www.bis.gov.in

उत्पाद मैनुअल

Medical Textiles- Elastic Bandage

IS 16111:2026 के अनुसार

PRODUCT MANUAL FOR

Medical Textiles-Elastic Bandage

ACCORDING TO IS 16111: 2026

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 16111 : 2026
	शीर्षक **Title**	:	Medical Textiles-Elastic Bandage
	संशोधनों की संख्या **No. of amendments**	:	NIL
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चा माल** **Raw material**	:	Elastic bandages shall be cellulosic/non-cellulosic yarn or combination of both yarn with following composition. - Hydrophilic/cellulosic fibre content, minimum 35 percent [*see* IS 1889 (Part 1)]. - Filament yarns made from partially oriented yarn (POY) of polyester, polyamide, polypropylene or equivalent material. It consist of a core made of high stretch spandex, lycra, polyurethane, rubber or similar material and covered/wrapped with synthetic filament yarn or grey/

			bleached/dyed cotton and/or viscose/rayon. (Conformity may be established through supplier's certificate) 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**	:	One sample of each type of bandage (based on type of yarn: I/II/III/IV/V/VI) of any size (width and stretched length) may be tested to cover all sizes of that type(s) of bandages in the scope of licence
c)	**नमूने का परिमाण** **Sample Quantity**	:	For Yarn – One Cone For Bandage – One Bandage Roll 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**	:	Type, Width, Stretched Length
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**		
	Cl 7 – Manufacture, Workmanship and Finish 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 1611:2026 with the following scope:		
	Name of the product	Medical Textiles-Elastic Bandage	
	Types (based on yarn used)	I/II/III/IV/V/VI	
	Sizes	Width … (in mm) and Stretched Length … (in m)	

PM/16111/2
May 2026

NEW DELHI-110002

ANNEX – A

LIST OF TEST EQUIPMENTS

(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No.	Tests Used In With Clause Reference	Test Equipment/Chemical
1	Dimensions and Tolerances, Cl. 5	Vernier Caliper, Steel Scale
2	Finish, Cl. 7.3	UV Lamp
3	Conditioning, Cl. 8	Humidity Chamber
4	Weight, Cl. 9.3	Weighing balance
5	Stretch Length Extensibility, Cl. 9.4	Apparatus for measurement of stretched length extensibility of elastic bandage consisting of Stretch table, clamps, mechanism (pneumatic or mechanical arrangement) to apply stretching load to the sample (Annex A), Standard weight up to 25 kg in denominations of 1 kg, 2 kg and 5 kg, whichever applicable.
6	Regain, Cl. 9.5	Apparatus for measuring of regain of elastic bandage (Annex B), Standard weight up to 25 kg in denominations of 1 kg, 2 kg and 5 kg, whichever applicable.

ANNEX B

SCHEME OF INSPECTION AND TESTING

1. QUALITY ASSURANCE PLAN

1.1 It is expected that during operation of BIS licence, manufacturers will implement a Quality Assurance Plan (QAP) i.e. a plan of regular testing and in-process controls, designed to ensure that the product bearing theStandard Mark conforms to all requirements of the Indian Standard.

1.2 The manufacturers shall define a Quality Assurance Plan (QAP) defining the control unit (i.e. lot/batch etc.), the levels of control (i.e. the frequency and number of samples for conducting the differenttests as per the Indian Standard) and declare the arrangement for testing i.e. whether in-house or subcontracting/sharing for each applicable test and submit the same to BIS Branch Office for information. The manufacturer shall comply with the QAP and maintain test records in accordance with para 2.1.

1.3 **RECOMMENDED LEVELS OF CONTROL/CONTROL UNIT**:

1.3.1 For the guidance of manufacturers, the recommended definition of control unit is: For the purpose of this scheme, the entire quantity of elastic bandage of same color, type, type of yarn and method of manufacture, manufactured in one day shall be taken as one control unit.

1.3.2 For the guidance of manufacturers in preparing the Quality Assurance Plan, recommended levels of control are given in **Table 1**. Manufacturer has the discretion of declaring their own levels of control or accept the levels of control given in this document.

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.

2. ENSURING COMPLIANCE THROUGH TESTING- manufacturers shall ensure compliance of their products to all the requirementsof the Indian Standard for which they may have in-house test facilities. However, there is no obligation to maintain in-house laboratory. Licensee may use alternative arrangements for tests of the production as per the declared QAP. Various alternatives are available for operation of BIS certification as given below and the relevant guidelines for availing such relaxations by the manufacturers, as amended from time to time, are to be referred:

i) Shared testing resources like common facility,

ii) Cluster based testing facility,

iii) Sub-contracting to outside laboratories which may either be:

a) BIS recognised/empanelled laboratories, or

b) Any accredited laboratory as per ISO/IEC 17025

2.1 **TEST RECORDS**- The manufacturers shall maintain test records for the tests carried out (either in-house or at a sub-contracted or at shared test facility) to establish conformity of the product to the Standard for operation of licence. For the tests being subcontracted or conducted at a shared test facility, test results issued by the laboratories or test facilities, shall be made 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 package of elastic bandages 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 packaging.

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

4. REJECTION - 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

LEVELS OF CONTROL

(1)				(3)		
Test Details				**Levels of Control**		
Cl.	**Requirement**	**Test Methods**		**No. of Sample**	**Frequency**	**Remarks**
		Clause	**Reference**			
5	Dimensions and Tolerances	5	IS 16111:2026	One	Each control unit	
6	Material	6.1, 6.2,6.3	-do-	One	Each consignment	No testing required if material is accompanied by supplier's test certificate
7	Workmanship and Finish	7.1, 7.2, 7.3	-do-	One	Each control unit	
9.3	Weight	9.3	-do-	One	Each control unit	
9.4	Stretch length and extensibility	Annex A	-do-	One	Each control unit	
9.5	Regain	Annex B	-do-	One	Each control unit	