www.bis.gov.in

उत्पाद मैन्युअल
चिकित्सीय वस्त्रादि सूती कपड़े की पट्टी — विशिष्टि
IS 863:2023 के अनुसार

PRODUCT MANUAL FOR
Medical Textiles — Cotton Bandage Cloth – Specification
ACCORDING TO IS 863: 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 863:2023
	शीर्षक **Title**	:	Medical Textiles — Cotton Bandage Cloth — Specification
	संशोधनों की संख्या **No. of amendments**	:	01
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चा माल** **Raw material**	:	The cotton yarn used in the manufacture of bandage cloth shall conform to the requirements specified in IS 171 (Cl. 3.1) and cloth shall conform to Cl. 3.2 of IS 863:2023. The material of bandage cloth shall be cotton fibre (Cl. 4.1). Conformity shall be established through supplier's test certificate, test report issued by BIS recognized/empaneled lab or any other accredited lab or in house testing or combination thereof. 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)	**नमूने का परिमाण** **Sample Quantity**	:	20 m + 12 pcs 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)
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**		
	Count of yarn, Threads, Mass, Length, Width, pH value of aqueous extract, Scouring loss, Freedom from optical whiteners 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 863 :2023 with the following scope:		
	उत्पाद का नाम Name of the product		Medical Textiles — Cotton Bandage Cloth
	Sterilization		Sterilized/Non-Sterilized
	Finishing		Bleached/Dyed

ANNEX-A

GROUPING GUIDELINES

Based on the classification of Cotton Bandage Cloth, the following grouping guidelines shall apply for Grant of Licence and Change in Scope of Licence:

i. If Sterilized cotton bandage cloth is drawn and tested, Non-sterilized cotton bandage cloth may also be covered in the scope of licence.

ii. If dyed cotton bandage cloth is drawn and tested, bleached cotton bandage cloth may also be covered in the scope of licence.

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

iv. 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	Fibre Identification, clause 4.2 and Table 1	• Microscope • iodinated zinc chloride solution • sulphuric acid (66 percent) • ammoniacal copper oxide solution • 1.25 M sodium hydroxide • zinc chloride solution • hot plate • thermometer • analytical balance and other standard laboratory apparatus and reagents. (Ref: IS 14944:2020)
2	Threads/dm, clause 4.2 and Table 1	• Steel Scale • Thermometer to determine atmospheric temperature • Hygrometer • Vernier calliper • Measuring tape • Thread counter equipped with low power microscope • Clamps- As per clause 6.1.1 of IS 1963:1981 • Forceps • Table (At least 4 m of length) • Marker Chalk/Pencil
3	Mass, 4.2 and Table 1	• Weighing balance
4	Length and width, clause 4.2 and Table 1	• Measuring Tape • Table (At least 4 m of length) • Marker/Pencil • Vernier Calliper • Steel Scale
5	pH value of aqueous extract, clause 4.2 and Table 1	• Distilled or deionized water • Potassium chloride solution (0.1 mol/l) • Buffer solutions (pH 4, 7 or 9) • Stoppered glass or polypropylene flasks • Beakers • Rods • pH meter • Weighing Balance • Volumetric Flask (1 Lit) • Mechanical Shaker/ Magnetic stirrer
6	Scouring loss, clause 4.2 and Table 1	• Soxhlet Apparatus • Hot Air Oven

		• Weighing Balance • Desizing Enzyme - Diastase (or other suitable enzyme) • Sodium Chloride- Solid • Caustic Soda Solution -2 % • Acetic Acid Solution-1% • Chloroform • Desiccator
7	Freedom from optical Whitener, clause 4.2 and Table 1	• 1. Ultra Violet Florescent lamp with cabin
8	Colour Fastness (a) Light, clause 4.2 and Table 1	• As per IS/ISO 105-B 01: 2014 • Exposure rack • Opaque cardboard • Grey scale for assessing change in colour- according with ISO 105-A02 When requested, instruments for determining climatological data As per IS/ISO 105-B 02: 2014 • Blue wool reference materials 1 to 8 • Blue wool reference materials L2 to L9 • Humidity-test control fabric • Light source • Hygrometer • Covers • Colour matching lamps • Assessment cabinet, complying with ISO 105A01. • Sample mounting card • Assessment mask, complying with ISO 105-A01 • Grey scale for assessing change in colour, complying with ISO 105-A02
9	Colour Fastness (b) Washing i) Change in colour ii) Staining on adjacent fabric, clause 4.2 and Table 1	• Suitable mechanical laundering device • Weighing Balance • Mechanical Stirrer • Non-corrodible (stainless) steel balls • Hot Plate • Soap • Sodium carbonate Anhydrous • Soap solution as per clause 5.3 of IS/ISO 105-C10 • Grade 3 water • Adjacent fabrics • Multi fibre adjacent fabric complying with ISO 105-F10 • Two single-fibre adjacent fabrics • Polypropylene

		• Grey Scales
10	Cleanliness–Microbial/Bioburden Test, Clause 4.2 and Table 1	Reagents: • Plate count agar (PCA) • Sabouraud chloramphenicol agar (SCA) • Sodium chloride (0.85%) Apparatus: • Autoclave • Hot air oven, Incubator (30-35 °C) • Incubator (20-25 °C) • pH meter • Water bath • Colony counter • Laminar Flow hood • Mechanical Shaker • Petri dishes • Flasks/bottles • Test tubes

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**

For the guidance of manufacturers, the recommended definition of control unit is: the entire quantity of the cotton bandage cloth bleached simultaneously as one batch by one processing unit.

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 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 packet of bandage cloth, 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 additional requirement on each packet of bandage cloth:

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 Methods Clause Reference**			**No. of Sample**	**Frequency**	**Remarks**
3.1	Yarn		IS 171	S	One	Each Consignment	Conformity shall be established through supplier's test certificate, test report issued by BIS recognized/empaneled lab or any other accredited lab or in house testing or combination thereof.
3.2	Cloth	3.2	IS 863:2023	R	Firm to have adequate in process controls and inspections to check compliance of this parameter as per the Indian Standard. However, appropriate records shall be maintained		
4.1	Fibre Identification		IS 14944	S	One	Each Consignment	Conformity shall be established through supplier's test certificate, test report issued by BIS recognized/empanelled lab or any other accredited lab or in house testing or combination thereof.

4.2 and Table 1	(i) Count of Yarn (for guidance only) (a) Warp (b) Weft	4.2 and Table 1	-do-	R	3 if control unit consists of 25 pcs or less and 5 otherwise	Each Control unit	
	(ii) Threads/dm a) Ends b) Picks		IS 1963	R	-do-	-do-	
	(iii) Mass		IS 1964	R	-do-	-do-	
	(iv) Length		IS 1954	R	Every piece		
	(v) Width		IS 1954	R	-do-		
	(vi) pH value of aqueous extract		IS 1390	R	Two	Each Control unit	
	(vii)Scouring loss		IS 1383 (Mild Method)	R	-do-	-do-	
	(viii) Freedom from optical whitener		IS 863	R	-do-	-do-	
	(ix) Colour Fastness to						
	(a) Light		IS/ISO 105-B 01: 2014 or IS/ISO 105-B 02: 2014	S	one	Once a month	
	b) Washing i) Change in colour ii) Staining on adjacent fabric		IS/ISO 105-C10:2006	S	one	Once a month	
4.3	Cleanliness– Microbial/Bioburden Test		IS/ISO 11737 (Part 2) or IS/ISO 11737 (Part 1)	S	The manufacturer shall perform the hygiene testing for the final product once in 03 months for monitoring purpose and whenever there is a change in the raw material, manufacturing premises, and the Supplier of the raw material.		