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Respiratory protection - Non-powered air-purifying particle respirator

呼吸防护 自吸过滤式防颗粒物呼吸器

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Respiratory protection - Non-powered air-purifying particle respirator

1 Scope

This standard specifies the classification and marking, technical requirements, testing methods, identification of non-powered air-purifying particle respirator.

This standard applies to non-powered air-purifying respirator that protects against particle.

This standard does not apply to respirators that protect against harmful gases and vapors. It does not apply to the respirators for hypoxic environments, underwater operations, escape, fire-fighting.

2 Normative references

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) are applicable to this standard.

GB 2890-2009 Respiratory protection - Non-powered air-purifying respirators

GB/T 5703 Basic human body measurements for technological design

GB/T 10586 Specifications for damp heat chambers

GB/T 10589 Specifications for low temperature test chambers

GB/T 11158 Specifications for high temperature test chambers

GB/T 18664-2002 Selection, use and maintenance of respiratory protective equipment

GB/T 23465-2009 Respiratory protective equipment - Practical performance evaluation methods

nose, and jaw.

Note: Half facepieces are divided into disposable facepieces and replaceable half facepieces.

3.6

Full facepiece

Tight-fitting facepiece that covers eyes, mouth, nose and jaw.

3.7

Disposable facepiece

A half facepiece mainly composed of a filter material, which can be provided with an exhalation valve.

3.8

Replaceable facepiece

Closed half-facepieces and full facepieces with single or multiple replaceable filter elements, which can be provided with breathing valves and / or breathing hose.

3.9

Inhalation valve

A one-way valve that only allows inhaled air to enter the facepiece and prevents exhaled air from exiting the facepiece through it.

[GB 2890-2009, definition 3.6]

3.10

Exhalation valve

A one-way valve that only allows exhaled air to exit the facepiece and prevents inhaled air from entering the facepiece through it.

[GB 2890-2009, definition 3.7]

3.11

Breathing hose

A flexible, air-tight air hose for connecting a facepiece to a filter element.

Under the specified laboratory testing environment, the ratio of the concentration of the simulant leaked into the facepiece from all other parts of the facepiece except the filter element when the subject inhaled to the concentration of the simulant in the test environment outside the respirator facepiece.

$$\text{Inward leakage} = C_i/C_0 \times 100\% \dots\dots\dots (2)$$

Where:

C_i - The concentration of the simulant in the respirator facepiece;

C_0 - Concentration of the simulant in the test environment outside the respirator facepiece.

3.17

Dead space

Volume fraction of carbon dioxide gas as re-inhaled from a previous exhalation.

3.18

Head harness

A part for fixing the facepiece on the head.

3.19

User face-seal check

A simple tightness check method performed by the respirator wearer, to ensure that the tight-fitting facepiece is worn correctly.

Note: Rewrite GB/T 18664-2002, definition 3.1.24.

3.20

Assigned protection factor

One type or category of respiratory protective equipment with suitable functions, which is expected to reduce the concentration of air pollutants on the premise that it is suitable for users to wear and use correctly.

Note: Rewrite GB/T 18664-2002, definition 3.1.29.

3.21

b) The structural design shall meet the following requirements:

- 1) It shall not be easy to cause structural damage; the design, composition, installation of components shall not pose any danger to the user;
- 2) The design of the head harness shall be elastic material or adjustable, for easy wearing and removal. It shall be able to firmly fit the facepiece on the face; there shall be no obvious compression or tenderness when wearing. The head harness of replaceable half facepiece and full facepiece shall be designed to be replaceable;
- 3) If the facepieces of the same size and the same style have different wearing methods, they shall be tested as different products;

Note 1: Different wearing methods of the same style facepiece will affect the tightness of the facepiece.

- 4) It shall not significantly affect the visual field;
- 5) When wearing, the lenses of the full facepiece shall not affect the vision, such as fogging;
- 6) Respirators which use replaceable filter elements, inhalation valves, exhalation valves, head harness shall be designed for easy replacement; meanwhile it allows the wearer to check the airtightness of the facepiece and face at any time and conveniently, to make user face-seal check;

Note 2: See Appendix G of GB/T 18664-2002 for user face-seal check method.

- 7) The breathing hose shall not restrict the movement of the head or the wearer; it shall not affect the tightness of the facepiece; it shall not restrict or block the airflow;
- 8) The front side of the exhalation valve shall be protected. The exhalation valve protection device can be a dedicated component, or it can be protected by other components on the facepiece;
- 9) The structure of the disposable facepiece shall ensure close fit with the face; meanwhile it shall not deform during normal use;
- 10) The parts of the replaceable facepiece (except the filter element) shall be washable.

5.2 Visual inspection

Check it in accordance with 6.1.

5.13.2 If the product is designed to be flame-retardant, it shall be tested in accordance with the method of 6.15. After the parts exposed to the flame are removed from the flame, the continuous burning time shall not exceed 5 s.

5.14 Cleaning and disinfection

5.14.1 If the product design allows the filter element to be reused after cleaning and / or disinfection, it shall meet the requirements of 5.16d); meanwhile the filter element shall be able to withstand the cleaning or disinfection treatment as recommended by the manufacturer. The cleaned or disinfected sample shall meet the requirements of 5.3 for filter efficiency, 5.4 for leakage, 5.5 for inhalation resistance. The manufacturer shall provide the user with the correct and effective method for determining whether the filter element will continue to be effective after cleaning or disinfection.

5.14.2 For replaceable facepieces, the facepieces shall be able to withstand the cleaning or disinfection treatment as recommended by the manufacturer; the samples after cleaning or disinfection shall meet the requirements of 5.4.

5.15 Practical performance

Perform test in accordance with the method of 6.16. Under the conditions of simulated use, the performance which is hard to be evaluated by the use of other testing methods, such as the performance specified in 5.1b) and 5.11, the subject will provide subjective evaluation.

If the respirator fails the test, the laboratory shall describe the test method in detail, so that other laboratories can repeat the test process.

5.16 Information to be provided by the manufacturer

Perform inspection in accordance with the method of 6.1.

The correctness of the information provided by the manufacturer shall be judged in accordance with the relevant provisions of GB/T 18664-2002.

The information provided by the manufacturer shall meet the following requirements:

- a) It shall be provided with the smallest sales package.
- b) There shall be instructions in Chinese.
- c) It shall include the following information that the user must know:

commentary, part number and labeling.

5.17 Packaging

Perform inspection in accordance with the method of 6.1.

Sales packaging shall protect the product from mechanical damage and contamination before use.

6 Testing methods

6.1 Visual inspection

According to the requirements of various technical requirements (see Appendix A), before performing laboratory performance testing, the samples shall be visually inspected.

6.2 Pretreatment

6.2.1 Temperature and humidity pretreatment

6.2.1.1 Number of samples and requirements

2 un-conditioned samples; or quantities required by other testing methods.

6.2.1.2 Testing equipment

The testing equipment shall meet the following requirements:

- a) The technical performance of the high temperature test chamber shall meet the requirements of GB/T 11158;
- b) The technical performance of the low temperature test chamber shall meet the requirements of GB/T 10589;
- c) The technical performance of the damp heat test chamber shall meet the requirements of GB/T 10586.

6.2.1.3 Testing methods

Remove the samples from the original packaging and process them in the following order:

- a) Place it at $(38 \pm 2.5) ^\circ\text{C}$ and $(85 \pm 5)\%$ relative humidity for (24 ± 1) h;

20 samples of disposable facepieces. If the products have different size numbers, there shall be at least 5 samples for each number. 20 samples of replaceable filter elements; it shall include filter cotton and the receiving seat part (if applicable) which accommodates the filter cotton, wherein 5 of them are samples after pretreatment in 6.2.1, whilst the other 5 are samples after pretreatment in 6.2.2 (if applicable). For products that meet the requirements of 5.14.1, it shall have at least 5 samples that after pretreatment in 6.2.3, the rest is the untreated samples. The pretreated sample shall be placed in an air-tight container and tested within 10 hours.

6.3.2 Testing equipment

6.3.2.1 NaCl particle filter efficiency testing system

The main technical parameters are as follows:

- a) The concentration of NaCl particles does not exceed 200 mg/m^3 , the count median diameter (CMD) is $(0.075 \pm 0.020) \mu\text{m}$; the geometric standard deviation of the particle size distribution is not greater than 1.86;

Note: Using the conversion method provided in Appendix B, the mass median aerodynamic diameter (MMAD) as converted from the count median diameter is about $0.3 \mu\text{m}$.

- b) The dynamic range of the particle detector is $0.001 \text{ mg/m}^3 \sim 200 \text{ mg/m}^3$; the accuracy is 1% or 0.001 mg/m^3 ;
- c) The testing flow range is $30 \text{ L/min} \sim 100 \text{ L/min}$; the accuracy is 2%;
- d) The testing range of filter efficiency is $0 \sim 99.999\%$; the resolution shall be at least 0.003%;
- e) There shall be a device capable of neutralizing the charge of the particles that has occurred.

6.3.2.2 Testing system for filtering efficiency of oily particles

The main technical parameters are as follows:

- a) The concentration of DOP or other applicable oily (such as paraffin oil) particles is $50 \text{ mg/m}^3 \sim 200 \text{ mg/m}^3$; the count median diameter (CMD) is $(0.185 \pm 0.020) \mu\text{m}$; the geometric standard deviation of the particle size distribution is not greater than 1.60;

Note 1: Using the conversion method provided in Appendix B, the mass median aerodynamic diameter (MMAD) as converted from the count median diameter is about $0.3 \mu\text{m}$.

6.3.4.1 First adjust the filter efficiency testing system to the testing state; adjust the relevant test parameters.

6.3.4.2 Use appropriate fixture to connect the filter element to the testing device in an air-tight manner. The filter element shall include the socket for the filter material and a gasket (if applicable). If the filter element cannot be separated from the facepiece (such as disposable facepiece), the exhalation valve on the facepiece shall be completely sealed.

6.3.4.3 After the test is started, it shall continuously record the filter efficiency results. When the filter efficiency has fallen below the limit of the filter efficiency of this grade of products, it shall stop testing immediately and judge the product to be nonconforming.

6.3.4.4 For KN type filter elements, during the loading process, if the filter efficiency is lower than the filter efficiency limit of the product of this grade, it shall stop testing. When reaching to the basic loading as specified in 6.3.3.1, if the filter efficiency has not been lower than the filter efficiency limit of this grade of product, it shall judge the product as qualified.

6.3.4.5 For KN type filter elements, only when following the requirements of 6.3.4.4 to grasp the regular change trend in the filtering efficiency of the product with the increase in loading through testing, the trend will show that there is a minimum point of filter efficiency, meanwhile the filter efficiency after this minimum point will continue to increase with the increase of the loading; then in the subsequent testing of other samples, it allows that before the loading reaches to the basic loading as specified in 6.3.3.1, when the filter efficiency curve appears the expected minimum value, this minimum value is not lower than the filter efficiency limit of this grade of product, meanwhile the filter efficiency in the subsequent loading process afterwards also shows an increasing trend, it allows to stop testing and judge this product as qualified.

6.3.4.6 For KP type filter elements, if the amount of accumulated particle on the filter material has reached the basic loading as specified in 6.3.3.1 and the filter efficiency has decreased, it shall continue loading. Before the loading reaches the maximum loading as specified in 6.3.3.2, if the filter efficiency is lower than the limit of the filter efficiency of this grade of product, it shall stop the testing immediately; otherwise it shall continue loading. When it is determined according to the method provided in Appendix C that the fluctuation bandwidth is not greater than the fluctuation bandwidth limit (BL) in Table 9, it can be judged that the curve stops falling, at this time the data is the minimum value of filter efficiency, it may stop testing. If the minimum value is not lower than the filter efficiency limit of the product of this grade, it shall be judged that the product is qualified. When the loading reaches the maximum loading as specified in 6.3.3.2, as long as the filter efficiency is not less than the filter efficiency limit of the product of this grade, it shall also judge the product as

6.4.3.5 The subjects first read the usage method of the tested samples. If the tested samples have different size numbers, they shall choose the most appropriate number for the subjects as required. The subject shall also understand the testing requirements and methods.

6.4.3.6 When testing the leakage of replaceable half facepieces and full facepieces, it shall use the filter element of at least KP100 and equivalent resistance instead of the original filter element of the facepiece.

6.4.4 Testing method

Prepare the sample to be tested and install the sampling tube. The mounting position of the sampling tube shall be as close to the right front side of the user's mouth and nose as possible. For disposable facepieces, it shall take necessary measures to prevent the sampling tube from affecting the position of the facepiece during the test. When applicable, connect KP100 grade filter elements. Check the testing system to confirm that it is in normal working condition.

Lead the particle into the testing chamber to make the concentration reach the requirements.

The subject wears the test sample in the clean air area; checks the airtightness according to the usage method; then connects the sampling tube to the particle tester. Measure the background concentration in the facepiece when the subject is breathing outside the testing chamber. Make 5 measurements. Take the arithmetic mean as the background concentration.

Have the subject enter the testing chamber and connect the sampling tube to the particle tester while avoiding particle contamination. Then the subject completes the following actions in order according to time requirements:

- a) The head is still and not talking, 2 min;
- b) Turn the head to the left and right to see the left and right walls of the testing chamber (about 15 times), 2 min;
- c) Look up and down to check the roof and ground (about 15 times), 2 min;
- d) Read a text aloud (such as counting numbers), or speak aloud, 2 min;
- e) The head is still and not talking, 2 min.

During each action, it shall test the particle concentration in the testing chamber and the facepiece at the same time. Generally, it only tests the last 100 s time interval of this action; avoids the cross section of the testing action. For each action, it shall test 5 data. Calculate the arithmetic mean as the result of the action.

calculated by person is calculated according to formula (5):

$$\frac{\text{Overall total inward leakage}_{\text{by person}}}{\text{Total inward leakage}_{\text{by action}}} = \frac{\text{Overall inward leakage}_{\text{by person}}}{\text{inward leakage}_{\text{by action}}} \times \frac{1}{5} \sum \dots \dots \dots (5)$$

6.4.5 Testing report

The testing report shall report the following:

- a) The arithmetic mean of the testing results of inward leakage or total inward leakage for each test subject for each test action;
- b) Calculation result of the overall inward leakage or overall total inward leakage for each test subject.

6.5 Inhalation resistance

6.5.1 Sample quantity and requirements

4 samples, wherein 2 of them are untreated samples and the other 2 are samples as pretreated in 6.2.1. For products that meet the requirements of 5.14.1, 2 are samples as pretreated in 6.2.3 and the other 2 are samples as pretreated in 6.2.1. If the products have different size numbers, there shall be two samples for each number, wherein 1 of them is an untreated sample or sample as pretreated in 6.2.3 (if applicable), the other is the sample as pretreated in 6.2.1.

6.5.2 Testing equipment

6.5.2.1 The schematic diagram of the inhalation resistance testing device is as shown in Figure 3.

6.5.2.2 The range of the flow meter is 0 L/min ~ 100 L/min; the accuracy is 3%.

6.5.2.3 The micro-pressure has a measurement range of -1000 Pa ~ 1000 Pa; the accuracy is 1%; the resolution is at least 1 Pa.

6.5.2.4 Test head mold: Breathing hose is installed at the mouth of the test head mold, as shown in Figure 4. The main dimensions of the head mold shall meet the requirements of Appendix D. It is divided into three size types: large, medium, small.

6.5.3 Testing conditions

6.5.3.1 If applicable, the sample to be tested shall include replaceable filter elements and breathing hoses.

6.6 Exhalation resistance

6.6.1 Sample quantity and requirements

4 samples, wherein 2 of them are untreated samples and the other 2 are samples as pretreated in 6.2.1. If the products have different size numbers, there shall be two samples for each number, wherein 1 of them is an untreated sample and the other is a sample as pretreated in 6.2.1.

6.6.2 Testing equipment

6.6.2.1 The schematic diagram of the testing device for exhalation resistance is as shown in Figure 3.

6.6.2.2 The flowmeter is the same as 6.5.2.2.

6.6.2.3 Micromanometer is the same as 6.5.2.3.

6.6.2.4 The test head mold is the same as 6.5.2.4.

6.6.3 Testing conditions

Same as 6.5.3.

6.6.4 Testing method

Check the air tightness and working status of the testing device. Adjust the ventilation volume to (85 ± 1) L/min. Set the system resistance of the testing device to 0.

It shall take appropriate measures (such as the use of sealants), to air-tightly wear the test sample on a matching test head mold. It shall ensure the correct wearing position of the facepiece. The fixing method shall neither affect the effective ventilation area of the filter element, nor deform the facepiece. Adjust the ventilation volume to (85 ± 1) L/min. Determine and record the maximum exhalation resistance.

6.7 Air tightness of exhalation valve

6.7.1 Sample quantity and requirements

Samples of 4 respirators, wherein 2 of the respirators are untreated samples and the other 2 are samples as pretreated in 6.2.1.

6.7.2 Testing conditions

6.7.2.1 At normal temperature and pressure, the relative humidity shall be less

Take an appropriate method (such as using a sealant), to seal the exhalation valve sample on the exhalation valve's test fixture in an air-tight manner; turn on the vacuum pump; adjust the regulating valve, to make the exhalation valve be subject to a pressure of -249 Pa, to test the leakage air flow of exhalation valve.

6.8 Protection device of exhalation valve

6.8.1 Sample quantity and requirements

3 untreated respirator samples.

6.8.2 Testing equipment

6.8.2.1 The measuring range of the material testing machine is 0 N ~ 1000 N; the accuracy is 1%. Or otherwise use the standard weight suspension method; it may apply a tensile force in accordance with Table 5.

6.8.2.2 The fixture has a proper structure and clamping degree.

6.8.2.3 The accuracy of the timer is 0.1 s.

6.8.3 Testing methods

Use appropriate clamps to respectively fix the exhalation valve's protection device and the facepiece of the tested sample (the fixing point shall be reasonably close to the corresponding connection site). Start the material testing machine or suspend the standard weight, to apply the axial tensile force as specified in Table 5. Record whether there are fractures, slippage, deformation.

6.9 Dead space

6.9.1 Sample quantity and requirements

Disposable facepiece, which are 3 untreated samples. Half facepiece or full facepiece, which is 1 untreated sample, or 1 untreated sample per number (if applicable).

6.9.2 Testing equipment

6.9.2.1 The schematic diagram of the testing device for the dead space (inhaled CO₂ content) is as shown in Figure 6. Except for the breathing simulator, the total volume of the gas path of the testing device shall not be greater than 2000 mL.

6.9.3.1 Testing shall be carried out at room temperature; room temperature's range is 16 °C ~ 32 °C.

6.9.3.2 The breathing frequency and tidal volume of the breathing simulator shall be set to 20 times/min and 1.5 L, respectively.

6.9.3.3 Adopt proper ventilation measures so that the concentration of CO₂ in the test environment is not higher than 0.1% (volume fraction). The testing point of the CO₂ concentration in the environment shall be located approximately 1 m directly in front of the tested sample.

6.9.3.4 Only when testing disposable facepiece samples, an electric fan is required to blow air on the side of the tested sample, meanwhile the velocity of the air flow in front of the facepiece shall be 0.5 m/s.

6.9.4 Testing method

Check the testing system to confirm that it is in normal working condition. Take necessary measures, to air-tightly wear the tested sample on a matching test head mold and prevent deformation of the facepiece.

Turn on the testing device for dead space, to continuously monitor and record the concentration of CO₂ in the inhaled gas and the testing environment, until it reaches a stable value.

The three samples of disposable facepieces shall be tested once for each; the half facepiece or full facepiece shall be tested repeatedly three times for each.

The test is valid only when the CO₂ concentration in the test environment is not greater than 0.1% (volume fraction); meanwhile the CO₂ concentration in the test environment shall be deducted. For the testing result of the CO₂ concentration in the inhaled air, take the arithmetic mean of 3 measurements.

6.10 View field

Perform testing according to the method specified in 6.8 of GB 2890-2009.

6.11 Head harness

6.11.1 Sample quantity and requirements

Two samples, wherein 1 of them is an untreated sample and the other is a sample as pretreated in 6.2.1.

6.11.2 Testing equipment

sample. Record the results.

6.13 Lens

6.13.1 Sample quantity and requirements

5 untreated samples.

6.13.2 Testing equipment

6.13.2.1 Test head mold: The main dimensions shall meet the requirements of Appendix C. They are divided into three sizes: large, medium, small.

6.13.2.2 The diameter of the steel ball is 22 mm, the mass is (45 ± 1) g, the surface shall be smooth.

6.13.3 Testing method

The test sample is correctly worn on a matching test head mold; the head mold is placed and fixed with the lens upward. The steel ball is allowed to fall freely from the height of 1.3 m to the center of the lens; record whether there is crack.

It shall respectively test each lens of the tested sample. Record the result.

6.14 Air tightness

6.14.1 Sample quantity and requirements

All untreated samples, or quantities required by other testing methods.

6.14.2 Testing equipment

6.14.2.1 The test head mold is the same as 6.5.2.4.

6.14.2.2 The micromanometer's measurement range is 0 Pa ~ 2000 Pa; the accuracy is 1%; the resolution is at least 1 Pa.

6.14.2.3 The accuracy of the timer is 0.1 s.

6.14.2.4 The pumping speed of the vacuum pump is about 2 L/min.

6.14.3 Testing methods

Wear the facepiece on the matching test head mold; seal the inhalation valve; wet the exhalation valve. Start the vacuum pump, to make the pressure in the facepiece reach -1000 Pa; stop pumping; start timekeeping; observe and record the pressure change in facepiece within 60 s.

Wear the test sample on a metal head mold. Adjust the height of the metal head mold, so that the vertical distance between the top of the burner and the bottom of the facepiece is (20 ± 2) mm; then allow the metal head mold to locate outside the burner's combustion zone.

After igniting the burner, adjust the flame so that the height of the flame at the top of the burner reaches (40 ± 4) mm, meanwhile the temperature of the flame at a distance of (20 ± 2) mm from the top of the burner reaches (800 ± 50) °C.

Start the metal head mold's motion control device, to make the tested sample pass through the combustion zone. Record the burning of the facepiece material as it passes over the flame.

It shall repeat the testing. Test all external surface materials of the facepiece. It shall make each part pass through the flame once.

6.16 Practical performance

6.16.1 Basic requirements

Before performing practical performance testing, the respirator shall undergo all laboratory performance tests (except for 6.15 flammability) to confirm that it is harmless to the subject.

6.16.2 Principle

The subject wears a respirator; simulates some actions in the actual application state; then provides a subjective evaluation of the use experience.

6.16.3 Sample quantity and requirements

Two samples, one of which is an untreated sample and the other is a sample pretreated in 6.2.1. All the samples are checked by the method of 6.1 and are in good working condition. Each subject uses 1 sample.

6.16.4 Requirements for subject

It shall meet the requirements of 4.2 of GB/T 23465-2009. It shall select two subjects.

6.16.5 Testing conditions

The test is performed in an environment with a temperature of $16\text{ °C} \sim 32\text{ °C}$ and a relative humidity of $30\% \sim 80\%$. It shall record the actual testing conditions.

6.16.6 Testing method

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