www.bis.gov.in

उत्पाद मैन्युअल

Medical Textiles Bed sheet and Pillow Cover - Specification

IS 17630:2021 के अनुसार

PRODUCT MANUAL
FOR Medical Textiles Bed sheet and Pillow Cover - Specification
ACCORDING TO IS 17630:2021

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.**	:	17630: 2021
	शीर्षक **Title**	:	**Medical Textiles Bedsheet and Pillow Cover - Specification**
	संशोधनों की संख्या **No. of amendments**	:	2
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चामाल** **Raw material**	:	The bed sheet and pillow cover shall be made from spun lace and/or spun bond non-woven fabric or woven fabric; made of cotton or polyester or their blends. The fabric used in the manufacture of reusable bed sheet and pillow cover set shall conform to requirements specified in Clause 6 of IS 17630: 2021. The raw material shall conform to the requirements of Biocompatibility Evaluation and Moisture vapour transmission rate (if applicable) as per clause 7.1. Conformity to the above requirements may be established through supplier test certificate/test report from BIS recognized lab/empanelled lab or any other lab having accreditation as per IS/ISO/IEC17025 or

			in-house testing/combination thereof,as applicable. 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**	:	Please refer to Annex-A
c)	**नमूनेका परिमाण Sample Quantity**	:	*2 Packs* 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 License/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)
3.	**परीक्षण उपकरणों की सूची List of Test Equipment**	:	Please refer to Annex-B
4.	**निरीक्षण और परीक्षण की स्कीम Scheme of Inspection and Testing**	:	Please refer to Annex-C
5.	**एक दिन में संभावित परीक्षण Possible tests in a day**		
	Workmanship and Finish, Size, Colour fastness to rubbing, scouring loss, Tensile strength, Bursting strength, Seam strength, pH, Particle release, Water soluble substance. 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 17630:2021 with the following scope:		
	Name of the product	Medical Textiles - Bedsheet and Pillow Cover	
	Dimensions/Size		
	Type	Single Use and/or Reusable (Declared life cycle/maximum wash cycle, if the product is reusable)	
	Optional requirement	1. With or without Water vapour resistance 2. With or without Biocompatibility Evaluation	

ANNEX-A

GROUPING GUIDELINES

The following grouping guidelines shall apply for Grant of Licence (GoL)/Change in Scope of Licence (CSoL):

i. The manufacturer shall declare the Dimensions/Size of the product intended to be covered in the scope of licence.

ii. Sample of any Dimensions/Size shall be tested to cover all the different Dimensions/Size of the product

iii. In case it is intended to cover reusable product in the scope of licence, the manufacturer shall declare the life cycle/maximum wash cycle and the sample shall be tested as per the requirement specified in Table 1 for Colour fastness and Dimensional Stability Requirement of Fabric (for Reusable) after subjecting it to the declared life cycle/maximum wash cycle.

iv. In case it is intended to cover the optional requirements for Water vapour resistance & Biocompatibility Evaluation in the scope, the samples shall be tested for Water vapour resistance & Biocompatibility Evaluation separately.

v. Scope of licence shall be restricted based on the manufacturing and testing facilities available.

vi. During operation of licence, samples of each variety covered in the scope of licence, shall be tested in rotation, to the extent possible.

ANNEX–B

LIST OF TEST EQUIPMENTS

(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No.	Tests Used In With Clause Reference	Test Equipment/Chemical
1.	Colour fastness to rubbing, Cl. 6	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) for the finger 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.
2.	Colour fastness to perspiration (acidic and alkaline) Cl. 6	Test devices, each consisting of a frame of stainless steel into which a weight-piece of mass approximately 5 kg and base 60 mm × 115 mm is closely fitted, so that a pressure of (12,5 ± 0,9) kPa can be applied on test specimens measuring (40 ± 2) mm × (100 ± 2) mm, placed between glass or acrylic resin plates measuring approximately 60 mm × 115 mm × 1,5 mm Oven, maintained at (37 ± 2) °C. Alkaline solution: grade 3 water, l-histidine monohydrochloride monohydrate, sodium chloride (NaCl), disodium hydrogen orthophosphate dodecahydrate or disodium hydrogen orthophosphate dihydrate Acid solution: grade 3 water, l-histidine monohydrochloride monohydrate, sodium chloride (NaCl), sodium dihydrogen orthophosphate dihydrate Adjacent fabrics Grey scale for assessing change in colour, complying with ISO 105-A02 and Grey scale for assessing staining, complying with ISO 105-A03. Spectrophotometer or colorimeter for assessing change in colour and staining A set of 11 glass or acrylic resin plates Flat-

		bottomed dish made of inert materials
3.	Colour fastness to washing, Cl. 6	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. Non-corrodible (stainless) steel balls, ≈ 6 mm in diameter. Adjacent fabrics: A multifibre adjacent fabric complying with ISO 105-F10, appropriate to the temperature used or Two single-fibre adjacent fabrics, complying with the relevant ISO 105-F01 to F07 standards non-dyeable fabric (e.g. polypropylene) if required Detergent, without optical brightener (WOB): Detergent solution, AATCC3) 1993 Standard Reference Detergent WOB. sodium carbonate (Na2CO3) – if required Sodium hypochlorite solution or lithium hypochlorite solution. sodium perborate tetrahydrate (NaBO3·4H2O). – if required 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. 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.	Colour fastness to light, Cl. 6	Reference materials Humidity test control fabric Light Source(xenon arc lamp) black-standard thermometer or a black-panel thermometer Humidity chamber

		Covers Colour matching lamps Assessment cabinet Sample mounting card Assessment mask
5.	Dimensional stability to washing, Cl. 6	Automatic washing machines Tumble dryers Ballasts Reference detergents Water Conditioning and testing chambers Laboratory equipment and glassware
6.	Pilling resistance, Cl. 6	Martindale abrasion testing machine Felt, in the form of circles as specified in ISO 12947-1, Abradant, against which the test specimen is abraded, normally the same as the fabric under test
7.	Scouring loss, Cl. 6	Soxhlet apparatus Drying Oven – capable of maintaining temperature of 105±3°C Weighing balance – capable of weighing to an accuracy of 0.001 g Desizing enzyme, sodium chloride, caustic soda solution, acetic acid solution, chloroform
8.	Tensile strength (dry and wet) , Cl. 7.1	Tensile Testing Machine
9.	Bursting strength (dry and wet) , Cl. 7.1	Bursting tester. Conditioning Chamber
10.	Seam strength (dry and wet) , Cl. 7.1	Tensile Testing Machine
11.	pH, Cl. 6	**Reagents:** Distilled or deionized water, Potassium chloride sol. (0.1mol/l), Buffer solutions (Having pH around 4, 7 or 9), **Apparatus**: pH-meter (with glass electrode, capable of measuring to at least 0.1pH units), Mechanical shaker, Weighing Balance (accurate to 0.01 g),Beakers (150ml), Volumetric flasks(1L), Stoppered glass or polypropylene flasks, Thermometer
12.	Water soluble substance, Cl. 7.1	Drying oven Beaker Hot Plate Thermometer Glass rod Weighing balance
13.	Cleanliness–microbial, Cl. 7.1	Apparatus, materials, reagents, culture media and incubators as per ISO 11737-1 : 2018 (Sterilization of Health Care Products — Microbiological Methods Part 1 Determination of a Population of Microorganisms on Products) based on the method selected

14.	Particle release, Cl. 7.1	Lamina flow hood, vertical, Flexing unit (modified Gelbo Flex) Flexing chamber and air collector Particle counter, with the following main characteristics: 8 measurement channels; overall size range: 0,3 µm or 0,5 µm to 25 µm; air flow: (28,3 ± 1,4) l/min; sampling time selectable between 1 s and 24 h. Glue, for sealing the cylindrical test piece. Gloves, for use in ISO class 5 clean room
15.	Biocompatibility Evaluation, Cl. 7.1(Optional) a) Cytotoxicity b) Irritation and skin sensitization	- Composting facilities where typical conditions of composting can be consistently obtained (i.e. a long thermophilic phase, aerobic conditions, sufficient water content, suitable carbon/nitrogen ratio, etc.) - Fillers (Calcium carbonate, Titanium dioxide etc) - Catalysts (Metal carboxylates, Metal complexes etc) - Sieve (2.0mm,10 mm) - Positive-control reference material (Microcrystalline cellulose) - TLC (thin-layer chromatography) grade cellulose - Vermiculite - Composting vessels (Glass flasks or bottles) - Air-supply system - Apparatus for the determination of carbon dioxide - Gas-tight tubes - pH-meter. - Analytical equipment for determination of dry solids (at 105°C), volatile solids (at 550°C) and total organic carbon (TOC), for elemental analysis of the test material - Analytical equipment for the determination of oxygen in the air, moisture, volatile fatty acids and total nitrogen - Balance - Bioreactors for activation of the vermiculite -Incubation room with dark or diffused light, constant temperature of 58 °C ± 2 °C and free from vapours inhibitory to microorganisms - Inoculum - Soda lime (particle size 2-4 mm) - Anhydrous calcium chloride (particle size 2-3 mm) - Sodium hydroxide on a talc support (Soda talc) - Silica gel (with moisture indicator). particle size between 2-4 mm - Sea sand (particle size between 20-35 mesh) - TLC (Thin-layer chromatography) grade microcrystalline cellulose with a particle size of less than 20 um, - Thermostatic-control unit - Composting bin with air supply system, Drainage, Sample nets - Apparatus for temperature measurement - Apparatus for oxygen measurement - Biowaste, - Composting reactor - Synthetic solid waste - - Distilled water - Hot air oven – Furnace

16.	Water vapour resistance (optional), Cl. 7.1	Measuring unit, with temperature and water supply control, consisting of a metal plate approximately 3 mm thick with a minimum area of 0,04 m2 (e.g. a square with each side 200 mm in length, l) fixed to a conductive metal block containing an electrical heating element Thermal guard with temperature control Test enclosure, into which is built the measuring unit and thermal guard, and in which the ambient air temperature and humidity are controlled.

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: entire quantity of Bedsheet and Pillow Cover sets of the same type (single use/reusable) manufactured from the same consignment of fabric under similar conditions 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 pack containing a set of bed sheet and pillow cover, provided always that the material so marked conforms to each requirement of the specification.

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

3.2 **Additional Marking requirements**: The material shall also be marked with the following additional requirement on each pack containing a set of bed sheet and pillow cover:

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

4. HYGIENIC CONDITIONS – Hygienic conditions shall be maintained in the production of single use and reusable bed sheet and pillow cover set intended for medical use.

5. REJECTION - All the production which conforms to the Indian Standard and covered under the scope of this license 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 (Material)	4	IS 17630:2021	S	Each consignment of fabric shall be accompanied by supplier's certificate		
5	Workmanship and Finish (and size)	5	IS 17630:2021	R	Manufacturer shall put in place adequate inspection/in process controls to ensure conformity to workmanship and finish as well as size requirements		
6	Colour fastness and Dimensional Stability Requirement of Fabric (for Reusable)						
i.	Colour fastness to rubbing a) Dry b) Wet	--	IS/ISO 105-X 12	S	One	Each consignment of fabric	
ii.	Colour fastness to perspiration (acidic and alkaline) a) Colour change b) Staining	--	IS/ISO 105-E04	S	One	Each consignment of fabric	
iii.	Colour fastness to washing a) Colour change b) Staining	--	IS/ISO 105-C06	S	One	Each consignment of fabric	
iv.	Colour fastness to light Color change	--	IS/ISO 105-B02	S	One	Each consignment of fabric	
v.	Dimensional stability to washing Length and width	--	IS 15370/ISO 6330	S	One	Each consignment of fabric	
vi.	Pilling resistance	--	IS 10971 (Part 2)	S	One	Each consignment of fabric	

vii.	Scouring loss	--	IS 10971 (Part 2)	S	One	Each consignment of fabric	
7.1	Requirements for Bedsheet and Pillow Cover Set						
i.	Tensile strength (dry and wet)	--	Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)	R	One	Each control unit	
ii.	Bursting strength (dry and wet)	--	IS 1966 (Part 1)	R	One	Each control unit	
iii.	Seam strength (dry and wet)	--	Nonwoven: IS 15891 (Part 18), Woven: IS/ISO 13935 (Part 1)	R	One	Each control unit	
iv.	pH	--	IS 1390	R	One	Each control unit	
v.	Water soluble substance	--	IS 14944	R	One	Each control unit	
vi.	Cleanliness–microbial	--	ISO 11737-1	S	The manufacturer shall perform the testing for the final product every quarter and whenever there is a change in the raw material, manufacturing premises, and the supplier of the raw material.		
vii.	Particle release	--	IS 15891 (Part 10)	R	One	Once a month	
viii.	Biocompatibility Evaluation(optional) a) Cytotoxicity b) Irritation and skin sensitization	--	IS/ISO 10993- 5	S	The biocompatibility of raw material shall be tested at design stage. The biocompatibility evaluation 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.		
ix.	Water vapour resistance (Max) (optional)	--	IS 17376	S	Moisture vapour transmission rate evaluation, where required, 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.		