www.bis.gov.in

उत्पाद मैन्युअल
श्वसन सुरक्षात्मक उपकरण आधा — मास्क और चौथाई मास्क — विशिष्टि 14746: 2025 के अनुसार

PRODUCT MANUAL FOR
RESPIRATORY PROTECTIVE DEVICES - HALF MASKS AND QUARTER MASKS — SPECIFICATION ACCORDING TO IS 14746 : 2025

विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन) विनियम, 2018 की योजना -I के तहत प्रमाणन के संचालन में एकरूपता और पारदर्शिता के लिए इस उत्पाद मैनुअल का उपयोग सभी क्षेत्रीय / शाखा कार्यालयों और लाइसेंसधारियों द्वारा संदर्भ सामग्री के रूप में किया जाएगा। दस्तावेज़ का उपयोग बीआईएस प्रमाणन प्राप्त करने के इच्छुक संभावित आवेदकों द्वारा भी किया जा सकता है।

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure uniformity 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.

1.	**मानक संख्या** **IS No.**	:	IS 14746: 2025
	शीर्षक **Title**	:	Respiratory Protective Devices - Half Masks and Quarter Masks – Specification
	संशोधनों की संख्या **No. of amendments**	:	NIL
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चा माल** **Raw material**	:	Material shall comply to the requirements of Cl 4.1 and 4.8 (Conformity may be established through supplier's certificate or manufacturer's declaration) Note: This section indicates the requirements for raw material(if specified in the IS)for which compliance is to be established during Grant of Licence/Change in Scope of Licence/Factory Surveillance.
b)	**समूहीकरण दिशानिर्देश** **Grouping Guidelines**	:	Each type of mask (half and quarter) shall be tested to be covered in the scope of Licence mask to be tested

c)	**नमूने का परिमाण** **Sample Quantity**	:	20 nos. Note: This section indicates the quantity of the sample of the product and/or the raw material (if applicable), required to be sent to the laboratory for testing, for the purpose of Grant of Licence/Change in Scope of Licence/ Factory Surveillance (in case of market surveillance, effort may be made to procure the required quantity of product sample, as far as possible since raw material sample may not be available in market)
d)	**परीक्षण अनुरोध में घोषित किए जाने वाले पैरामीटर** **Parameters to be Declared in Test Request**	**:**	**Type** Note: This section indicates declared values to be specified against a parameter (to be specified in Test Requests) to enable testing of sample against the requirement and determine its conformity. Any other requirements/parameters may also be declared as per the standard, as applicable.
3.	**परीक्षण उपकरणों की सूची** **List of Test Equipment**	:	Please refer to Annex - A
4.	**निरीक्षण और परीक्षण की स्कीम** **Scheme of Inspection and Testing**	:	Please refer to Annex - B
5.	**एक दिन में संभावित परीक्षण** **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 visit required for complete testing. Note: This section is for the guidance of BIS Certification Officers/Technical Auditors of BIS Authorized Outside Surveillance Agencies(OSAs) during factory inspection to provide ready reference regarding the tests which can be witnessed during the inspection in the factory by the officer/auditor.		
6.	**लाइसेंस का दायरा/Scope of the Licence:**		
	IS 14746 : 2025 के अनुसार मानक मुहर का उपयोग करने के लिए लाइसेंस निम्नलिखित कार्यक्षेत्र के लिए प्रदान किया जाता है “Licence is granted to use Standard Mark as per IS 14746 : 2025 with the following scope:		
	उत्पाद का नाम **Name of the product**	Respiratory protective devices	
	Type	Half masks and/or quarter masks	

ANNEX– A

LIST OF TEST EQUIPMENTS

(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No.	Tests used in with Clause Reference	Test Equipment
1	Cleaning and disinfection (Cl 4.3)	• Cleaning and disinfection agents as recommended by manufacturer
2	Visual Inspection (B-1)	• Dummy Head,
3	Practical Performance Test (Cl. 4.5)	• Practical performance testing set up as per IS 17274 (Part 7)
4	Resistance of Temperature (Cl. 4.6)	• Deep freezer which can maintain low temperature up to -30±3º C, Oven which can maintain temperature up to 70±3º C.
5	Inward Leakage of Facepiece (Cl. 4.7)	• Test panel of ten clean shaven person selected as per the criteria given in IS 17274 (Part 1). • Test agents Sulphur Hexafluoride (SF_6)/ sodium chloride aerosol (NaCl)/ corn oil, Test agent generator, Detection system • Enclosure, • Treadmill • Arrangement for the ambient conditions for testing as per IS 17274 (Part 1).
6	Flammability (Cl. 4.9)	• Test rig as per 6.2.4 of IS 17274 (part 10), propane cylinder with flow control device, pressure gauge, flash back arrester, specimen support, rotation motor with speed controller, timer, and burner
7	Carbon Dioxide content of the Inhalation Air (Cl. 4.10)	• Apparatus as per IS 17274(Part 9) • RPD head form/torso • Breathing Machine • Exhalation and inhalation reservoirs • CO2 Analyzer • CO2 Cylinder • CO2 Flow meter
8	Head Harness (Cl. 4.11) & Facepiece Connector (Cl. 4.12)	• Pull Test setup to apply 50 N • Stop Watch • Dummy head • Humidity Chamber ±1 °C
9	Field of Vision (Cl. 4.13)	• Apertometer as per IS 17274 (Part 11), • Headforms • Visual field score plotting chart • Ambient conditions for testing

10	Inhalation and Exhalation Valves (Cl. 4.14)	• Breathing Machine • Pull Testing Machine to apply 50N • Stop Watch • Human test panel • air flow meter • Treadmill • Sulfur hexafluoride (SF6) • Sodium chloride (NaCl) • Flame photometer • filtering devices • Flow Pump • Corn oil aerosol
11	Breathing Resistance (Cl. 4.15)	• Breathing Machine • Support for the RPD, • Pressure gauge and recording device, • ambient conditions for testing as per IS 17274 (Part 2) and Ambient temperature and ambient atmospheric pressure measuring equipment.

ANNEX B

SCHEME OF INSPECTION AND TESTING

1. QUALITY ASSURANCE PLAN

1.1 It is expected that manufacturers (licensees/applicants) will implement a Quality Assurance Plan i.e. a plan of regular testing and in-process controls, designed to ensure that the product bearing the Standard Mark conforms to all requirements of the Indian Standard.

1.2 The manufacturers shall define a Quality Assurance Plan defining the control unit (i.e. lot/batch etc.) and the levels of control (i.e. the frequency and number of samples for conducting the differenttests as per the Indian Standard) and submit the same to BIS Branch Office for information. The manufacturer shall comply with the same and maintain test records in accordance with para 2.4.

1.3 **RECOMMENDED LEVELS OF CONTROL/CONTROL UNIT**:

For the guidance of manufacturers, the recommended definition of control unit is: Masks of each type (half or quarter) produced under similar conditions in a day from the same batch/consignment of raw materials

1.3.1 For the guidance of manufacturers in preparing the Quality Assurance Plan, recommended levels of control are given in **Table 1**.

1.3.2 The manufacturer shall ensure inspection and testing as per the Quality Assurance Plan submitted by them on the whole production of the factory which is covered by this plan. Alternatively, the manufacturer has the option of adherence to the quality plan as per levels of control recommended in column 3 of Table 1.

1.4 However, all manufacturers shall ensure compliance of their products to all the requirementsof the Indian Standard.

2. ENSURING COMPLIANCE THROUGH TESTING- It is expected that manufacturers (licensees/applicants) will establish a suitably equipped and staffed in house laboratory (In housetesting facility) for testing at least those parameters of the Indian Standard which require routine testing for ensuring quality of the product. This includes in-process controls as may be defined and put in place by the manufacturer and testing parameters/requirements which can only be performed in the factory.

2.1 For the guidance of manufacturers, Table 1 giving the recommended levels of control is givenbelow. Column 2 of Table 1 indicates routine tests where test equipment is required in house as “R”

2.2 Manufacturers shall also implement a calibration plan for the in-house test equipment.

2.2.1 In lieu of an in-house laboratory, manufacturers can also utilize the provisions of Sharing of testing facilities as per the Guidelines for Grant of Licence available on BIS website www.bis.gov.in. (Under Conformity Assessment>Product Certification Process).

2.3 **TEST RECORDS**- The manufacturers maintaining an in-house laboratory or utilizing commoncluster based facilities or shared test facilities 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 incorporated legibly and indelibly on each mask and on its package (if used). provided always that the material so marked conforms to each requirement of the specification.

3.1 Packing and Marking shall be done as per the Indian Standard.

3.2 **Additional Marking requirements**: The mask and/or its packaging shall also be marked with the following

a) "For BIS certification details please visit www.bis.gov.in"

4. REJECTION - All the production which conforms to the Indian Standard and covered under the scope of this licence shall be marked with the Standard Mark. 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
(ONLY FOR GUIDANCE PURPOSE)

(1)				(2)	(3)		
Test Details				**Test equipment requirement R: required (or) S: Subcontracting permitted**	**Levels of Control**		
Cl.	**Requirement**	**Test Method**			**No. of Sample**	**Frequency**	**Remarks**
		Clause	**Reference**				
4.1	Materials	**-**	IS 14746	**-**	Each consignment	Each lot of material received	Conformity may be established through material supplier's certificate or manufacturer's declaration
4.2	Design	-	-do-	**R**	Firm to have adequate in- process controls to check compliance of this parameter given in the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity		
4.3	Cleaning and Disinfecting	-	-do-	**R**			
4.4	Replaceable Component	**Annex B-1**	-do-	**R**			
4.5	Practical Performance Test	-	IS 17274 (Part 7)	**R**	One	Once a month	
4.6	Resistance of Temperature	**Annex B-2**	-do-	**R**	One	Once a month	
4.7	Inward Leakage of Face Piece	-	IS 17274 (Part 1)	**R**	One	Once a month	
4.8	Compatibility with Skin	-	IS 14746	**-**	Each consignment of material	Each lot of material received	Conformity may be established through material supplier's certificate or manufacturer's declaration
4.9	Flammability	-	IS 17274 (Part 10)	**R**	One	Once a month	
4.10	Carbon Dioxide Content of the Inhalation Air	-	IS 17274 (Part 9)	**R**	One	Each control unit	
4.11	Head Harness	-	IS 17274 (Part 7)	**R**	One	Once a month	

4.11.3	Head Harness pull up test	-	IS 14746	**R**	One	Each control unit	
4.12	Face Piece Connector	**Annex B1**	-do-	**R**	Firm to have adequate in- process controls to check compliance of this parameter given in the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity		
4.12.3	Tensile Force of the Connection	**Annex B3**	-do-	**R**	One	Each control unit	
4.13	Field of Vision	-	17274 (Part 11)	**R**	One	Once a month	
4.14	Inhalation and Exhalation Valves	-	IS 14746	**R**	Firm to have adequate in- process controls to check compliance of this parameter given in the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity		
4.14.2.4	Exhalation flow	-	-do-	**R**	One	Each control unit	
4.14.3	Exhalation Valve Housing	-	-do-	**R**	One	Each control unit	
4.15	Breathing Resistance	-	IS 17274 (Part 2)	**R**	One	Each control unit	
4.16	De-mountable Parts	-	IS 14746	**R**	Firm to have adequate in- process controls to check compliance of this parameter given in the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity		