



उत्पाद मैनुअल
Medical Textiles — Barrier Face Covering — Specification
IS 19022:2023 के अनुसार

PRODUCT MANUAL
FOR Medical Textiles — Barrier Face Covering — Specification
ACCORDING TO IS 19022:2023

विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन) विनियम, 2018 की योजना- I के तहत प्रमाणन के संचालन में अभ्यास और पारदर्शिता के संचालन में पारदर्शिता सुनिश्चित करने 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 लाइसेंस/प्रमाणपत्र 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 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.

1.	उत्पाद Product	:	IS 19022:2023
	शीर्षक Title	:	Medical Textiles — Barrier Face Covering — Specification
	संशोधनों की संख्या No. of amendments	:	1
2.	नमूना दिशानिर्देश Sampling Guidelines		
a)	कच्चा माल Raw material	:	The raw material/fabric shall conform to the requirements given in Cl. 4.1 and for reusable face coverings it shall also conform to Cl. 7.1 (Table 1) of Indian Standard. For Cl. 4.1, manufacturer shall submit a declaration indicating that the materials used conform to the requirements of the standard. Conformity to requirements of Cl. 7.1 (Table 1) for reusable face coverings shall be established through test reports issued by BIS recognized labs or through in house testing.

b)	समूहीकरण दिशानिर्देश Grouping Guidelines	:	Separate samples of single use and reusable barrier face coverings (of any size and/or design) shall be tested. Further, in case optional requirement of flammability is to be covered in the scope of the licence, the sample(s) shall be tested for flammability requirement as well.
c)	नमूने का आकार Sample Size	:	20 pcs.
3.	परीक्षण उपकरणों की सूची List of Test Equipment	:	Please refer Annex-A
4.	निरीक्षण और परीक्षण की स्कीम Scheme of Inspection and Testing	:	Please refer Annex-B
5.	एक दिन में संभावित परीक्षण Possible tests in a day		
	Differential pressure, Particulate filtration efficiency (6 h conditioning period) Tie and Attachment Strength, Size and Design, Visual Examination		
6.	लाइसेंस का दायरा /Scope of the Licence:		
	"Licence is granted to use Standard Mark as per IS 19022:2023 with the following scope:		
	Name of the product	Medical Textiles — Barrier Face Covering	
	Types	Single Use/Reusable	
	Optional requirement	With/Without Flammability	

**BUREAU OF INDIAN STANDARDS
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ANNEX-A

LIST OF TEST EQUIPMENTS

Major test equipment required to test as per the Indian Standard

Sl. No.	Tests Used In With Clause Reference	Test Equipment/Chemical
1	Colour fastness to rubbing, Cl. 7.1	Suitable testing device for determining the colour fastness to rubbing, using a reciprocating Straight line rubbing motion and two alternative sizes of rubbing fingers. Cotton rubbing cloth, desized, bleached, without finish, cut into 50 mm squares (± 2 mm) Soft-back waterproof abrasive paper, or grating of stainless steel wire 1 mm in diameter and Mesh width about 20 mm. Grey scale, for assessing staining, in accordance with ISO 105-A03 Weighing balance White rubbing cloth Wire mesh or soft-back waterproof abrasive paper Rotary device, as described in ISO 105-X16 (recommended)
2	Colour fastness to perspiration (acidic and alkaline), Cl. 7.1	Test devices, each consisting of a frame of stainless steel into which a weight-piece of mass approximately 5 kg and base 60 mm $\times$ 115 mm is closely fitted, so that a pressure of ($12,5 \pm 0,9$) kPa can be applied on test specimens measuring (40 $\pm$ 2) mm $\times$ (100 $\pm$ 2) mm, placed between glass or acrylic resin plates measuring approximately 60 mm $\times$ 115 mm $\times$ 1,5 mm. The test device shall be constructed so that, if the weight-piece is removed during the test, the pressure remains unchanged. Oven, maintained at (37 ± 2) °C. Alkaline solution, freshly prepared, using grade 3 water complying with ISO 3696, containing, per litre: — 0.5 g of l-histidine monohydrochloride monohydrate ($C_6H_9O_2N_3 \cdot HCl \cdot H_2O$); — 5 g of sodium chloride (NaCl); and either

		— 5 g of disodium hydrogen orthophosphate dodecahydrate ($\text{Na}_2\text{HPO}_4 \cdot 12\text{H}_2\text{O}$) or — 2.5 g of disodium hydrogen orthophosphate dihydrate ($\text{Na}_2\text{HPO}_4 \cdot 2\text{H}_2\text{O}$). The solution is brought to pH 8 ($\pm 0,2$) with 0,1 mol/l sodium hydroxide solution. Acid solution, freshly prepared, using grade 3 water complying with ISO 3696, containing, per litre: — 0.5 g of l-histidine monohydrochloride monohydrate ($\text{C}_6\text{H}_9\text{O}_2\text{N}_3 \cdot \text{HCl} \cdot \text{H}_2\text{O}$); — 5 g of sodium chloride (NaCl); — 2.2 g of sodium dihydrogen orthophosphate dihydrate ($\text{NaH}_2\text{PO}_4 \cdot 2\text{H}_2\text{O}$). Adjacent fabrics (see ISO 105-A01). Either: A multifibre adjacent fabric complying with ISO 105-F10. or: Two single-fibre adjacent fabrics, complying with the relevant document selected from ISO 105-F01 to F06. Grey scale for assessing change in colour, complying with ISO 105-A02 Grey scale for assessing staining, complying with ISO 105-A03. Spectrophotometer or colorimeter for assessing change in colour and staining, complying with ISO 105-A04 and ISO 105-A05. A set of 11 glass or acrylic resin plates. Flat-bottomed dish made of inert materials. pH meter
3	Colour fastness to washing (A1S), Cl. 7.1	Suitable mechanical device, consisting of a water bath containing a rotatable shaft which supports, radially, stainless steel containers with a diameter of (75 ± 5) mm and a height of (125 ± 10) mm, of capacity (550 ± 50) ml, the bottom of the containers being (45 ± 10) mm from the centre of the shaft. The shaft/container assembly is rotated at a frequency of (40 ± 2) min⁻¹. The temperature of the water bath is thermostatically controlled to maintain the test solution at the prescribed temperature ± 2 °C. (Other mechanical devices may be used for this test, provided that the results

	are identical to those obtained using the apparatus described). Non-corrodible (stainless) steel balls, ≈ 6 mm in diameter A multifibre adjacent fabric, complying with ISO 105-F10, appropriate to the temperature used: – a multifibre adjacent fabric [DW1]] containing wool and acetate (tests at 40 °C and 50 °C and in certain cases, to be indicated in the test report, also at 60 °C); – a multifibre adjacent fabric [TV2]] not containing wool and acetate (in certain tests at 60 °C, and in all tests at 70 °C and 95 °C) Two single-fibre adjacent fabrics, complying with the relevant ISO 105-F01 to F07 standards. One of the adjacent fabrics shall be made of the same kind of fibre as that of the textile to be tested, or that predominating in the case of blends, and the second piece made of the fibre as indicated in Table 1 or, in the case of blends, of the kind of fibre second in order of predominance, or as otherwise specified. If required, a non-dyeable fabric (e.g. polypropylene). Detergent, without optical brightener (WOB). - AATCC3) 1993 Standard Reference Detergent WOB as per table 2 or ECE4) Detergent with Phosphates as per table 3 of IS/ISO 105-C06 : 2010 If required, sodium carbonate (Na_2CO_3) Sodium hypochlorite solution or lithium hypochlorite solution Sodium hypochlorite solution or lithium hypochlorite solution If required, sodium perborate tetrahydrate ($\text{NaBO}_3 \cdot 4\text{H}_2\text{O}$). Grade 3 water, complying with ISO 3696. Grey scale for assessing change in colour, complying with ISO 105-A02. Grey scale for assessing staining, complying with ISO 105-A03
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		Spectrophotometer or colorimeter for assessing change in colour and staining, complying with ISO 105-A04 and ISO 105-A05. If required for souring treatment, acetic acid solution containing 0,2 g of glacial acetic acid per litre
4	Dimensional stability to washing, Cl. 7.1 and Cl. 6	Ruler or flexible steel ruler or glass-fibre tape, marked in millimetres and longer than the greatest dimension being measured Equipment for marking precise reference points, such as: a) indelible ink, for use, if necessary, with a template with a measuring grid; b) fine threads of contrasting colour, sewn into the fabric; c) heated wire for making small holes in thermoplastics materials; d) staples (suitable for tests during which specimens are not agitated, e.g. for soaking in water). Smooth, flat surface, large enough to lay out complete articles. Workroom stands, to support garments Automatic washing machines (Type A or B) Tumble dryers Reference detergent 2
5	Differential pressure, Cl. 9.1	Suitable breathing resistance test apparatus for measurement of pressure differential equipped with flow meter, pressure gauges etc (such as the apparatus given in Fig. 2) or Equivalent automated instruments validated against the test method prescribed
6	Particulate filtration efficiency (at 3.0 µm) , Cl. 9.1	Aerosol containing suspended polystyrene latex (PSL) spheres or NaCl aerosol Aerosol test system consisting of clean, dry compressed air supply, high-efficiency particulate air (HEPA) filters, aerosol generator capable to generate aerosol size of 3.0 microns, charge neutralizer, humidifier, test filter holder and duct assembly, pressure drop measuring device, air flow rate measuring device, temperature and humidity detectors and optical particle counters, or Equivalent automated instruments validated against the test method prescribed

7	Fastening Mechanism, Cl. 8	Apparatus/instrument for subjecting laces, elastic strips, fabric tie etc used as fastening mechanism to force of 10 N (for single use face covering) or 50 N (for reusable face covering), Dummy head, Stop watch
8	Flammability (optional), Cl 7.2	Test Rig for flammability test as per IS 14166:1994 consisting mainly of a propane storage tank with control device and fine pressure gauge, flash back arrester, 6 propane burners being adjustable in height and with a vertically and horizontally pivotable metal dummy head.

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

ANNEX B

SCHEME OF INSPECTION AND TESTING

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

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

2. **TEST RECORD-** 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 incorporated legibly and indelibly on each piece of barrier face covering (and on the primary packaging of each face covering, in case of opaque packaging) provided always that the material so marked conforms to each requirement of the specification.

3.2 Packing and Marking shall be done as per the requirements of the standard. The face covering and/or its packaging shall also be marked with the following:

a) BIS licence number and “For BIS certification details please visit www.bis.gov.in”

3.3 The manufacturer shall provide the washing, drying, handling and storage instruction on every packet of reusable barrier face covering to ensure proper use and care by the consumer

5. **CONTROL UNIT-** For the purpose of this scheme, entire quantity of barrier face covering of the same type (single use/reusable), of the same size/design, manufactured using the same raw material/fabric under similar conditions of manufacture in a day shall be taken as one control unit.

6. **LEVELS OF CONTROL :-** The tests as indicate in Table 1 and at the levels of controls in column 3 of Table 1, shall be carried out on the whole production of the factory which is covered by this plan and records maintained in accordance with paragraph 2 above.

6.1 All the production which conforms to the Indian Standard and covered under the scope of this licence shall be marked with the Standard Mark.

7. **HYGIENIC CONDITIONS** – The manufacturer shall follow good manufacturing practices to maintain hygienic conditions as prescribed in Annex C of IS 17514 (reproduced at Annex C of this product manual)

8. **REJECTION** - 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.

TABLE1
LEVELS OF CONTROL

(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	Raw material/fabric	4.1	IS 19022	S	Each consignment	For each consignment, a declaration shall be made by the manufacturer indicating that the materials used conform to the requirements of the standard.	
4.2	Visual Examination	4.2	IS 19022	R	Manufacturer shall put in place adequate inspections and in process controls to ensure the material conforms to specified requirements		
5	Size and Design	5	IS 19022	R	Manufacturer shall put in place adequate inspections and in process controls to ensure the material		

					conforms to specified requirements		
6	Washing and drying cycles (for reusable barrier face coverings)		IS 15370	R	One	Each control unit	Manufacturer shall put in place adequate inspections and in process controls to ensure the washing drying and handling instructions are marked on every packet
7	General requirements	Table 1					
7.1	Raw Material/Fabric requirements (Applicable for reusable masks only)						
i)	Colour fastness to rubbing		IS/ISO 105- X12	S	One	Each consignment	
ii)	Colour fastness to perspiration (acidic and alkaline)		IS/ISO 105- E04	S	One	Each consignment	
iii)	Colour fastness to washing (A1S):		IS/ISO 105-C06	S	One	Each consignment	
iv)	Dimensional stability to washing	Annex C	IS 16394	S	One	Each consignment	
7.2	Flammability (Optional)	A-5	IS 9473	S	As per agreement with purchaser		
8	FASTENING MECHANISM	8	IS 19022	R	05	Each control unit	Levels of control specified are applicable for testing strength of laces, elastic strips, fabric tie etc. used as fastening mechanism. For compliance of material to the specified requirements, the manufacturer shall exercise suitable controls

9	PERFORMANCE REQUIREMENTS	Table 2					
i)	Differential pressure	Annex B	IS 19022	R	03	Each control unit	Separate samples of single use and reusable types to be tested
ii)	Particulate filtration efficiency (at 3.0 µm)	Annex C	IS 19022	R	03	Every week	Separate samples of single use and reusable types to be tested

Note-1: Whether test equipment is required or sub-contracting is permitted in column 2 shall be decided by the Bureau and shall be mandatory. Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empanelled by the Bureau.

Note-2: Levels of control given in column 3 are only recommendatory in nature. The manufacturer may define the control unit/batch/lot and submit his own levels of control in column 3 with proper justification for approval by BO Head.

ANNEX C

GOOD MANUFACTURING PRACTICE FOR HYGIENE REQUIREMENT

Maintaining hygiene at production facility is essential for ensuring products are appropriate for consumers use. Following are recommended guidelines for ensuring hygiene at facilities:

- a) Location should be free from objectionable odours, smoke, dust and other contaminants.
- b) Separate areas shall be demarcated for storing raw materials, production and final product storage.
- c) Separate area shall be demarcated for storing personal effects and personal protective equipment of unit workers to minimize risk of contamination.
- d) Toilet and hand-washing station shall be provisioned away from storage/production area.
- e) Provision of 70 percent isopropyl alcohol (IPA) solution or equivalent or soap for hand sanitization inside the production facility.
- f) Appropriate lighting and proper ventilation of the facility shall be ensured.
- g) Flooring shall be either concrete, tiled or with chips to ensure ease of cleaning. Floors, walls, ceilings, doors and windows shall be easy to clean and without crevices or openings that shall not allow accumulation of dirt.
- h) Regular pest control measures shall be put in place.
- j) Adequate receptacles for disposing waste generated within the facility shall be made available and shall be frequently emptied and cleaned.
- k) Poster/sign encouraging safety and hygiene practices like use of personal protective equipment, use of hand sanitizer etc. shall be displayed.
- m) Pre-packaged finished product shall be checked thoroughly and ensured to be free from foreign particles, dirt, hair, and other visible contaminants.
- n) Hand hygiene shall be practised during manufacturing.
- p) A cleaning and maintenance schedule shall be drawn up for cleaning of the facility, toilets, washing areas, waste receptacles and for cleaning/disinfection of the equipment