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उत्पाद मैन्युअल

Textiles – Medical Respirator - Specification

IS 18266:2023 के अनुसार

PRODUCT MANUAL

FOR Textiles – Medical Respirator - Specification

ACCORDINGTO IS 18266:2023

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 18266:2023
	शीर्षक **Title**	:	Textiles – Medical Respirator - Specification
	संशोधनों की संख्या **No. of amendments**	:	01
2.	नमूना दिशानिर्देश **Sampling Guidelines**		

a)	**कच्चा माल** **Raw material**	:	Material shall conform to the requirements as per Cl. 4.1 of IS 18266:2023. Manufacturer shall submit a declaration/undertaking that the textile material used meets the specified requirements. For fabric requirements as per Cl. 4.1, compliance shall be established through supplier's test certificate, or test report issued by a BIS recognized/empanelled lab or any other lab having valid NABL accreditation as per IS/ISO/IEC 17025 or in house testing. 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**	:	Samples of each class of respirator intended to be covered in the scope of licence shall be tested In case optional requirements of biocompatibility evaluation and flammability are intended to be covered in the scope of licence, compliance to these requirements shall be confirmed at design stage.
c)	**नमूने का परिमाण** **Sample Quantity**	:	90 pieces 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**	:	i. Class ii. Optional Requirements: a) With/without resistance to flammability b) With/without Biocompatibility evaluation Note: Apart from the above, 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**		

	Breathing resistance, Splash resistance, Penetration of filter Sodium chloride test, Inward leakage, CO_2 content & Flammability (resistance to flame, single burner, dynamic test) 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:**	
	Licence is granted to use Standard Mark as per IS 18266:2023 with the following scope:	
	Name of the product	Medical Respirator
	Class	IN95 and/or IN99
	Optional requirements	With/without resistance to flammability With/without Biocompatibility evaluation

ANNEX – A

LIST OF TEST EQUIPMENTS

(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No.	Tests Used In With Clause Reference	Test Equipment/Chemical
1	Breathing resistance, Clause 5.1 Table 1 Sl no. i	IS 17274 (Part 2) (Method 1: Static breathing resistance) Pressure gauge, Flowmeter(s), Ambient temperature and ambient atmospheric pressure measuring equipment, Regulated blower/compressed air source and/or a variable suction device. Support for the device (e.g. filter holder or relevant RPD headform)
2	Splash resistance, Clause 5.1 Table 1 Sl no. ii	• Splash resistance test apparatus: A suitable test apparatus to dispense a specified volume of synthetic blood through a small diameter canula (1.27 cm long with an internal diameter of 0.084 cm and length more than 30.5cm) over a controlled amount of time at a specimen mask a set distance away. The test apparatus consists of a specimen holding fixture, a targeting plate, a pressurized fluid reservoir, a pneumatically actuated valve with interchangeable canula and a valve controller. The test apparatus includes a base for more convenient mounting of the components and a hood or other components to contain or control the splash. • Synthetic Blood • Isopropanol, laboratory grade, for cleaning the apparatus. • Talcum Powder, Pipette capable of dispensing 0.1 ml, Stop Watch Test method: Annex B of IS 18266
3	Penetration of filter, Sodium chloride test method (Full exposure particle penetration test) Clause 5.1 Table 1 Sl no. iii	Full exposure penetration tests as per IS 17274 (Part 3) Reference aerosols - Sodium Chloride (solid aerosol) and paraffin oil (liquid aerosol) as per IS 17274 (Part 3) - Test apparatus for determination of particle filter penetration consisting of four modules: aerosol generator, flow control, filter test chamber and aerosol detector as per IS 17274 (Part 3)
4	Inward leakage, Clause 5.1 Table 1 Sl no. iv	Sodium Chloride (NaCl) Method: Test enclosure and apparatus for the determination of inward leakage using sodium chloride incorporating Level Treadmill capable of working at 6 km/h, NaCl aerosol generator, test agent, sampling probe, sample pump, pressure detection probe, manometer, flame photometer, sample selector etc Test method:

5	CO_2 content, Clause 5.1 Table 1 Sl no. v	IS 17274 (Part 9) RPD head form, Breathing machine, Any air or breathable gas supply is operated in the manufacturer's minimum condition, Breathing gas containing a defined concentration of carbon dioxide is supplied at a specified rate from a breathing machine to the RPD head form.
6	Cleanliness-microbial, Clause 5.1 Table 1 Sl no. vi	As per ISO 11737 (Part 1)
7	Flammability (resistance to flame, single burner, dynamic test	Test rig for flammability as per IS 17274 Part 10 clause 6.2.4 consisting of propane storage tank with control device and fine pressure gauge, flash back arrester, one Bunsen burner adjustable in height. Metallic dummy head with motorization arrangement capable of describing a horizontal circle with variable control speed. Thermometer/Temperature measuring device to record flame temperature Refer Figure 7 of IS 17274 Part 10— Typical arrangement of apparatus for single burner dynamic test
8	Biocompatibility Evaluation: a) Cytotoxicity b) Irritation and skin sensitization	a) As per IS/ISO 10993-5 b) IS/ISO 10993-10 & IS/ISO 10993-23

ANNEX C

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 different tests 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**:

1.3.1 For the guidance of manufacturers, the recommended definition of control unit is: *The quantity of respirators of the same class made from the same consignment of material under similar conditions of manufacture, in a day.*

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

1.3.3 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 requirements of 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 house testing 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 given below. Column 2 of Table 1 indicates routine tests where test equipment is required in house as "R" or other tests which can be subcontracted as "S". Subcontracting is permitted to BIS recognized/empanelled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025.

2.2 **For MSME manufacturers, the requirement of maintaining a laboratory/in-house testing facility for routine tests (indicated as "R" in Column 2 of Table 1) is also optional.**

2.2.1 MSME manufacturers may utilize common cluster based facilities as per guidelines for the utilization of cluster based test facilities by MSMEs or the provisions of Sharing of testing facilities or get testing done from BIS recognized/empaneled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025.

2.3 **Large Scale manufacturers shall maintain an in-house laboratory equipped at least with test facilities for routine tests (indicated as "R" in Column 2 of Table 1)**, where different tests given in the specification shall be carried out in accordance with the method given in the specification**.** They shall also implement a calibration plan for the in-house test equipment.

2.3.1 Alternatively, in lieu of an in-house laboratory, large scale 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). Even for subcontracted tests, provisions for sharing of testing facilities can be utilized.

2.4 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 laboratory or 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 medical respirator and its packaging 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 material shall also be marked with the following on the product or its packaging:

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

4. HYGIENIC CONDITIONS – Hygienic conditions shall be maintained while producing medical respirators.

5. 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 Methods Clause Reference**			**No. of Sample**	**Frequency**	**Remarks**
4	Manufacture and Workmanship						
4.1	Material	4.1	IS 18266	S	One	Each consignment	For fabric requirements as per Cl. 4.1, compliance shall be established through supplier's test certificate, or test report issued by a BIS recognized/empanelled lab or any other lab having valid NABL accreditation as per IS/ISO/IEC 17025 or in house testing.
4.2	Construction/Workmanship	4.2	IS 18266	R	Firm to have adequate in-process controls to check compliance of this parameter as per the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity		

4.3	Head harness	4.3	IS 18266	R	Firm to have adequate in-process controls to check compliance of this parameter as per the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity		
5	Performance requirements						
i)	Breathing Resistance		IS 17274 (Part 2)	R	5	Each Control unit	
ii)	Splash resistance	Annex B	IS 18266	R	5	Each Control unit	
iii)	Penetration of filter		IS 17274 (Part 3)	R	5	Each Control unit	
iv)	Inward leakage		IS 17274 (Part 1)	S	5	Once a year	
v)	CO_2 content		IS 17274 (Part 9)	S	5	Once a year	
vi)	Cleanliness-microbial		ISO 11737 (Part 1)	S	5	Once a year	
vii)	Flammability (resistance to flame, single burner, dynamic test) as received, (optional)		IS 17274 (Part 10)	S	The requirement of biocompatibility evaluation and flammability of raw material shall be confirmed at design stage. The biocompatibility evaluation and flammability test shall be carried out once for existing raw material and whenever there is a change in the raw material or source of supply for manufacturing the product.		
viii)	Biocompatibility Evaluation (optional) a) Cytotoxicity b) Irritation and skin sensitization		 a) IS/ISO 10993-5 b) IS/ISO 10993-10 and ISO 10993-23	S			