



DRAFT TANZANIA STANDARD

Textile - Permeable nonwoven surgical adhesive tape - Specification

Draft for Stakeholders' Comments Only

Foreword

This Draft Tanzania Standard is being developed by the Hospital Textiles Technical Committee under supervision of the Textile and Leather Divisional Standards Committee and it is in accordance with the procedures of the Bureau.

In the preparation of this standard, assistance has been obtained from the following standard:

IS 16948: 2018 Medical Textiles — Permeable Nonwoven Surgical Adhesive Tape — Specification

In reporting the result of a test or analysis made in accordance with this standard if the final value, calculated or observed is to be rounded off, it shall be done in accordance with TZS 4 *Rounding off numerical values*.

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1. Scope

This Draft Tanzania Standard specifies performance requirements, test method and sampling procedure for permeable nonwoven surgical adhesive tapes intended for medical use.

2. Normative reference

For the purpose of this Draft Tanzania Standard, the following references shall apply. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies:

TZS 3, *Atmospheric condition for testing*.

TZS 4, *Rounding off numerical values*.

TDC 9 (1666) CD1, *Surgical dressings — Methods of test*.

3. Terms and definitions

For the purpose of this Draft Tanzania Standard, the following term shall apply:

3.1 permeable nonwoven surgical adhesive tape

a backing of a nonwoven material spread evenly with a water insoluble polymeric adhesive mass that does not off-set when the tape is unrolled and which does not separate from the backing under normal conditions of use. The tape is permeable to air and water vapour.

4. Requirements

4.1 General

4.1.1 Manufacture

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

4.1.2 Workmanship and finish

4.1.2.1 The permeable nonwoven surgical adhesive tapes shall be clean and free from substances liable to cause tendering during storage.

4.1.2.2 The product shall be free from toxic or harmful substances and non-irritating to the skin.

4.2 Specific requirements

The permeable nonwoven surgical adhesive tapes shall conform to the requirements specified in Table 1.

Table 1 – Requirements for permeable nonwoven surgical adhesive tapes

S/N	Characteristics	Requirements	Test Method
1.	Weight of backing material, g/m ² , min	25	TDC 9 (1666)CD1
2.	Weight of adhesive mass, g/m ² , min	15	TDC 9 (1666)CD1
3.	Water vapour permeability, g/m ² , min	2 000	TDC 9 (1666)CD1
4.	Adhesiveness	Complies with the test	TDC 9 (1666)CD1
5.	Cytotoxicity	Complies as per the test method	TDC 9 (1697)CD1
6.	Width of the tape	Tape, not more than 5 cm wide does not vary more than +/- 1.5 mm from the declared width; tape more than 5 cm does not vary more than +/- 2.5 mm from the declared width	
7.	Perforations (If required)	Diameter, not more than 1 mm; area not more than 20 percent of the total area of the backing material	

5. Packaging and marking

5.1 Packaging

5.1.1 The permeable nonwoven surgical adhesive tapes shall be packed securely to allow normal handling and transport without tearing and exposing the contents.

5.1.2 Packaging of the product should be such as to maintain the integrity of the product throughout its shelf life.

5.2 Marking

Each pack of the permeable nonwoven surgical adhesive tapes shall be legibly marked with the following information:

- Name of the product;
- Country of origin.
- Manufacturer's name and site.
- Month and year of manufacture and expiry date;
- Size; and
- Batch /lot number
- A number of pieces in a single package.

6. Sampling and criteria for conformity

6.1 Lot

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

- 6.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.
- 6.1.2 The number of tapes to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 2, column 3 and column 5 of Table 2.
- 6.1.3 These tapes shall be selected at random from the lot.

Table 2: Number of Permeable nonwoven surgical adhesive tapes to be selected

S/N	Lot size	Non-destructive testing		Destructive testing	
		Number of tapes to be selected	Acceptance number	Number of tapes to be selected	Acceptance number
1.	Up to 280	13 ¹⁾	1	8	0
2.	281 to 500	20	2	8	0
3.	501 to 1200	32	3	13	0
4.	1201 to 3200	50	5	13	0
5.	3201 to 10000	80	7	20	1
¹⁾ or lot size when less than 13.					

6.2 Number of tests and criteria for conformity

- 6.2.1 All tapes selected as per column 3 of Table 2 shall be examined for workmanship and finish stage. (**see 4.1.2**).
- 6.2.1.1 Any 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 column 4 of Table 2. Otherwise, the lot shall be rejected.
- 6.2.2 Out of the sample already found satisfactory according to **6.2.1.1**, a sub-sample as per column 5 of Table 2 shall be taken. This sub-sample shall be further tested for the remaining requirements.
- 6.2.3 The lot shall be considered as conforming to the requirements of the specification, if the total number of defective tapes found in the sample (**see 6.2.2**) is less than or equal to the acceptance number as given in column 6 of Table 2.