



DRAFT TANZANIA STANDARD

Textiles - Specification for zinc oxide elastic self-adhesive bandage

Draft for Stakeholders' Comments Only

Foreword

This Draft Tanzania Standard is being developed by the Hospital Textiles Technical Committee under the supervision of 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 4739: 2017 Medical Textiles - Specification for zinc oxide elastic self-adhesive bandage.

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 requirements pertaining to material, construction and performance of zinc oxide elastic self-adhesive bandage.

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 conditions for testing*.

TZS 4, *Rounding off numerical values*.

TZS 20/ ISO 7211-2:1984, *Textiles — Woven fabrics — Construction — Methods of analysis — Part 2: Determination of number of threads per unit length*

TZS 3376/ ISO 7211-4:1984, *Textiles — Woven fabrics — Construction — Methods of analysis — Part 4: Determination of twist in yarn removed from fabric*

TDC 9 (1666) CD2, *Surgical dressings — Methods of test*.

3. Terms and definitions

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

3.1 bandage

a strip of woven or nonwoven fabric used specifically as a secondary dressing to cover, dress, and protect wounds.

3.2 Zinc oxide self-adhesive bandage

Adhesive bandage consisting of a strip of woven or non-woven fabric coated on one side with zinc oxide as a mild antiseptic.

4. Requirements

4.1 General

4.1.1 Materials

4.1.1.1 Basic cloth

4.1.1.1.1 Basic cloth shall be plain-woven cotton cloth. The weft threads can be either soft-spun cotton, rayon or blend of cotton and rayon. It shall be reasonably free from spinning, weaving and processing defects. The cloth shall be bleached white or tinted flesh with a suitable dye. The edges of the bandage may be indicated as fast edges.

4.1.1.1.2 The cloth shall be woven with two threads right twist (Z) and two threads reverse twist (S) along the warp. It shall conform to the particulars given in Table 1.

4.1.1.2 Self-adhesive Material

It shall be an adhesive mass containing zinc oxide free from toxic materials and materials known to be injurious to human health.

4.1.2 Manufacture

4.1.2.1 The adhesive mass shall be spread evenly and uniformly over the bandage and shall not be less than 120 gm/m² when tested according to method given in Annex A and calculated from unstretched width and fully-stretched length.

4.1.2.2 Zinc oxide content shall be not less than 10 percent, calculated as zinc oxide, when determined according to method given in Annex B.

4.1.2.3 Dimensions

The stretched bandage shall be either of the following sizes:

Width, (cm)	Length (stretched),(m)
6	4-6
8	
10	
15	

NOTE: The stretched length shall not be less than 95 percent of the stated length when tested by the stretch-ability test as specified in British Pharmacopeia 1980. Width shall not be less than 95 percent of the stated width.

Table 1: Manufacturing particulars of basic cloth

S/N	Characteristics	Requirements	Test Method
1.	Weight, g/m ² ,min	133	Annex A
2.	Ends per dm	174 ± 5%	TZS 20/ISO 7211-2:1984
3.	Picks per dm	80 ± 5%	
4.	Minimum number of turns per cm	18	TZS 3376/ISO 7211-4:1984
	a) Warp		
	b) Weft	-	

5. Performance

5.1 Stretchability and recovery

5.1.1 Stretchability details

The stretchability of the bandage shall not be less than 65 percent when tested as described in Annex C.

5.1.2 Recovery

The length of the test specimen of the stretched bandage after release shall not be more than four-fifths of the stretched length when determined as described in Annex C.

5.2 Adhesion strength

5.2.1 Adhesion to metal

The adhesion strength of plaster to metal shall be a minimum of 40 gf/cm and a maximum of 200 gf/cm of width when tested by the method given in Annex D.

5.2.2 Adhesion to self

The adhesion strength of plaster to itself shall be not more than 100 gf/cm width when tested according to the method given in Annex D.

NOTE: This test would not be applicable to bandages which are supplied with an interline or a release paper.

6. Tests

6.1 Test for various requirements shall be conducted as prescribed in appropriate annexes and relevant clauses of this standard.

6.2 Conditioning

Each roll selected for the test shall be conditioned for a minimum period of 24 hours at $27 \pm 2^\circ\text{C}$ and 65 ± 5 percent relative humidity (see TZS 3) prior to testing and testing shall be in the same atmosphere. When the tests cannot be carried out in the same atmosphere, the testing shall commence within 2 minutes of withdrawal of the specimens from the conditioning atmosphere.

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

6.4 All specimens shall be removed from the roll at an approximate 30 cm/min speed.

6.5 The adhesive surface shall not be permitted to come in contact with the fingers, or to be contaminated with dust, or to come in contact with foreign matter.

7. Packing

The adhesive bandage shall be wound on a spool, wrapped in suitable paper and packed in suitable containers as agreed to between the buyer and the seller.

8. Sampling

See Annex E.

9. Marking

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

- a) Name of the product;
- b) Product composition
- c) Manufacturer's name and site;
- d) Size of the bandage;
- e) Manufacturing and expiry date;
- f) Batch and lot number;
- g) Direction for use and storage
- h) If the adhesive is made porous, it shall be stated on the label.

**Annex A
(Table 1)****DETERMINATION OF WEIGHT OF CLOTH AND WEIGHT OF ADHESIVE MASS****A-1. TEST SPECIMEN**

A-1.1 Cut about 10 g of the sample from the sample and weigh it accurately Take care to cut parallel to the warp and weft threads.

A-2. PROCEDURE

A-2.1 Measure the area of the specimen accurately and extract with chloroform in a Soxhlet extractor until the adhesive mass completely disintegrates. Take out the fabric, dry to remove residual chloroform and immerse in dilute acetic acid for 3 hours. Remove sample in a suitable vessel and wash 12 times with boiling water, using 1 000 ml for each washing. Dry the residue to constant weight at $100 \pm 2^\circ\text{C}$ and correct the weight for moisture regain.

A-2.2 Calculate the weight of fabric in g/m^2 . Calculate weight of the adhesive mass in g/m^2 by subtracting the weight of the fabric from the weight of sample originally taken as given below:

$$\text{Weight of adhesive mass} = \left(\frac{W-w}{A} \right) \text{g/m}^2$$

where

W = weight in grams of the sample taken,

w = weight in grams of the residual fabric corrected by moisture regain, and

A = area in square metre of the sample taken.

Correction for moisture regain = 8.53 percent.

Annex B
(Clause 4.1.2.2)

METHOD FOR DETERMINATION OF ZINC OXIDE CONTENT

B-1. REAGENTS

B-1.1 Nitric Acid

B-1.2 Dilute Ammonium Hydroxide - approximately 6N.

B-1.3 pH 10 Buffer - Dissolve 68 g of ammonium chloride in 200 ml of water, add 570 ml of concentrated ammonia, and dilute to one litre.

B-1.4 Eriochrome Black T Indicator - Dissolve 0.5 g of the dye and 5 g of hydroxylamine hydrochloride in 100 ml of alcohol.

B-1.5 Standard EDTA Solution — Dry ethylenediamine tetra-acetate dihydrate disodium salt (EDTA) at 80°C and a relative humidity of 50 percent (25°C) for a period of 2 to 3 days to give a product approaching 100 percent in assay. Dissolve about 5 g of EDTA in 500 to 800 ml of water in a 1 000 ml volumetric flask. When solution is complete, dilute to the mark and mix thoroughly. Transfer the solution to a polyethylene bottle. This solution is approximately 0.01 M.

Standardize this solution with standard calcium chloride solution. Calculate the exact strength of EDTA solution and adjust the strength of the concentrated EDTA solution to exactly 0.01 M. Carry out the operations as in **B-1.5.1** and **B-1.5.2**.

B-1.5.1 Using GBHA - Transfer 25 ml of the standard calcium solution to a 250-ml Orlonmeyer flask. Add about 25 ml of water. Add by means of graduated pipettes, 4 ml of 2N sodium hydroxide solution, 15 ml of ethanol and 1 ml of GBHA indicator solution. Stand for about 2 minutes. Titrate with EDTA until colour turns from red to pure yellow.

B-1.5.2 Prepare colour comparison blanks in all the above cases by successively transferring to 250 ml conical flask approximately the same amount of water, the reagents, the indicator and sufficient EDTA to produce an unchanging colour.

B-2. PROCEDURE

B-2.1 Cut from the sample under test, two specimens weighing one gram each taking as much care as possible to cut parallel to the warp and weft threads. Take one specimen and find the weight of adhesive mass as in Annex A. Heat the second specimen with 10 ml of nitric acid in a round bottom flask until the plaster disintegrates. Boil it for 10 to 15 minutes on a low flame. Cool and dilute with 10 to 15 ml of water. Neutralize using dilute ammonia solution. Add 20 ml of pH 10 buffer and two drops of eriochrome black T indicator to obtain a clear visible red colouration in the solution. Titrate it with EDTA solution until the colour changes from red to blue.

B-3. CALCULATION

B-3.1 Zinc oxide (as ZnO), percent by weight = $0.08138 \times \frac{V}{W}$

where

V = volume in ml of 0.01 M EDTA solution used for titration, and

W = weight in grams of the adhesive mass.

Annex C
(Clauses 5.1.1 and 5.1.2)

METHOD FOR DETERMINATION OF STRETCHABILITY AND RECOVERY

C-1. PREPARATION OF TEST SPECIMEN

C-1.1 Cut three test strips of a length of 30 cm from the bandage. Mark two parallel lines across the piece at a distance of 20 cm from each other, starting at a distance of 5 cm from one end.

C 2. PROCEDURE

C-2.1 Stretchability — Fix one end of the material in a fixed grip and other in a movable grip in such a way that the gauge marks are visible between the grips and the material can stretch longitudinally (crepe yarn way). Suspend a load of 1 kg/cm width on the movable grip (weight of movable grip shall be taken into account) for a period of one minute and determine the stretched length between the marks. Express the increase in length as percentage of the unstretched length of the sample.

C-2.2 Recovery — Keep the fabric under tension of 1 kgf/cm width for one minute as given in **C-2.1**. Remove the fabric from grips and lay on a smooth flat surface without any tension. After five minutes, measure the distance between the two marks.

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Annex D
(Clauses 5.2.1 and 5.2.2)
METHOD FOR DETERMINATION OF ADHESION STRENGTH

D-0. OUTLINE OF THE METHOD

D-0.1 Adhesion strength is determined by finding the force required to peel a strip of tape from a standard test panel at a specified angle and speed.

D-1. NUMBER OF TESTS

D-1.1 Carry out the determination on five test specimens taken from the same roll.

D-2. APPARATUS

D-2.1 Tensile Testing Machine - A pendulum or spring balance type tensile testing machine, with a uniform rate of travel of 30 cm/min of the moving head or carriage, and a scale graduated to 0.05 kg or less.

D-2.2 Stainless Steel Plates - Rectangular 10 × 30 cm polished stainless steel plates.

D-2.2.1 The stainless steel plates shall have a standard abrasive satin finish (180 grit) with the direction of gritting lying parallel to the longer side of the plate.

D-2.2.2 The stainless steel plates shall also be marked boldly or etched at intervals of 2 cm along both the longitudinal edges.

D-2.3 Roller - A steel roller of minimum 80 mm diameter and 45 ± 1 mm in width covered with rubber approximately 6 mm thick having a hardness of 80 ± 5 1RHD. The weight of the roller which applies pressure to the specimen shall be 2.05 ± 0.05 kg. It shall be so constructed that the weight of the handle is not added to the weight of the roller during use (see Figure 1).

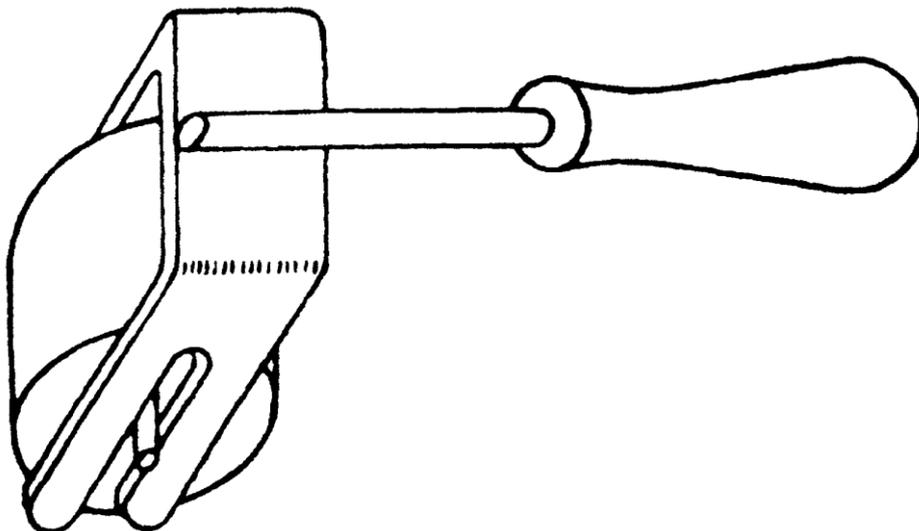


Figure 1: Roller

D-3. PREPARATION OF TEST SPECIMEN

D-3.1 Condition the rolls as specified in 6.2 and take all precautions as specified in 6.3 to 6.5 for taking the test specimen. Test specimen shall be 0.5 to 3 cm in width and not less than 50 cm in

length. If the width of the tape is greater than 3 cm, then reduce it to 3 cm by cutting with a sharp blade.

D-4. PROCEDURE

D-4.1 Clean thoroughly the surface of the stainless steel plate with redistilled toluene using a clean piece of untreated tissue paper or cotton wool for each cleaning. When all the solvent has evaporated, wipe the surface with a piece of clean dry tissue paper or cotton wool while taking precautions not to touch the steel plate with the fingers. Apply at least 25 cm of the test specimen without stretching, adhesive side down, to the centre of the surface of the steel plate and parallel to the longer sides, leaving the remainder of the test specimen extending beyond the steel plate sufficient to be accommodated in the testing equipment. Precautions shall be taken that no air bubbles are trapped between the tape and the plate.

NOTE: In the case of tapes less than 3 cm wide, cut other strips from the same sample roll and apply them parallel and adjacent to the test specimen to provide a total width of 3 cm for rolling purposes only.

D-4.1.1 Place the roller centrally across the test specimen at one end of the plate and pass the roller once in each direction at constant speed of approximately 30 cm/min, ensuring that no additional pressure on the weight of the roller is applied during the process. Allow the steel plate with the test specimen to remain undisturbed for 10 ± 0.5 minutes at a temperature of $27 \pm 2^\circ\text{C}$ and 65 ± 5 percent relative humidity.

D-4.1.2 Fold the free end of the test specimen at an angle of 180° and peel off 3 cm from the steel plate leaving at least 22 cm in contact with the steel plate. Clamp this exposed end of the plate in the lower jaw (if using a vertical pendulum or spring balance type machine), or attach the whole plate to the moving carriage if the testing machine is of the horizontal type. Attach the free end of the tape to the head of the tension measuring device and disengage the pawls, if any. Start the tensile testing machine and take readings at 2 cm intervals when the tape is pulled from the steel plate, disregarding the pulling first 5 cm and last 3 cm. The mean of five readings shall give the load required to cause the separation of the tape from the steel plate. If the specimen breaks during the test, repeat the test on another specimen cut from the same roll.

D-4.2 Adhesion to Self

D-4.2.1 Clean thoroughly the surface of stainless steel plate with redistilled toluene using a clean piece of untreated paper tissue or cotton wool for each cleaning. When all the solvent has evaporated, wipe the surface with a piece of clean dry tissue paper or cotton wool while taking precautions not to touch the steel plate with fingers.

Apply about 4 cm wide strip of the sample with the adhesive side downward to the centre of the surface of the steel plate and parallel to the longer sides, and carry the free end of the bandage over the back

side. Place a second piece of sample 2.5 cm wide and about 25 cm long centrally over the sample already mounted leaving the remainder of the test specimen extending beyond the steel plate sufficient to be accommodated in the testing equipment. Precaution shall be taken that no air bubbles are trapped between the two tapes.

D-4.2.2 Place the roller centrally across the test specimen at one end of the plate and pass the roller once in each direction at constant speed of approximately 30 cm/min, ensuring that no additional pressure on the weight of the roller is applied during the process. Allow the steel plate with the test specimen to remain undisturbed for 10 ± 0.5 minutes at a temperature of $27 \pm 2^\circ\text{C}$ and 65 ± 5 percent relative humidity.

D-4.2.3 Fold the free end of the test specimen at an angle of 180° and peel off 8 cm from the steel plate leaving at least 22 cm in contact with the steel plate. Clamp this exposed end of the plate in the lower jaw (if using a vertical pendulum or spring balance type machine), or attach the whole plate to

the moving carriage if the testing machine is of the horizontal type. Attach the free end of the tape to the head of the tension measuring device and disengage the pawls, if any. Start the tensile testing machine and take readings at 2 cm intervals when the tape is pulled from the piece of tape itself, disregarding the pulling of first 5 cm and last 3 cm. The mean of five readings shall give the load required to cause the separation of the tape from the steel plate. If the specimen breaks during the test, repeat the test on another specimen cut from the same roll.

D-5. CALCULATION AND REPORTING

D-5.1 Adhesion Strength - Calculate the load required to cause the separation of the tape from the steel plate (or from a piece of tape itself as the case may be) in terms of g/cm of width. The mean of five values obtained shall be reported as adhesion strength.

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**Annex E
(Clause 8)**

**SAMPLING AND CRITERIA FOR CONFORMITY FOR ZINC OXIDE SELF
ADHESIVE BANDAGE**

E-1. Lot

E-1.1 In any consignment, all spools of zinc oxide self-adhesive bandage of similar size produced under similar conditions shall constitute a lot.

E-1.2 The number of spools to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 2.

Table 2: Sample size and criteria for conformity for zinc oxide self-adhesive bandage

S/N	Lot size	Sample size	Acceptance number
1.	Up to 300	13 ¹⁾	1
2.	3001 to 500	13	1
3.	501 to 1000	20	2
4.	1001 to 3000	32	3
5.	3001 to 10000	32	3
6.	10001 to 35000	50	5
7.	35001 and above	80	7
¹⁾ or lot size when less than 13.			

E-1.2.1 These spools shall be selected from the lot at random and in order to ensure the randomness of selection.

E-2. NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

E-2.1 The number of spools selected at random in accordance with column 2 of Table 2 shall be tested for dimensions (4.1.2.3). The lot shall be considered as conforming to this requirement if the number of defectives found in the sample is less than or equal to the corresponding acceptance number of defectives as given in column 3 of Table 2.

E-2.2 If the lot is conforming to the requirements as mentioned in E-2.1 the test for weight of adhesive mass (4.1.2.1), zinc oxide content (4.1.2.2), tensile strength of plaster (5.1), adhesive property (5.2) and conditioning (6.2) shall be carried out. The number of times each test to be repeated shall be in accordance with column 1 and 2 of Table 3. If the sample passes each number of times, the lot shall be considered as conforming to these tests.

Table 3: For manufacture, performance requirements and conditioning tests

S/N	Lot size	Number of times tests to be repeated
1.	Up to 500	1
2.	501 to 1 000	2
3.	1001 to 3 000	3
4.	3 001 to 10 000	4
5.	10 001 and above	5

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