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|---|---|
| **Applicant .....:** | Yiwu Ori-power Medtech Co.,Ltd<br>#86 Xiahe Rd., Beiyuan Industrial Park , Yiwu, China 322000 |
| **Manufacturer ..... :** | The same as applicant |

| | |
|---|---|
| **Test Item.....:** | **Protective mask** |
| **Mark of origin .....:** | N/A |
| **Type Designation(s)..... :** | **HH-KN95-001 ,HH-KN95-002 , HH-001, HH-002** |
| **Serial No(s)..... :** | Prototype |

| | |
|---|---|
| **Test requirements.....:** | **EN 149:2001+A1:2009** |
| **Test result.....:** | The test item passed the test requirement(s). |

| | |
|---|---|
| **Testing Laboratory..... :** | Shanghai MICEZ Equipment Testing & Technical Co., LTD |
| **Testing location.....:** | At manufacturer's premises |

| | |
|---|---|
| **Compiled by (+ signature).....:** | Eric. Zhang<br>Shanghai MICEZ Equipment Testing & Technical Co., LTD |
| **Approved by (+ signature)..... :** | Thomas<br>Shanghai MICEZ Equipment Testing & Technical Co., LTD |
| **Date of issue.....:** | 2020-Mar.-07 |

**Other Aspects:**

This report is only valid together with 1 parts which named -01

**General remarks:**

The test result presented in this report relate only to the object(s) tested.

This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.

”(see Annex #)” refers to additional information appended to the report.

“(see appended table)” refers to a table appended to the report.

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

**Additional Information :**

Abbreviations used in this report :

None

Others:

None

**Brief description of the test item:**

/

**Technical Specifications:**



| EN 149:2001+A1:2009<br>Respiratory protective devices<br>— Filtering half masks to protect against particles<br>—Requirements, testing, marking | | | |
|---|---|---|---|
| Clause | Requirements - Test | Result - Remark | Verdict |
| **1** | **Scope** | | **P** |
| | This European Standard specifies minimum requirements for filtering half masks as respiratory protective devices to protect against particles except for escape purposes. | | **P** |
| **2** | **Normative references** | | **P** |
| **3** | **Terms and definitions** | | **P** |
| **4** | **Description** | | **P** |
| | 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 | | **P** |
| **5** | **Classification** | | **P** |
| | Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage. There are three classes of devices:<br>FFP1, FFP2 and FFP3.<br>The protection provided by an FFP2 - or FFP3 - device includes that provided by the device of lower class or classes. | | **P** |
| **6** | **Designation** | | **P** |
| | Particle filtering half masks meeting the requirements of this European Standard shall be designated in the following manner:<br>〈A1〉 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). 〈A1〉<br>〈A1〉 EXAMPLE Particle filtering half mask EN 149:2001 FFP1 NR D 〈A1〉 | | **P** |
| **7** | **Requirements** | | **P** |
| **7.1** | **General** | | **P** |
| | In all tests all test samples shall meet the requirements. | | **P** |
| **7.2** | **Nominal values and tolerances** | | **P** |
| | Unless otherwise specified, the values stated in this European Standard are expressed as nominal values. 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** | | **P** |
| | The visual inspection shall also include the marking and the information supplied by the manufacturer. | | **P** |
| **7.4** | **Packaging** | | **P** |

| EN 149:2001+A1:2009<br>Respiratory protective devices<br>— Filtering half masks to protect against particles<br>—Requirements, testing, marking | | | |
|---|---|---|---|
| Clause | Requirements - Test | Result - Remark | Verdict |
| | 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.<br>Testing shall be done in accordance with 8.2. | | **P** |
| **7.5** | **Material** | | **P** |
| | 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.<br>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.<br>Three particle filtering half masks shall be tested.<br>When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.<br>Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.<br>Testing shall be done in accordance with 8.2. | | **P** |
| **7.6** | **Cleaning and disinfecting** | | **P** |
| | 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.<br>Testing shall be done in accordance with 8.4 and 8.5. | | **P** |
| **7.7** | **Practical performance** | | **P** |
| | 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.<br>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.<br>Testing shall be done in accordance with 8.4. | | **P** |
| **7.8** | **Finish of parts** | | **P** |
| | Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.<br>Testing shall be done in accordance with 8.2. | | **P** |
| **7.9** | **Leakage** | | **P** |
| **7.9.1** | **Total inward leakage** | | **P** |

| EN 149:2001+A1:2009<br>Respiratory protective devices<br>— Filtering half masks to protect against particles<br>—Requirements, testing, marking | | | |
|---|---|---|---|
| Clause | Requirements - Test | Result - Remark | Verdict |
| | 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.<br>The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration.<br>Testing shall be done in accordance with 8.5. | | **P** |
| **7.9.2** | **Penetration of filter material** | | **P** |
| | The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1. | | **P** |
| **7.10** | **Compatibility with skin** | | **P** |
| | Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.<br>Testing shall be done in accordance with 8.4 and 8.5. | | **P** |
| **7.11** | **Flammability** | | **P** |
| | The material used shall not present a danger for the wearer and shall not be of highly flammable nature.<br>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.<br>The particle filtering half mask does not have to be usable after the test. Testing shall be done in accordance with 8.6. | | **P** |
| **7.12** | **Carbon dioxide content of the inhalation air** | | **P** |
| | The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).<br>Testing shall be done in accordance with 8.7. | | **P** |
| **7.13** | **Head harness** | | **P** |
| | The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.<br>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.<br>Testing shall be done in accordance with 8.4 and 8.5. | | **P** |
| **7.14** | **Field of vision** | | **P** |
| | The field of vision is acceptable if determined so in practical performance tests.<br>Testing shall be done in accordance with 8.4. | | **P** |
| **7.15** | **Exhalation valve(s)** | | **P** |

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|---|---|---|---|
| Clause | Requirements - Test | Result - Remark | Verdict |
| | A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.<br>Testing shall be done in accordance with 8.2 and 8.9.1. | | **P** |
| **7.16** | **Breathing resistance** | | **P** |
| | The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 2.<br>Testing shall be done in accordance with 8.9. | | **P** |
| **7.17** | **Clogging** | | **P** |
| **7.17.1** | **General** | | **P** |
| | For single shift use devices, the clogging test is an optional test. For re-usable devices the test is<br>mandatory.<br>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.<br>The specified breathing resistances shall not be exceeded before the required dust load of 833 mg.h/m3 is reached. | | **P** |
| **7.17.2** | **Breathing resistance** | | **P** |
| | After clogging the inhalation resistances shall not exceed<br>— FFP1: 4 mbar<br>— FFP2: 5 mbar<br>— FFP3: 7 mbar<br>at 95 l/min continuous flow;<br>The exhalation resistance shall not exceed 3 mbar at 160 l/min continuous flow.<br>Testing shall be done in accordance with 8.9. | | **P** |
| | After clogging the inhalation and exhalation resistances shall not exceed<br>— FFP1: 3 mbar<br>— FFP2: 4 mbar<br>— FFP3: 5 mbar<br>at 95 l/min continuous flow.<br>Testing shall be done in accordance with 8.9. | | **P** |
| **7.17.3** | **Penetration of filter material** | | **P** |
| | 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.<br>Testing shall be done in accordance with 8.11 using EN 13274-7 | | **P** |
| **7.18** | **Demountable parts** | | **P** |

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|---|---|---|---|
| Clause | Requirements - Test | Result - Remark | Verdict |
| | All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.<br>Testing shall be done in accordance with 8.2. | | P |
| **8** | **Testing** | | P |
| **8.1** | **General** | | P |
| | If no special measuring devices and methods are specified, commonly used devices and methods shall be used. | | P |
| **8.2** | **Visual inspection** | | P |
| | The visual inspection is carried out where appropriate by the test house prior to laboratory or practical performance tests. | | P |
| **8.3** | **Conditioning** | | P |
| **8.3.1** | **Simulated wearing treatment** | | P |
| | Conditioning by simulated wearing treatment shall be carried out by the following process.<br>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.<br>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** | | P |
| | Expose the particle filtering half masks to the following thermal cycle:<br>a) for 24 h to a dry atmosphere of (70 ± 3) °C;<br>b) for 24 h to a temperature of (-30 ± 3) °C;<br>and allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing.<br>The conditioning shall be carried out in a manner which ensures that no thermal shock occurs. | | P |
| **8.3.3** | **Mechanical strength** | | P |
| | Conditioning shall be done in accordance with EN 143. | | P |
| **8.3.4** | **Flow conditioning** | | P |

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|---|---|---|---|
| Clause | Requirements - Test | Result - Remark | Verdict |
| | 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** |
| **8.4** | **Practical performance** | | **P** |
| **8.4.1** | **General** | | **P** |
| | A total of 2 particle filtering half masks shall be tested: both as received.<br>All tests shall be carried out by two test subjects at ambient temperature and the test temperature and humidity shall be recorded.<br>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.<br>Examination shall be done in accordance with 8.2.<br>For the test, persons shall be selected who are familiar with using such or similar equipment. | | **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:<br>a) head harness comfort;<br>b) security of fastenings;<br>c) field of vision;<br>d) any other comments reported by the wearer on request. | | **P** |
| **8.4.2** | **Walking test** | | **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** |
| **8.4.3** | **Work simulation test** | | **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.<br>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. | | **P** |
| **8.5** | **Leakage** | | **P** |
| **8.5.1** | **General test procedure** | | **P** |
| | A total of 10 test specimens shall be tested: 5 as received and 5 after temperature conditioning in accordance with 8.3.2.<br>The total inward leakage shall be tested using sodium chloride aerosol.<br>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** |

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|---|---|---|---|
| Clause | Requirements - Test | Result - Remark | Verdict |
| | 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.<br>A level treadmill is required capable of working at 6 km/h. | | **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 supervisor shall show the test subjects how to fit the particle filtering half mask correctly in accordance with the fitting information. | | **P** |
| | The test sequence shall be as follows:<br>a) Ensure the test atmosphere is OFF.<br>b) Place the test subject in the enclosure. Connect up the facepiece sampling probe. Have the test subject walk at 6 km/h for 2 min. Measure the test agent concentration inside the particle filtering half mask to establish the background level.<br>c) Obtain a stable reading.<br>d) Turn the test atmosphere ON.<br>e) The subject shall continue to walk for a further 2 min or until the test atmosphere has stabilized.<br>f) Whilst still walking the subject shall perform the following exercises:<br>1) walking for 2 min without head movement or talking;<br>2) turning head from side to side (approx. 15 times), as if inspecting the walls of a tunnel for 2 min;<br>3) moving the head up and down (approx. 15 times), as if inspecting the roof and floor for 2 min;<br>4) reciting the alphabet or an agreed text out loud as if communicating with a colleague for 2 min;<br>5) walking for 2 min without head movement or talking.<br>g) Record<br>1) enclosure concentration;<br>2) the leakage over each exercise period.<br>h) Turn off the test atmosphere and when the test agent has cleared from the enclosure remove the subject.<br>After each test, replace the particle filtering half mask by a new sample. | | **P** |
| **8.5.2** | **Method** | | **P** |
| | The subject wearing the particle filtering half mask under test walks on a treadmill over which is an enclosure.<br>Through this enclosure flows a constant concentration of NaCl aerosol. The air inside the particle filtering half mask is sampled and analysed during the inhalation phase of the respiratory cycle to determine the NaCl content. The sample is extracted by punching a hole in the particle filtering half mask and inserting a probe through which the sample is drawn. The pressure variation inside the particle filtering half mask is used to actuate a change-over valve so that inhaled air only is sampled. A second probe is inserted for this purpose. | | **P** |

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|---|---|---|---|
| Clause | Requirements - Test | Result - Remark | Verdict |
| | 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:<br>a) It should be a flame photometer specifically designed for the direct analysis of NaCl aerosol;<br>b) It should be capable of measuring concentrations of NaCl aerosol between 15 mg/m$^3$ and 5 ng/m$^3$;<br>c) The total aerosol sample required by the photometer should not be greater than 15 l/min;<br>d) The response time of the photometer, excluding the sampling system, should not be greater than 500 ms;<br>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 |
| | 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:<br>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;<br>b) A pressure sensor which is capable of detecting a minimum pressure change of approx. 0,05 mbar and which 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;<br>c) An interfacing system to actuate the valve in response to a signal from the pressure sensor;<br>d) timing device to record the proportion of the total respiratory cycle during which sampling took place. | | P |
| **8.6** | **Flammability** | | P |
| | A total of four particle filtering half masks shall be tested: two in the state as received and two after temperature conditioning in accordance with 8.3.2. | | P |
| **8.7** | **Carbon dioxide content of the inhalation air** | | P |
| | A total of 3 particle filtering half masks shall be tested: all 3 as received.<br>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. | | P |
| **8.8** | **Strength of attachment of exhalation valve housing** | | P |
| | A total of three particle filtering half masks shall be tested: one as received, one temperature conditioned in accordance with 8.3.2 and one after the test described for mechanical strength in EN 143.<br>Mount the particle filtering half mask securely to a fixture as shown in Figure 9. Apply an axial tensile force of 10 N to the valve (housing) for 10 s, and note the results. | | P |
| **8.9** | **Breathing Resistance** | | P |
| **8.9.1** | **Test samples and fixture** | | P |
| | The particle filtering half mask shall be fitted securely in a leak tight manner but without deformation on the Sheffield dummy head.<br>The flow rate at which the resistance is measured shall be corrected to 23°C and 1 bar absolute. | | P |

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|---|---|---|---|
| Clause | Requirements - Test | Result - Remark | Verdict |
| **8.9.2** | **Exhalation resistance** | | **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 2.0 l/stroke or a continous flow 160 l/min. Use a suitable pressure transducer. | | **P** |
| **8.9.3** | **Inhalation resistance** | | **P** |
| | Test the inhalation resistance at 30 l/min and 95 l/min continuous flow. | | **P** |
| **8.10** | **Clogging** | | **P** |
| **8.10.1** | **Principle** | | **P** |
| | The test aerosol shall be dolomite. A total of 3 particle filtering half masks shall be tested: 1 as received and 2 after temperature conditioning in accordance with 8.3.2.<br>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** | | **P** |
| | 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 x 650 mm.<br>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** | | **P** |
| **8.10.4** | **Test procedure** | | **P** |
| **8.10.5** | **Assessment of clogging** | | **P** |
| **8.11** | **Penetration of filter material** | | **P** |
| | The device shall be mounted in a leak tight 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. | | **P** |
| **9** | **Marking** | | **P** |
| **9.1** | **Packaging** | | **P** |

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|---|---|---|---|
| Clause | Requirements - Test | Result - Remark | Verdict |
| **9.2** | **Particle filtering half mask** | | **P** |
| **10** | **Information to be supplied by the manufacturer** | | **P** |
| | Information supplied by the manufacturer shall accompany every smallest commercial available package. | | **P** |
| | Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination. | | **P** |
| | The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on<br>— application/limitations;<br>— the meaning of any colour coding;<br>— checks prior to use;<br>— donning, fitting;<br>— use;<br>— maintenance (e.g. cleaning, disinfecting), if applicable;<br>— storage;<br>— the meaning of any symbols/pictograms used<br>of the equipment. | | **P** |
| | The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added. | | **P** |
| | Warning shall be given against problems likely to be encountered | | **P** |
| | The information shall provide recommendations as to when the particle filtering half mask shall be discarded. | | **P** |
| | 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** |

End of report