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आसंजक टेप — विशिष्टि

**Medical Textiles — Elastic Surgical
Adhesive Tapes — Specification**

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FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by Technical Textiles for Medtech Applications Sectional Committee had been approved by the Textile Division Council.

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 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

MEDICAL TEXTILES — ELASTIC SURGICAL ADHESIVE TAPES — SPECIFICATION

1 SCOPE

This standard specifies performance requirements for elastic surgical adhesive tapes intended for medical use.

2 REFERENCES

The standards listed in Annex A contain provisions, which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are 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 standards indicated in Annex A.

3 TERM AND DEFINITION

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

3.1 Elastic Surgical Adhesive Tape — It consists of woven fabric, elastic in warp, which has been spread evenly with an adhesive mass containing zinc oxide which does not off-set when the tape is unrolled. The warp threads consist of two fold cotton threads, crepe twisted to contain not less than 19 turns per cm, arranged two threads S-twist, two threads Z-twist, repeated. The weft threads consist of cotton, or of viscose, or of combined cotton and viscose yarn. The fabric is clean, reasonably free from weaving defects, and contains not more than traces of leaf residue, seed coat, and other impurities. The tape is supplied wound on spools and suitably protected. It is in one continuous length with no joints. Elastic surgical adhesive tapes may be dyed.

4 WORKMANSIP AND FINISH

4.1 The elastic surgical adhesive tapes shall be clean and free from substances liable to cause tendering during storage. The product shall be free from toxic or harmful substances.

4.2 The manufacture and preparation of the tapes shall be conducted under proper hygienic conditions

5 REQUIREMENTS

The elastic surgical adhesive tape shall conform to the requirements specified in Table 1.

Table 1 Performance Requirements for Elastic Surgical Adhesive Tapes
(Clause 5)

Sl No. (1)	Characteristic (2)	Requirement (3)	Method of Test, Ref to (4)
i)	Fibre identification	Complies with the specification	IS 667
ii)	Yarn count, tex, <i>Min</i> :		IS 1315
	a) Warp	28	
	b) Weft	59	
iii)	Threads per dm, <i>Min</i> :		IS 1963
	a) Warp	190	
	b) Weft	82	
iv)	Weight per square metre, g/m^2 , <i>Min</i>	110	IS 1964
v)	Breaking strength, kg/cm, <i>Min</i>	8	IS 1969 (Part 2)
vi)	Weight of adhesive mass, g/m^2 , <i>Min</i>	120	IS 14944
vii)	Adhesiveness	Complies with the specification	IS 14944
viii)	Content of zinc oxide, percent, <i>min</i>	10	IS 14944
ix)	Width of the tape:		
	a) Up to 5 cm	Declared \pm 4 mm	—
	b) More than 5 cm	Declared \pm 4 mm	—
x)	Elasticity	The regain length is not more than 80 percent of the fully stretched length	

6 MARKING

6.1 Each piece of the elastic surgical adhesive tape shall be legibly marked with the following information:

- a) Name of the product, that is elastic surgical adhesive tape;
- b) Manufacturer's name, initials or trade-mark, if any;
- c) Month and year of manufacture;
- d) Size; and
- e) Any other statutory requirement as required by the law in force

6.2 BIS Certification Marking

The product may also be marked with the Standard Mark.

6.2.1 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act, 1986* and the Rules and Regulations made thereunder. The details of conditions under which a licence for the use

of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

7 SAMPLING AND CRITERIA FOR CONFORMITY

7.1 LOT

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

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

7.1.2 The number of elastic surgical adhesive tapes to be selected from the lot shall depend on the size of the lot and shall be in accordance with cols 2, 3 and 5 of Table 2.

7.1.3 These elastic surgical adhesive tapes shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

7.2 Number of Tests and Criteria for Conformity

7.2.1 All the elastic surgical adhesive tapes selected as per col 3 of Table 2 shall be examined for workmanship and finish (*see 4.1*).

7.2.1.1 Any elastic surgical adhesive tape 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 4 of Table 2. Otherwise, the lot shall be rejected.

7.2.2 Out of the sample already found satisfactory according to **7.2.1.1**, a sub-sample as per col 5 of Table 2 shall be taken. This sub-sample shall be further tested for the remaining requirements.

7.2.3 The lot shall be considered as conforming to the requirements of the specification, if the total number of defective dressings found in the sample (as per **7.2.2**) is less than, or equal to the acceptance number as given in col 6 of Table 2.

8 PACKING

The elastic surgical adhesive tapes 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.

Table 2 Number of Tapes to be Selected

(Clause 7.1.2)

Sl No.	Lot Size <i>N</i>	Non-Destructive Testing		Destructive Testing	
		No. of Tapes to be Selected <i>n</i>	Acceptance Number <i>a</i>	No. of Tapes to be Selected <i>n₁</i>	Acceptance Number <i>a₁</i>
(1)	(2)	(3)	(4)	(5)	(6)
i)	Up to 280	13 ¹⁾	1	8	0
ii)	281 - 500	20	2	8	0
iii)	501 - 1 200	32	3	13	0
iv)	1 201 - 3 200	50	5	13	0
v)	3 201 - 10 000	80	7	20	1

¹⁾ Or lot size when less than 13.

ANNEX A

(Clause 2)

LIST OF REFERRED INDIAN STANDARDS

<i>IS No.</i>	<i>Title</i>	<i>IS No.</i>	<i>Title</i>
667 : 1981	Methods for identification of textile fibres (<i>first revision</i>)		per unit length and mass per unit area of fabrics (<i>second revision</i>)
1315 : 1977	Method for determination of linear density of yarn spun on cotton system (<i>first revision</i>)	1969 (Part 2) : 2010/ ISO 13934-2 :	Textiles — Tensile properties of fabrics — Determination of maximum force and elongation at maximum force
1963 : 1981	Methods for determination of threads per unit length in woven fabrics (<i>second revision</i>)	1999	Part 2 Grab method (<i>third revision</i>)
1964 : 2001	Method for determination of mass	4905 : 1968 14944 : 2001	Methods for random sampling Surgical dressings — Methods of tests

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Amendments Issued Since Publication

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