



**PRODUCT MANUAL FOR
RESPIRATORY PROTECTIVE DEVICES–
FILTER HALF MASKS TO PROTECT AGAINST PARTICLES
According to IS 9473:2002**

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure coherence of practice and transparency in operation of certification under Scheme-I of Bureau of Indian Standards (Conformity Assessment) Regulations, 2018 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification/licence/certificate.

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|----|--|---|--|
| 1. | Product | : | IS 9473:2002 |
| | Title | : | RESPIRATORY PROTECTIVE DEVICES – FILTER HALF MASKS TO PROTECT AGAINST PARTICLES-SPECIFICATION |
| | No. of Amendments | : | 0 |
| 2. | Sampling Guidelines: | | |
| a) | Raw material | : | No specific requirement |
| b) | Grouping guidelines | : | Please refer ANNEX- A |
| c) | Sample Size | : | 70 numbers |
| 3. | List of Test Equipment | : | Please refer ANNEX –B |
| 4. | Scheme of Inspection and Testing | : | Please refer ANNEX –C |
| 5. | Possible tests in a day : | | |
| | Since testing facility is not available in any BIS/BIS recognized lab, complete testing has to be carried out in the Factory.3 days required for complete testing. | | |
| 6. | Scope of the Licence : | | |
| | “Licence is granted to use Standard Mark as per IS9473:2002 with the following scope: | | |
| | Name of the product | RESPIRATORY PROTECTIVE DEVICES – FILTER HALF MASKS TO PROTECT AGAINST PARTICLES | |
| | Class | Class FFP1/FFP2/FFP3 | |
| | Sub-Class | S (Solid) / SL (Solid and Liquid) | |
| | Type | With / without Valves; For single use only or not | |
| | Clogging | Without resistance to clogging /With resistance to clogging for use in mining applications /With resistance to clogging for use in other than mining applications | |

ANNEX A

GROUPING GUIDELINES

Following grouping guidelines shall apply while defining the scope of the licence in case of application for grant of licence or application for change in scope of licence

1. If higher class filtering half mask is tested, lower class may be considered with same configuration. i.e.,
 - a. If FFP3 sample is tested, FFP1 & FFP2 may also be covered.
 - b. If FFP2 sample is tested, FFP1 may also be covered.
2. If subclass SL (Solid and Liquid) is tested, subclass S (Solid) may also be covered.
3. If sample with valves is tested, without valves also may be covered
4. If sample not for single use only is tested, single use only product also may be covered.

However, it shall be ensured that the firm has the requisite manufacturing and testing facilities to produce the varieties intended to be covered in the scope of licence

During operation of licence, samples of all varieties shall be drawn and tested by rotation.

ANNEX B
List of Test Equipment

Major test equipment required to test as per the Indian Standard

| Sl. No. | Tests used in with Clause Reference | Test Equipment |
|---------|--|---|
| 1 | Material Cl 5.1 | Breathing Machine as per A-1.1 Dummy Head Temperature Conditioning – oven and freezer |
| 2 | Practical performance testing, Cl. 5.3 | Practical performance testing set up as per A-2 |
| 3 | Total inward leakage consists of 3 components 1) face seal leakage, 2) exhalation valve leakage 3) filter penetration, Cl.5.4.1 | Treadmill working at 6km/h Flow Distributor A panel of ten clean shaven person Flow rate meter Apparatus as per Fig 3 consisting Sodium Chloride (NaCl) Aerosol generator as per A-3.2.2.2 & Fig 4 Flame photometer as per A-3.2.2.4 Sample selector as per A-3.2.2.5 Sampling probe as per 3.2.2.6 Sample pump as per A-3.2.2.7 Sample Probe Fig 5 |
| 4 | Penetration of filter media Cl, 5.4.2 | a) Sodium Chloride test (A-4.2) as per apparatus at Fig 6 & 7 b) Paraffin Oil Test as per A-4.3, apparatus as per Fig 9, 10 & 11 |
| 5 | Flammability Cl 5.6 | Flammability Rig, measuring instrument to measure temperature |
| 6 | Carbon Dioxide Content of the inhalation air, Cl 5.7 | CO2 Gas Analyser Apparatus as per Fig 15, 16 & 17 |
| 7 | The field of vision, Cl. 5.9 | Apertometer (Field of Vision) |
| 8 | Inhalation and Exhalation Valves, Cl 5.10 | Fixture as per Fig 18 Arrangement to apply an axial force of 10 N |
| 9 | Breathing resistance of the valved & valveless filtering masks, Cl. 5.11 | Breathing Resistance Rig as per Fig 15, Dummy Head 9 type (Sheffield), breathing machine, |

| | | |
|----|---|---|
| | | barometer/pressure indicator, flow meter, stop watch |
| 10 | Clogging, CI 5.12 i) CoalDust ii) Dolomite Dust | i) Test Apparatus as perFig19 ii) Test Apparatus as perFig20 |
| 11 | Air Conditioner to maintain Temperature and humidity in lab | |

The above list is indicative only and may not be treated as exhaustive.

ANNEXURE-C

**SCHEME OF INSPECTION AND TESTING
FOR RESPIRATORY PROTECTIVE DEVICES – FILTER HALF MASKS TO PROTECT
AGAINST PARTICLES ACCORDING TO IS 9473:2002**

1. LABORATORY - A laboratory shall be maintained which shall be suitably equipped (as per the requirement given in column 2 of Table 1) and staffed, where different tests given in the specification shall be carried out in accordance with the methods given in the specification.

1.1 The manufacturer shall prepare a calibration plan for the test equipment.

2. TEST RECORDS – The manufacturer shall maintain test records for the tests carried out to establish conformity.

3. PACKING AND MARKING– The Standard Mark as given in the Schedule of the licence, shall be suitably marked on each half filter masks and its container, provided always that the half filter masks to which this mark is thus applied, conform to every requirement of the specification.

3.1 Packing and marking shall be done as per the requirements of IS 9473:2002. In addition, the following shall be marked on each half filter mask or its container:

- i) BIS Licence No, CM/L-
- ii) BIS website details: For BIS certification details visit www.bis.gov.in

3.2 **INSTRUCTION FOR USE** – Instructions for use as given in IS 9473:2002 shall be supplied in English and Hindi/the local language with every half filter mask marked with Standard Mark.

4. CONTROL UNIT – For the purpose of this scheme, all filtering half masks of one class and variety produced in **one day** shall be considered as a control unit.

5. LEVELS OF CONTROL - The tests as indicated in column 1 of Table 1 and the levels of control in column 3 of Table 1, shall be carried out on the whole production of the factory which is covered by this plan and appropriate records maintained in accordance with paragraph 2 above.

5.1 In case of failure in any requirements the entire control unit shall not be marked with the Standard mark. After the cause of failure is investigated and necessary corrective actions taken, the Filtering half masks in a control unit of 1000 nos. with improvements incorporated therein shall be tested as per the levels of control on the full control unit and the marking shall be resumed only if these Filtering half masks satisfy with all the requirements of the specification. The Bureau shall be kept informed at every stage.

5.2 All the production which conforms to the Indian Standards and covered by the licence should be marked with Standard Mark.

6. STORAGE – Instructions for storage as given in the Indian Standard shall be complied.

7. REJECTIONS– Disposal of non-conforming product shall be done in such a way so as to ensure that there is no violation of provisions of BIS Act, 2016.

TABLE 1
LEVELS OF CONTROL

| (1) | | | | (3) | | | |
|--------------|------------------------------------|--------------|--------------|--|--------------------|------------------------------------|---------|
| Test Details | | | | Levels of Control | | | |
| Cl. | Requirement | Test Methods | | Test equipment requirement R: required (or)S: Sub-contracting permitted | No. of Samples | Frequency | Remarks |
| | | Clause | Reference | | | | |
| 5.1 | Materials | 5.1 | IS9473: 2002 | S | | | Note 4 |
| 5.1.1 | Component/Straps | 5.1.1 | Do | S | 3 | Every 7 th control unit | |
| 5.1.2 | Facepiece | 5.1.2 | Do | S | (above 3 nos) | Do | |
| 5.1.3 | Material Suitability | 5.1.2 | Do | S | All | Do | |
| 5.1.4 | Metal Parts | 5.1.4 | Do | S | All | Do | |
| 5.2 | Cleaning and Disinfection | 5.2 | Do | S | 5 nos (A.R) | Once in a year | Note 1 |
| 5.3 | Practical Performance Test | 5.3 | Do | S | 2 nos (A.R.) | Once in a year | Note 1 |
| 5.4 | LEAKAGE | 5.4 | | S | | | |
| 5.4.1 | Total Inward Leakage | 5.4.1 | do | S | 10 nos | | Note 1 |
| (A.R) 5 nos | | | | | Once in a year | | |
| (T.C) 5 nos | | | | | Once in a year | | |
| 5.4.2 | Penetration of Filter Material | 5.4.2 | Do | S | 12 foreach aerosol | | Note 1 |
| (A.R) 3 nos | Every 7 th control unit | | | | | | |
| (S.W) 3 nos | Once in a Year | | | | | | |
| (M.S) 3 nos | Once in a year | | | | | | |
| (T.C) 3 nos | Once in a year | | | | | | |
| 5.5 | Compatibility with Skin | 5.5 | Do | S | 10 nos. | | |

| | | | | | | | |
|----------|--|----------|---------------------|---|--------------|------------------------------------|---|
| | | | | | (A.R) 5 nos | Every 7 th control unit | |
| | | | | | (T.C) 5 nos | Once in a year | |
| 5.6 | Flammability | 5.6 | | S | 4 nos. | | Note 1 |
| | | | IS 9473:20 02 | | (A.R) 2 nos | Once in a year | |
| | | | | | (T.C) 2 nos. | Once in a year | |
| 5.7 | Carbon dioxide content of the inhalation air | A-6 | -do- | S | (A.R) 3 nos | Every 7 th control unit | |
| 5.8 | Head Harness | 5.8 | | S | | Once in a year | |
| 5.8.1 | Head Harness comfort | 5.8.1 | Do | S | - | Do | To be conducted with clause 5.3 |
| 5.8.2 | During leakage test | 5.8.2 | Do | S | - | Do | To be conducted with clause 5.3 & 5.4.1 |
| 5.9 | Field of Vision | 5.9 | Do | S | 2 nos. (A.R) | Once in a year | To be conducted with clause 5.3, Note 1 |
| 5.10 | Inhalation and Exhalation Valve | 5.10 | Do | S | | | |
| 5.10.2 | Exhalation Valve (s) | 5.10.2 | Do | S | | | To be verified during test 5.4.1.1 |
| 5.10.2.1 | During leakage test | 5.10.2.1 | Do | S | | | do |
| 5.10.2.2 | After leakage test | 5.10.2.2 | Do | S | | | do |
| 5.10.2.3 | Exhalation Valve Flow | 5.10.2.3 | Do | S | 3 nos. | | Note 1 |
| | | | | | (A.R) 1 nos | Every 7 th control unit | |
| | | | | | (T.C) 2 nos | Once in a year | |

| | | | | | | | |
|---------------|--|----------------|----|---|---------------|---------------------------------------|---|
| 5.10..2.4 | Exhalation Valvetensile force | 5.10.2.4 | Do | S | 3 nos. | | Note 1 |
| | | | | | (A.R)1 nos | Every 7 th control unit | |
| | | | | | (T.C) 1No | Once in a year | |
| | | | | | (M.S.) 1no | Once in ayear | |
| 5.11 | BREATHING Resistance | 5.11 | Do | S | 12 nos. | | Note 1 |
| | | | | | (A.R) 3 nos | Every 7 th control unit | |
| | | | | | (T.C) 3 nos | Once in a year | |
| | | | | | (S.W)3 nos | Once in a year | |
| | | | | | (M.S.) 3 nos | Once in ayear | |
| 5.12 | Clogging | 5.12 | Do | S | 3 nos | | Respirator s shall be tested for clogging either with coal dust or dolomite depending on end use. |
| | | | | | (A.R) 1 nos | Once in ayear | |
| | | | | | (T.C) 2 nos | Do | |
| 5.12.1 | Coal mining/Dolomite dust | 5.12.1 | | S | As above | As above | For single use respirator this test is optional |
| 5.12.2 | Breathing Resistance After Clogging | 5.12.2 | | S | As above | As above | |
| 5.12.2.1 | Valved filtering half mask | 5.12.2 | | S | As above | As above | |
| 5.12.2.2 | Valveless filtering half mask | 5.12.2.2 | | S | As above | As above | |
| 5.12.2.3 | Filtering Penetration | 5.12.2.3 | | S | As above | As above | |
| 5.13.6 & 7 | De- mountableParts, Visual inspection & UserInstructions | 5.13.,6 & 7 | | S | 5 | Every 7 th control unit | |

Abbreviations/Footnotes:

- A.R. As received
- M.S. Mechanical Strength
- S.W. Simulated wearing
- T.C. TemperatureConditioning
- 1) Two Tests available
- a) Coal dust for mining application
- b) Dolomite dust for other

Note 1 : Whenever there is a change in the design or material, compliance to all the requirements of the standards to be ensured by carrying out all the tests as per IS 9473 and product shall be marked only after conformity has been established. This testing may be conducted either in-house or in the factory of a BIS licensee (with that variety covered in their scope) or laboratory established or recognized by the Bureau or Government laboratories empaneled by the Bureau

Note 2: Sub-contracting is permitted for all tests only if the manufacturer has applied for grant of licence or addition in scope of licence for FFP2 Masks. Subcontracting may be done to a laboratory of a BIS licensee (whose scope covers the variety to be tested), or a laboratory established or recognized by the Bureau or Government laboratories empaneled by the Bureau

Note 3: Levels of control given in column 3 are only recommendatory in nature. The manufacturer may define the control unit/control unit/lot and submit his own levels of control in column 3 with proper justification to BO head.

Note 4: Conformity of the materials to the requirements of the standard may be established either through the supplier/manufacturer's test certificate, or test report issued by BIS lab/BIS recognized Lab/BIS Empaneled Lab or through in-house testing.