When tested in accordance with ISO 22609:2004 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1.		N/A
5.2.5	Microbial cleanliness (Bioburden)		--
	When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ⩽ 30 CFU/g tested (see Table 1). To determine the mask's bioburden according to EN ISO 11737-1:2018, refer to the procedure as described in Annex D. The number of masks that shall be tested is minimum 5 of the same batch/lot. Other test conditions as described in EN ISO 11737-1:2018 may be applied. In the test report, indicate the total bioburden per individual mask and based on the mask weight, the total bioburden per gram.		P
5.2.6	Biocompatibility		--
	According to the definition and classification in EN ISO 10993-1:2009, a medical face mask is a surface device with limited contact. The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1:2009 and determine the applicable toxicology testing regime. The results of testing should be documented according to the applicable parts of the EN ISO 10993 series. The test results shall be available upon request.		P
5.2.7	Summary of performance requirements		--
	Table 1 — Performance requirements for medical face masks Test / Type I [a] / Type II / Type IIR Bacterial filtration efficiency (BFE), (%) / ≥ 95 / ≥ 98 / ≥ 98 Differential pressure (Pa/cm²) / < 40 / < 40 / < 60 Splash resistance pressure (kPa) / Not required / Not required / ≥ 16,0 Microbial cleanliness (cfu/g) / ≤ 30 / ≤ 30 / ≤ 30 [a] Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.		--

6	Marking, labelling and packaging		--
	Annex I, § 13, of the Medical Devices Directive (93/42/EEC) or Annex I, § 23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied. The following information shall be supplied: a) number of this European Standard; b) type of mask (as indicated in Table 1). c) EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.		P

- End of Review Report -

Annex I: Photo documentation

Type of equipment, model: Disposable Medical masks

Details of:

View:

[X] general

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[ ] bottom

Details of:

View:

[X] general

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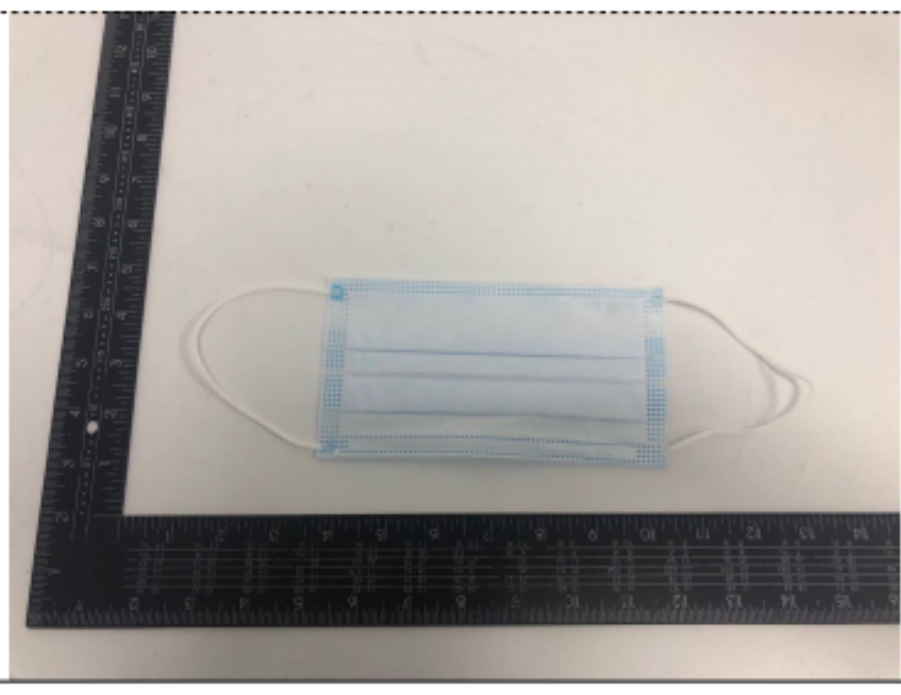

- End of Annex I -

Technical Construction File
EN 149: 2001+A1:2009
Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

Report reference No.	TMHN20031222436
Compiled by (+ signature)	Stephen Zhang / Test Engineer
Approved by (+ signature)	Kosco Vent / Project Manager
Date of issue	March 19,2020
Reviewing laboratory	Shanghai Global Testing Services Co., Ltd.
Reviewing location	Floor 2nd, Building D-1, No. 128, Shenfu Road, Minhang District, Shanghai, China.
Applicant	Hunan Bei'er An'qin Medical Technology Co., Ltd.
Address	No. 502 Juxing Chuangye Jidi, No.8 Lujing Road, Changsha High-tech development Zone, Changsha City, China
Manufacturer	Hunan Bei'er An'qin Medical Technology Co., Ltd.
Address	No. 502 Juxing Chuangye Jidi, No.8 Lujing Road, Changsha High-tech development Zone, Changsha City, China
Factory	The same as applicant
Address	
Standard	☒ EN 149: 2001+A1:2009
Review Report Form No.	149
TRF originator	GTS
Master TRF	Reference No. EN 149: 2001+A1:2009
Review procedure	GTS
Type of Review object	Disposable protective masks
Trademark	-
Model/type reference	-
Rating	/

Possible review case verdicts:
- review case does not apply to the test object: N(.A.)
- review object does meet the requirement: P(ass)
- review object does not meet the requirement: F(ail)

General remarks:

"(see remark #)" refers to a remark appended to the report.

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Testing:	
Date of receipt of review item:	March 16,2020
Date(s) of performance of review:	March 16,2020 to March 19,2020

General product information:
Disposable protective masks

Summary of reviewing:

This review report includes:

Annex I: 1 page(s) of photo documentation.

Copy of marking plate

Disposable protective masks Hunan Bei'er An'qin Medical Technology Co., Ltd.	Marking CE

4	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.	No inhalation and/or exhalation valve(s)	P
5	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. The protection provided by an FFP2 - or FFP3 - device includes that provided by the device of lower class or classes.	FFP2	P
6	Designation		--
	Particle filtering half masks meeting the requirements of this European Standard shall be designated in the following manner:		P
7	Requirements		--
7.1	General		--
	In all tests all test samples shall meet the requirements.		P
7.2	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 ± 5 %. Unless otherwise specified, the ambient temperature for testing shall be (16 - 32) ° C, and the temperature limits shall be subject to an accuracy of ± 1 ° C.		P
7.3	Visual inspection		--
	The visual inspection shall also include the marking and the information supplied by the manufacturer.		P
7.4	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
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. 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. Three particle filtering half masks shall be tested. When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer. Testing shall be done in accordance with 8.2.		P
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.		N/A
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		--
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. The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration. 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. Testing shall be done in accordance with 8.5.		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. Table 1 — Penetration of filter material Classification | Maximum penetration of test aerosol Sodium chloride test 95 l/min, % max. | Paraffin oil test 95 l/min, % max. FFP1 | 20 | 20 FFP2 | 6 | 6 FFP3 | 1 | 1		P
	A total of 9 samples of particle filtering half masks shall be tested for each aerosol. Testing in accordance with 8.11 using the Penetration test according to EN 13274-7, shall be performed on: - 3 samples as received; - 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: - 3 samples after the test for mechanical strength in accordance with 8.3.3 followed by temperature conditioning in accordance with 8.3.2. - for re-usable devices on: - 3 samples after the test for mechanical strength in accordance with 8.3.3 followed by temperature		P

	conditioning in accordance with 8.3.2. and followed by one cleaning and disinfecting cycle according to the manufacturer's instruction. "		
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 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.	No more than 5s	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. 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.		N/A

	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.		
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
	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		--
7.17	Clogging		--
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		--
7.17.2.1	Valved particle filtering half masks		N/A
7.17.2.2	Valveless particle filtering half masks		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		--

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
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		--
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.		P
8.3.3	Mechanical strength		--
	Conditioning shall be done in accordance with EN 143.	Withstand 10N tension for 10s	P

8.3.4	Flow conditioning		--
	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	Practical performance		--
8.4.1	General		--
	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. 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: a) head harness comfort; b) security of fastenings; c) field of vision; d) any other comments reported by the wearer on request.		P
8.4.2	Walking test		--
	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.		N/A
8.4.3	Work simulation test		--
	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. The sequence of activities is at the discretion of the test house. The individual activities shall be arranged so that sufficient time is left for the comments prescribed. a) walking on the level with headroom of (1,3 ± 0,2) m for 5 min; b) b) crawling on the level with headroom of (0,70 ± 0,05) m for 5 min; c) filling a small basket (see Figure 1, approximate volume = 8 l) with chippings or other suitable		N/A

	c) 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. 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.		
8.5	Leakage		--
8.5.1	General test procedure		--
8.5.1.1	Total inward leakage		--
8.5.1.2	Test equipment		--
8.5.1.3	Test procedure		--
8.5.2	Method		--
8.5.2.1	Principle		--
8.5.2.2	Test equipment (see Figure 3)		--
8.5.2.3	Expression of results		--
8.6	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 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. 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. 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 heigt 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. Failure to meet the temperature requirement indicates that a fault such as a partially blocked burner exists. This shall be rectified before testing.		P

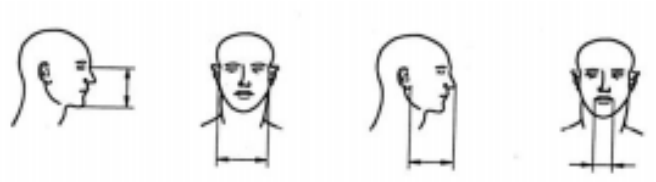
	The head is set in motion and the effect of passing the facepiece once through the flame shall be noted. The test shall be repeated to enable an assessment to be made of all materials on the exterior of the device. Any one component shall be passed through the flame once only.		
8.7	Carbon dioxide content of the inhalation air		--
	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 CO 2 flowmeter and a CO 2 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). 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 CO 2 build-up a CO 2 absorber shall be used in the inhalation branch between solenoid valve and breathing machine. The CO 2 is fed into the breathing machine via a control valve, a flowmeter, a compensating bag and two non-return valves. 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. 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. 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. 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 sampling tube with the carbon dioxide supply turned off. Results are deemed acceptable		P

	only if 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		
8.8	Strength of attachment of exhalation valve housing		--
	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. 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.		N/A
8.9	Breathing Resistance		--
8.9.1	Test samples and fixture		--
8.9.1.1	Valveless particle filtering half masks		P
8.9.1.2	Valved particle filtering half masks		N/A
8.9.2	Exhalation resistance		--
	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 2.0 l/stroke or a continous 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 upwards - facing vertically downwards - lying on the left side - lying on the right side		P
8.9.3	Inhalation resistance		--
	Test the inhalation resistance at 30 l/min and 95 l/min continuous flow		P
8.10	Clogging		--
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		P

	exposure, the breathing resistance and the filter penetration of the sample particle filtering half mask are measured.		
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. **Table 3 — Size distribution of dolomite dust** Coulter counter: Size (equivalent spherical diameter) µm; % Number particles oversize Sedimentation analysis: 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		P
	The particle size distribution of the airborne dust at the working area of the dust chamber is given in Figure 11. 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; – 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		P

	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.		
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 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.		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 be done in accordance with EN 13274-7.		P
9	Marking		--
9.1	Packaging		--
	The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.		P
9.1.1	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. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.		P
9.1.4	The number and year of publication of this European Standard.		P
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.		P
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.		P
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.		P
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.		P
9.2	Particle filtering half mask		--
	Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:		P
9.2.1	The name, trademark or other means of identification of the manufacturer or supplier.		P
9.2.2	Type-identifying marking.		P
9.2.3	The number and year of publication of this European Standard.		P
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.		P
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 (see 9.2.4).		P
9.2.6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.		P
10	Information to be supplied by the manufacturer		--
10.1	Information supplied by the manufacturer shall		P

	accompany every smallest commercial available package.		
10.2	Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.		P
10.3	The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on – application/limitations; – the meaning of any colour coding; – checks prior to use; – donning, fitting; – use; – maintenance (e.g. cleaning, disinfecting), if applicable; – storage; – the meaning of any symbols/pictograms used of the equipment.		P
10.4	The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.		P
10.5	Warning shall be given against problems likely to be encountered, for example: – fit of particle filtering half mask (check prior to use); – it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal; – air quality (contaminants, oxygen deficiency); – use of equipment in explosive atmosphere.		P
10.6	The information shall provide recommendations as to when the particle filtering half mask shall be discarded.		P
10.7	For devices marked "NR", a warning shall be given that the particle filtering half mask shall not be used for more than one shift.		P
	 Figure 2 — Facial dimensions		P

- End of Review Report -

Type of equipment, model: Disposable protective masks

Details of:

View:

[X] general

[ ] front

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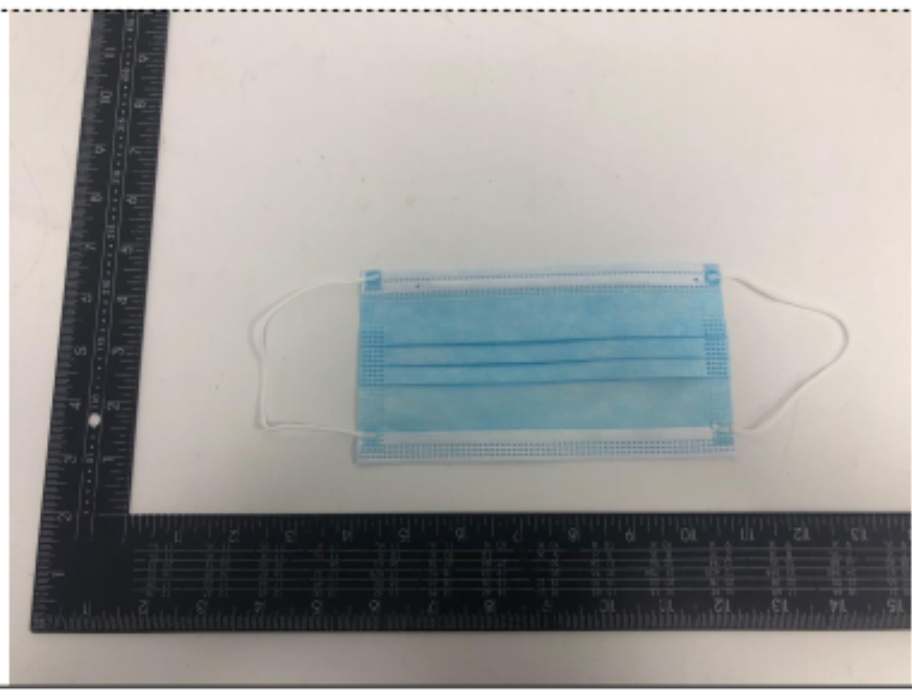

Details of:

View:

[X] general

[ ] front

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- End of Annex I -