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उत्पाद मैन्युअल
श्वसन संरक्षी युक्तियाँ सम्पूर्ण चेहरे के मुखौटे — विशिष्टि
14166: 2024 के अनुसार

PRODUCT MANUAL FOR
RESPIRATORY PROTECTIVE DEVICES FULL FACE MASKS — SPECIFICATION
ACCORDING TO IS 14166: 2024

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 14166: 2024
	शीर्षक **Title**	:	Respiratory Protective Devices Full-Face 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 5.2 (Conformity may be established through material 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**	:	All class of face masks is to be tested to be covered in the scope of licence

c)	**नमूने का परिमाण** **Sample Quantity**	:	40 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**	**:**	Class 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**		
	Complete testing is not available in any lab and has to be carried out in the Factory requiring **4 days of** visit. 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:**		
	आईएस 14166:2024 के अनुसार मानक चिह्न का उपयोग करने के लिए लाइसेंस निम्नलिखित दायरे में प्रदान किया जाता है: “ Licence is granted to use Standard Mark as per IS 14166: 2024 with the following scope:		
	Name of the product		RESPIRATORY PROTECTIVE DEVICES FULL- FACE MASKS
	Class		Class 1 and/or Class 2 and/or Class 3

ANNEX– A
LIST OF TEST EQUIPMENTS
(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No.	Tests used in with Clause Reference	Test Equipment
1	Speech Diaphragm assembly	fixture to fit Speech diaphragm as per Cl 6.4, air pump to apply a differential pressure
2	Practical Performance Test	arrangement for exercises as per Table A.1 of IS 17274 (Part 7) : 2023, filter simulator/filter as per Cl 6.5, arrangement for ambient conditions of temperature and humidity
3	Resistance to temperature	Thread guage
4	Leak tightness	dummy head, arrangement for creating a pressure of -10 mbar in the cavity of the facepiece
5	Flammability	Metallic dummy head,,Test rig as per 6.2.4.2 of IS 17274 (part 10),
6	Resistance to Thermal Radiation	two flat radiant heat panels, arrangement for ambient temperature, manikin
7	Inward Leakage of Facepiece	Enclosure, Treadmill, Test agent generator (NaCl/SF6), Detection system,
8	Carbon Dioxide Content of the Inhalation Air	sheffield dummy head, Breathing Machine, Carbon dioxide analyser (as per IS 17274 (Part 9))
9	Strength for Head Harness	Pull Test machine, Measuring Scale
10	Face piece Connector	Thread gauges, Dummy Head, arrangement to apply tensile force,
11	Test for Field of Vision	Headforms. Apertometer, Visual field score plotting chart, arrangement for ambient conditions
12	Impact resistance of visor	Dummy Head, Steel ball 22 mm Diameter 43.8 g with stand to drop from 1.3m, Weighing Scale. Measuring Tape.
13	Inhalation and Exhalation Valves	Gauges for connections in accordance with IS 14138 (Part 2) and IS 14138 (Part 1)
14	Breathing Resistance Test	Dummy head, Breathing Machine, Pressure Transducer, Ambient temperature and ambient atmospheric pressure measuring equipment
15	Conditioning	Oven, conditioning chamber, deep freezer (- 30 ± 3 ^{o}C)

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: all Respiratory Protective Devices-Full Face Masks of same variety produced under similar conditions in a day/shift 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 Alternatively, in lieu of an in-house laboratory, manufacturers can also utilize theprovisions 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 common cluster based facilities or shared test facilities shall maintain test records for the tests carried out to establish conformity. For the tests being subcontracted to BIS recognized/empanelled laboratoryor any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025, test reports issued by the laboratories shall be available for inspection by BIS.

3. PACKING AND MARKING - The Standard Mark as given in the Schedule of the licence shall be incorporated legibly and indelibly on each full face masks for respiratory protective devices 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 shall also be marked with the following additional requirement

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: Sub-contracting permitted**	**Levels of Control**		
Cl.	**Requirement**	**Test Method**			**No. of Sample**	**Frequency**	**Remarks**
		Clause	**Reference**				
5.2	Material	6.2	IS 14166	R	Each consignment	Each lot of material received	Conformity may be established through material supplier's certificate or manufacturer's declaration
5.3	Cleaning and disinfection	6.3	-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		
5.4	Finish of Parts	6.2 & 6.5	-Do-	R	One	Once a month	
5.5	Speech Diaphragm Assembly	6.2 and 6.4.1	-Do-	R	One	Each Control Unit	
5.6	Replaceable Component	6.2	-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		applicable to Class 3 full face masks only.
5.7	Practical Performance Test	6.5	-Do-	R	One	Once a month	
5.8	Resistance to Temperature	6.2, 6.14, 6.6 and 6.7	-Do-	R	one	Once a month	
5.9	Leak Tightness	6.6		R	Each apparatus		
5.9.2	Compatibility with Skin	6.2 and 6.5.	-Do-	R	One	Once a month	

5.10	Flammability	6.2 and 6.13.1, 6.13.2.	-Do-	R	One	Once a month	
5.11	Resistance to Thermal Radiation	6.6 and 6.15	-Do-	R	one	Once a month	Applicable for Class 3
5.12	Inward Leakage of face piece	6.7	-Do-	R	one	Once a month	
5.13	Carbon Dioxide content of the Inhalation Air	6.8	-Do-	R	One	Each Control Unit	
5.14	Head Harness	6.2 and 6.5	-Do-	R	one	Once a month	
5.14.3	Strength of Harness	6.2 and 6.9, 6.9.2	-Do-	R	One	Each Control Unit	
5.15	Facepiece Connector	6.2, 6.5 and 6.7	-Do-	R	one	Once a month	
5.15.3	Strength of Connectors	6.6, 6.10.	-Do-	R	One	Each Control Unit	
5.16	Eyepiece (s) and Visor(s)	6.2, 6.5, 6.11, 6.6	IS 14166, IS 17274 (Part 11)	R	one	Once a month	
5.17	Inhalation and Exhalation Valves	6.2, 6.12 and 6.16	IS 14166	R	One	Each Control Unit	
5.18	Breathing Resistance	6.12	-Do-	R	One	-Do-	