भारतीय मानक Indian Standard

IS 16469 : 2016

चिकित्सीय वस्त्रादि — खुली बुनाई वाली पट्टियां — विशिष्टि

Medical Textiles — Open Weave Bandages — Specification

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भारतीय मानक ब्यूरो

BUREAU OF INDIAN STANDARDS

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Technical Textiles for Medtech Applications Sectional Committee, TXD 36

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 — OPEN WEAVE BANDAGES — SPECIFICATION

1 SCOPE

This standard specifies performance requirements for open weave bandages 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 Open Weave Bandages — It consists of fabric of plain weave, in which warp threads are of cotton and weft threads of cotton, viscose or of combined cotton and viscose yarn, bleached to a good white. It is practically odourless, reasonably free from weaving defects, and contains not more than traces of leaf residue, seed coat and other impurities. The edges are evenly cut, parallel to warp threads and are reasonably free from loose threads.

4 WORKMANSIP AND FINISH

- **4.1** The open weave bandages 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 open weave bandages shall be conducted under proper hygienic conditions

5 REQUIREMENTS

The open weave bandages shall conform to the requirements specified in Table 1.

6 MARKING

- **6.1** Each piece of the open weave bandage shall be legibly marked with the following information:
 - a) Name of the product, that is open weave bandage;

- 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 open weave bandages of the same material, shape and dimensions produced under similar conditions of manufacture shall constitute a lot.

Table 1 Performance Requirements for Open Weave Bandages

(Clause 5)

| Sl No. | Characteristic | Requirement | Method of Test, Ref to | |
|-----------|---|---|---------------------------|--|
| (1) | (2) | (3) | (4) | |
| i) | Fibre identification | Complies with the specification | IS 667 | |
| ii) | Threads per dm: a) Warp | 107 - 129 | IS 1963 | |
| | b) Weft | 73 - 83 | | |
| iii) | Weight per square metre, g/m ² , min | 28 | IS 1964 | |
| iv) | Water and ether soluble substances (Total), percent, <i>Max</i> | 1.5 | IS 14944 | |
| v) | Fluorescence | Examine a layer al thickness under an | | |
| | | having a maximum output at 365 nm. It displays only slight brownish-violet fluorescence and | | |
| | | | | |
| | | few yellow particles; not more than a few isolated fibres show an | | |
| | | intense blue fluore | scence | |

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- **7.1.1** Each lot shall be tested separately for ascertaining the conformity of the lot.
- **7.1.2** The number of open weave bandages 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 open weave bandages 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 open weave bandages selected as per col 3 of Table 2 shall be examined for workmanship and finish (*see* **4.1**).
- **7.2.1.1** Any open weave bandages dressing 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 open weave 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.

Table 2 Number of Bandages to be Selected

(Clause 7.1.2)

| Sl | Lot Size | Non-Destructive Testing | | Destructive Testing | |
|------|----------------|-----------------------------------|-------------------|-----------------------------------|-------------------|
| No. | | No. of Bandages to be Selected | Acceptance Number | No. of Bandages to be Selected | Acceptance Number |
| | N | n | а | n_1 | a_1 |
| (1) | (2) | (3) | (4) | (5) | (6) |
| i) | Up to 280 | 131) | 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 |

ANNEX A

(Clause 2)

LIST OF REFERRED INDIAN STANDARDS

| IS No. | Title | IS No. | Title |
|-------------|---------------------------------------|--------------|--|
| 667 : 1981 | Methods for identification of textile | 1964 : 2001 | Method for determination of mass |
| | fibres (first revision) | | per unit length and mass per unit area |
| 1963 : 1981 | Methods for determination of threads | | of fabrics (second revision) |
| | per unit length in woven fabrics | 4905 : 1968 | Methods for random sampling |
| | (second revision) | 14944 : 2001 | Surgical dressings — Methods of tests |

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Amendments Issued Since Publication

| Amend No. | Date of Issue | Text Affected |
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