भारतीय मानक ब्यूरो

BUREAU OF INDIAN STANDRADS

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प्रस्तावित मसौदा

चिकित्सीय वस्त्रादि — इलास्टिक पट्टी — विशिष्टि

(आई एस 16111 का *पहला पुनरीक्षण*)

Preliminary Draft

Medical Textiles — Elastic Bandage — Specification

(*first revision* of IS 16111)

ICS: 11.040.20

Technical Textiles for Medtech Applications Sectional Committee, TXD 36

last date for receipt of comments is 28 October, 2024

FOREWORD

(*Formal clauses will be added later*)

This standard was originally published in 2013. The first revision has been made in the light of experience gained since its first adoption and to incorporate the following major changes:

a) Title of the standard has been updated.
b) All amendments have been incorporated.
c) Type of elastic bandage has been modified.
d) The requirement of manufacture, workmanship and finish has been updated.
e) The requirement of conditioning has been modified.
f) Sampling and criteria of conformity has been incorporated.
g) Packing and marking clause has been incorporated.
h) BIS certification marking clause has been updated.
i) References to Indian standards is updated.

An elastic bandage is one continuous strip without joints, of woven/knitted material stretches along its intended to provide support and immobilize dressings covering the wounds besides the function of compression and support for orthopaedic purposes.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*second revision*).' The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Draft *Indian Standard*

Medical Textiles — Elastic Bandage — Specification

(*First Revision* of IS 16111)

1 SCOPE

This standard covers the dimensions and other requirement for elastic bandages.

2 REFERENCE

The following standard contains provisions, which, through reference in this text, constitute provision of this standard. At the time of publication, the edition indicated was valid. This standard is subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standard indicated below:

IS No.	*Title*
1889 (Part 1) : 2024/ISO 1833-5 : 2006	Textiles — Quantitative chemical analysis — Mixtures of viscose cupro or modal and cotton fibres method using sodium zincate (*second revision*)
6359 : 2023	Method for conditioning of textiles (*first revision*)
4905 : 2015	Random sampling and randomization procedures (*first revision*)

3 DEFINITION

For the purpose of this standard, the following definition shall apply.

3.1 Elastic Bandages — An elastic bandage is intended to provide support and immobilize dressings covering the wounds besides the function of compression and support for orthopaedic purposes to be used in intact skin only.

4 TYPES

Elastic bandages can be classified as follows based on type of yarn with their method of manufacturer:

a) Type I — woven cellulosic yarn bandage
b) Type II — knitted cellulosic yarn bandage
c) Type III — woven non-cellulosic yarn bandage
d) Type IV — knitted non-cellulosic yarn bandage
e) Type V — combination of both cellulosic yarn/non-cellulosic yarns woven knitted
f) Type VI — combination of both cellulosic yarn/non-cellulosic yarns knitted.

Based on functionality and end-use, elastic bandages can be classified as follows in table 1.

Table 1 General Guideline on Functionality of Elastic Bandage

(for reference only)

(*Clause* 4)

Sl No (1)	**Product category** (2)	**General Guideline on Functionality** (3)
(i)	Fixation	Retaining the primary wound dressing
(ii)	Support	Support for soft tissue, for post fracture treatment
(iii)	Compression	Compression therapy
(iv)	Elastic Crepe Bandage	Support and mild compression

5 DIMENSIONS AND TOLERANCES

The stretch length and width of the elastic bandage shall comply with the following requirements as given in Tables 2 :-

Table 2 Dimension of Elastic Bandage

(*Clause* 5)

Sl No. (1)	**Description** (2)	**Width** (cm) (3)	**Tolerance for width** (cm) (4)	**Stretched Length** (m) (5)	**Tolerance for Stretched Length** (cm) (6)
(i)	Elastic Bandages	2 - 4	± 0.2	2.0 - 4.0	± 20
				Above 4.0 - 10.0	± 40
				Above 10.0 - 20.0	± 60
		Above 4 - 12	± 0.5	2.0 - 4.0	± 20
				Above 4.0 - 10.0	± 40

				Above 10.0 - 20.0	± 60
		Above 12 - 20	± 0.7	2.0 - 4.0	± 20
				Above 4.0 - 10.0	± 40
				Above 10.0 - 20.0	± 60

6 MATERIAL

6.1 Elastic bandages shall be made from cellulosic/non-cellulosic yarn or combination of both yarn with following composition.

6.1.1 Hydrophilic/cellulosic fibre content, minimum 35 percent [*see* IS 1889 (Part 1)].

6.2 Filament yarns made from partially oriented yarn (POY) of polyester, polyamide, polypropylene or equivalent material.

6.3 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.

7 MANUFACTURE, WORKMANSHIP AND FINISH

7.1 The elastic bandages shall be in woven/knitted bandages containing cellulosic, non-cellulosic yarns or a combination of both with non-fraying closed selvedges /edges and or grey/while/coloured shade.

7.2 The elastic bandages shall be clean and free from substances liable to cause tendering during storage. The product shall be free from toxic or harmful substances. The manufacture and preparation of the elastic bandages should be conducted under proper hygienic conditions.

7.3 Finish

The use of optical brightening agents is prohibited. Under UV lamp no fluorescence shall be observed except for a few brightly illuminated individual fibres.

8 CONDITIONING

8.1 Each roll of elastic bandage selected for test shall be conditioned for a minimum period of 24 h at 27 ± 2 °C and 65 ± 2 percent relative humidity (*see* IS 6359) prior to testing, and testing shall be in the same atmosphere. When the tests cannot be carried out in same atmosphere, the testing shall be commenced within 2 min of withdrawal of specimens from the conditioning atmosphere.

8.2 The outer three layers of each roll shall be discarded before taking the specimen for test.

9 REQUIREMENTS

9.1 Test for Width

The portion between and including the fast edges of the unstretched bandage.

9.2 Test for Diameter

The distance as measured at the outer circumference while holding the bandage but not pressing the bandage.

9.3 Weight

The weight of the elastic bandage shall be from 25 to 170 g/m^2.

9.1.1 The weight of elastic bandage determined by weighing the whole bandage divided by the stretched surface area gives the weight per unit area.

9.4 Stretched Length and Extensibility

The extensibility of elastic bandage shall be 55 to 270 percent. The requirement of stretched length and extensibility of elastic bandage shall be tested as per method given in Annex A.

9.5 Regain

The regain of the elastic bandage shall be not less than 70 percent when tested as per method given in Annex B.

10 SAMPLING AND CRITERIA FOR CONFORMITY

10.1 Lot

All the elastic bandage of the same material, shape and dimensions produced under similar conditions of manufacture shall constitute a lot.

10.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

10.1.2 The number of bandages to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 1, 3 and 5 of Table 3.

Table 3 Number of Elastic Bandages to be Selected

(*Clauses* 10.1.2 *and* 10.2)

Sl No.	**Lot Size**	**Non-destructive Testing**		**Destructive Testing**	
		No. of Bandages to be Selected	Acceptance Number	No. of Bandages to be Selected	Acceptance Number
	N	N	a	n_1	a_1

(1)	(2)	(3)	(4)	(5)	(6)
i)	Up to 280	13*	1	8	0
ii)	281 to 500	20	2	8	0
iii)	501 to 1200	32	3	13	0
iv)	1201 to 3200	50	5	13	0
v)	3201 to 10000 and above	80	7	20	1

* or lot size when less than 13

10.1.3 These bandages shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

10.2 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

10.2.1 All the bandages selected as per column 3 of Table 1 shall be examined for workmanship and finish (**7**).

10.2.1.1 Any bandage failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements if the total number of defectives found in the sample is less than or equal to the acceptance number given in col 3 of Table 3. Otherwise, the lot shall be rejected.

10.2.2 Out of the sample already found satisfactory according to **10.2.1.1**, a sub-sample as per column 5 of Table 3 shall be taken. This sub-sample shall be further tested for the remaining requirements.

10.2.3 The lot shall be considered as conforming to the requirements of the specification if the total number of defective bandages found in the sample (as per **10.2.2**) is less than or equal to the acceptance number as given in column 6 of Table 3.

11 MARKING

11.1 Each package of elastic bandage shall be legibly and indelibly marked with the following information:-

a) Name and trade-mark of the manufacturer;
b) Colour, if any;
c) Width and stretched length; and
d) Batch/lot number.
e) Month and year of manufacture; and
f) Any other requirement as per Medical Device Rule 2017 or as agreed between buyer and seller.

11.2 BIS Certification Marking

The elastic bandage may also be marked with the Standard Mark. The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes

under the provisions of the Bureau of Indian Standards Act, 2016 and the Rules and Regulations framed thereunder, and the products may be marked with the Standard Mark.

12 PACKING

The bandage shall be rolled and packed suitably to prevent contamination from dust. The elastic bandages shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. Details of the packing shall be as agreed to between the buyer and the seller. Packaging of the product should be, such as to maintain the integrity of the product throughout its shelf life

ANNEX A
(*Clause* **9.4**)

METHOD FOR MEASURING OF STRETCHED LENGTH AND EXTENSIBILITY OF ELASTIC BANDAGE

A-1 TEST SPECIMEN

For the purpose of this test, all rolls in the test sample constitute the test specimen.

A-2 APPARATUS

A-2.1 Stretch testing table of marked length 6 m with fixed clamp A at left end and moving clamp B at right end. The table has mechanical and pneumatic arrangement for the loading and un-loading the weights (*see* Fig. 1). The table is attached with a fixed measuring tape arrangement.

A-2.2 Standard weight up to 25 kg in denominations of 1 kg, 2 kg and 5 kg, whichever applicable.

A-3 PROCEDURE

A-3.1 Unwind the bandage on the stretch table and measure its unstretched length L_1 immediately. Mark 5 cm on both ends and fix clamp A and clamp B on the bandage at both ends X_1 and X_2 (5 cm from the ends). Connect the loading pan C weighing 1 kg to the moving clamp B (*see* Fig. 1). Now apply load of 1 kg for each cm of bandage width. Keep the load applied on the bandage kept in extended condition for 30 s. Measure the distance between two marks and record the stretched length L_2 in cm and release the load mechanically or by pneumatic arrangement. To compensate for the clamped part at both ends (that is 5 cm + 5 cm = 10 cm) we need to add correction factor (CF) to this stretched length L_2 and derive the final stretched length $L_3 = L_2 + CF$.

A-3.1.1 For bandage of stretched length above 5 m, measure the unstretched length L_1, mark the centre point by dividing the unstretched length by two. Find the stretched length for the first part and second part separately by the same method.

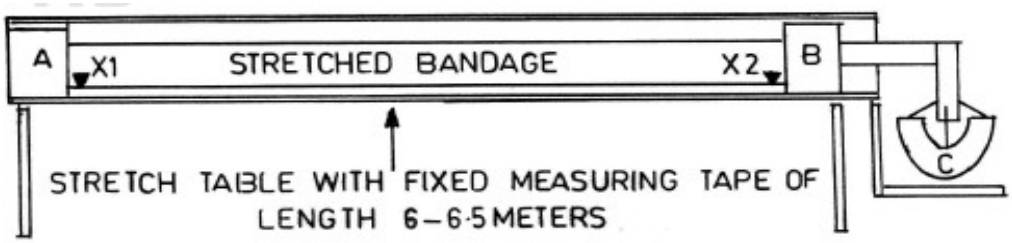

FIG. 1 APPARATUS FOR MEASURING OF STRETCHED LENGTH EXTENSIBILITY OF ELASTIC BANDAGE

A-3.2 Calculate the extensibility percent and correction factor (CF) as follows:

$$\text{Extensibility percent} = \frac{L3-L_1}{L_1}\times 100$$

NOTES

1 Correction factor, in cm = 10 + (Standard extensibility percent of bandage) / 10
2 Standard extensibility percent of bandage (S)—This standard extensibility percent is determined by measuring one time the stretched length for 100 cm unstretched length. This is added for all subsequent tests for that product.

Find out standard extensibility percent as follows:

$$S = \frac{\text{Stretched length (for 100 cm unstretched length)} - \text{Unstreched length (100 cm)} \times 100}{\text{Unstreched length (100 cm)}}$$

ANNEX B
(*Clause* **9.5**)

METHOD FOR MEASURING OF REGAIN

B-1 TEST SPECIMEN

For the purpose of this test all rolls in the test sample constitute the test specimen.

B-2 APPARATUS

B-2.1 Stretch testing table of marked length 6 m with fixed clamp A at left end and moving clamp B at right end. The table has mechanical and pneumatic arrangement for the loading and un-loading the weights (*see* Fig. 2). The table is attached with a fixed measuring tape arrangement.

B-2.1.1 Standard weight up to 25 kg in denominations of 1 kg, 2 kg and 5 kg, whichever applicable.

B-3 PROCEDURES

B.3.1 Measure the un-stretched length and marked 5 cm at the beginning and at the end of the bandage. In order to determine the regain, the remaining length must be determined. Make a second mark at the beginning of the bandage at a distance of 10 cm from the first mark. Measure the stretched length as per test procedure. Wait for 2 min and in this time the bandage must

laying in zig-zag relaxed position (length of about 30 cm). To get the remaining length, measure the length of the marks at the beginning and at the end of the bandage. Add the small part between the first and the second mark. This will give the remaining length.

B-3.2 Calculate the regain in percentage as:

$$\text{Regain in percent} = \frac{\text{Stretched length} - \text{Remaining length}}{\text{Stretched length} - \text{Unstretched length}} \times 100$$

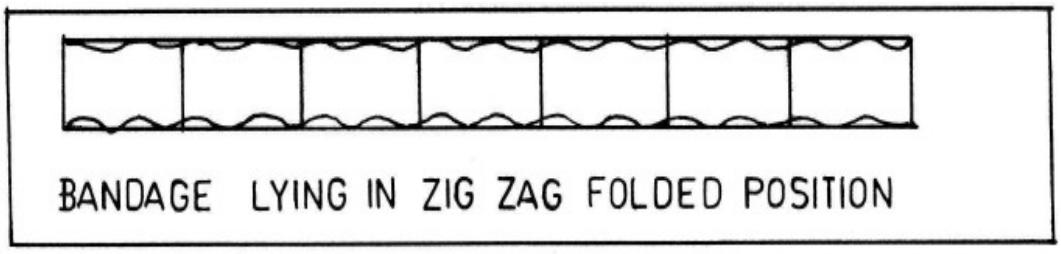

FIG. 2 APPARATUS FOR MEASURING OF REGAIN OF ELASTIC BANDAGE