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DRAFT TANZANIA STANDARD

Textiles — Medical Eye Pad — Specification

Drafts for Stakeholders Comments Only!

TANZANIA BUREAU OF STANDARDS

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First Edition 2024

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0 Foreword

This Draft Tanzania Standard was 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.

This Draft Tanzania Standard is a First edition.

In the preparation of this Draft Tanzania Standard, assistance was derived from:

IS 17628, *Medical Textiles – Eye Pad - Specification*

For the purpose of deciding whether a particular requirement of this Draft Tanzania Standard is complied with, the final value observed or calculated expressing the result (s) of a test or analysis shall be rounded off in accordance with TZS 4 (see clause 2).

1 Scope

This Draft Tanzania Standard specifies the requirements of eye pad intended for medical use.

2 Normative references

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

TZS 21/ISO 3801, *Textiles – Woven or knitted fabrics – Determination of mass per unit length and per unit area*

TZS 26, *Textiles – Determination of the conductivity, pH, water soluble matter, chloride and sulphate in aqueous extracts*

TZS 2584-1/ISO 9073-1, Textiles – Test methods for nonwovens – Part 1- Determination for mass per unit area.

TZS 278, Textiles - Absorbent cotton gauze - Specification

TZS 327/ISO 1833-11, Textiles - Binary fibre mixtures - Quantitative chemical analysis

ISO 15223-1, Medical devices — Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements

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3 Terms and definitions

For the purpose of this Draft Tanzania standard, the following terms and definitions shall apply:

3.1 Eye pad

absorbent cotton patch enclosed in a woven/non-woven fine mesh gauze shaped to fit the eye socket

3.2 **Medical eye pad**

an eye pad intended for medical use such as to cover a lost, infected, treated or injured eye; can also be used as therapeutic use.

3.3 Manufacturer

natural or legal person with responsibility for the processing of raw material or inputs in any manner that results in a new product having a distinct name, character and use.

4 General Requirements

4.1 Material

4.1.1 The cover of eye pad shall be manufactured from cellulosic (natural) fibers or their blends.

4.1.2 The absorbent cotton used as filler material in eye pad shall conform to TZS 278

4.1.3 The minimum weight in grams per square meter of the eye pad shall be 150 when tested according to method prescribed in TZS 21/ISO 3801

4.2 Dimensions

The dimensions of the eye pad shall be as agreed to between the purchaser and the manufacture. However, the recommended dimension of eye pad shall be length 7±1cm and width 6±1 cm.

4.3 Workmanship and Finish

4.3.1 The eye pad shall be clean and free from substances liable to cause tendering during storage. It shall be reasonably free from objectionable defects, leaf residues, seed coat and other contaminants.

4.3.2 The manufacturing and preparation of the eye pads shall be conducted under proper hygienic condition.

4.3 Sterility

The eye pad shall be sterilized as per ISO 11737 – 1

4.4 **Hygiene Testing Requirement**

4.4.1 Total viable count

Total number of bacteria and fungi *Pseudomonas Aeruginosa, Staphylococcus* aureus, *Candida Albicans and Escherichia Coli* shall be as specified in Table 2.

4.4.2 Bacterial and Fungal Bioburden

The eye pad shall be tested for bacterial and fungal bioburden in accordance with method given in **8.3.1.1**. For selecting sample item portion (SIP), appropriate eluent and methods of extraction; ISO 11737 (Part 1) shall be referred.

The Hygiene Testing Requirements shall be as specified in Table 2

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4.5 Biocompatibility Evaluation — Cytotoxicity, Irritation and Skin Sensitization (Optional)

4.5.1 If required by the buyer, the manufacturer shall ensure that raw material used for manufacturing the final product are safe for user based on its known toxicological characteristics at intended use.

4.5.2 The biocompatibility of the material shall be detected by evaluating cytotoxicity, irritation and skin sensitization test as per IS/ISO 10993 (Part 5) and IS/ISO 10993 (Part 10) respectively.

4.5.3 For cytotoxicity, the material shall show reactivity as “None” when tested as per ISO 10995 (Part 5). Similarly, the material shall be “Non-irritant and Non-sensitizer” when tested as per ISO 10993 (Part 10). For preparation of samples for these tests, ISO 10993 (Part 12) shall be referred.

5 Performance requirements

5.1 The covering of eye pad shall conform to the requirements specified in table1.

Table 1 Performance Requirements for eye pad covering (clause 6.1)

Sl No.	Characteristics	Requirement	Method of test, ref to
i.	Fiber identification	cellulosic or natural fibres or their blends	TZS 327/ISO 1833-11
ii.	Weight (g/m^2), min		
	a) Woven	35	TZS 21/ ISO 3801
	b) Nonwoven	20	TZS 2584-1:2019/ISO 9073-1: 1989
iii.	Absorbency rate (sinking time), sec, Max	10	Annex A
iv.	pH of aqueous extract	6.5 to 7.5	TZS 26
v.	Either soluble substance, (percent, Max)	0.5	Annex C
vi.	Water soluble substances (percent, Max)	0.5	Annex B

Table 2 – Hygiene Testing Requirements for Eye pad

S/N	Quality	Requirement, cfu/g	Test method
1	Total viable count	<10	TZS 1823
2	*Pseudomonas Aeruginosa*	Not detectable per gram of sample	TZS 1826
3	*Staphylococcus Aureus*	Not Detectable per Gram of sample	TZS 1827
4	*Candida Albicans*	Not detectable per gram of sample	TZS 1830
5	*Escherichia Coli*	Not detectable per gram of sample	TZS 1825

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6 Marking

6.1 Each pack of the eye pad shall be legibly, marked/labelled with the following information:

a) Name of the product;

b) Manufacturers name, site initial or trade -mark, if any;

c) Month, year of manufacture and Expiry:

d) Batch /Lot No

e) Dimensions;

f) Storage conditions;

g) medical devices symbol as per ISO 15223-1

h) Country of origin; and

i) Any other statutory requirement as required by the law in force. (ISO medical devices symbols)

7 Packing

7.1 The eye pad shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. Detailed of the packing shall be as agreed to between the buyer and seller. Packing of the product shall be such as to maintain the integrity of the product thought its shelf life.

7.2 For packing of the sterilized products, requirements as per ISO 11607-1 and 2 should be followed.

8 Sampling and Criteria for Conformity

8.1 Lot

All the eye pad of the same material and dimensions produced under similar conditions of manufacture shall constitute a lot

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

8.1.2 Unless otherwise agreed, the number of eye pad to be selected from the lot shall depend on the size column 3 and column 5 of Table 2.

8.1.3 These eye pads shall be selected at a random from the lot.

8.2 Number of test and criteria for conformity

8.2.1 All pads selected as per column 3 of Table 2 shall be examined for workmanship and finish (see 5.1)

8.2.1.1 Any pad failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as confirming to the above requirement, if 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

8.2.2 Out of the sample already found satisfactory according to 8.2.1.1, a sub -sample as per column 5 of Table 2 shall be taken. This sub -sample shall be further tested for the remaining requirements

8.2.3 The lot shall be considered as confirming to be requirements of the specification, if the total number of detective pad found in the sample (see 8.2.2) is less than or equal to the acceptance number as given in column 6 of Table 2.

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Table 2 Number of the eye pad to be selected (Clause 8.1.2, 8.2.2, 8.2.1.1, 8.2.3, 8.3.3)

SI NO	**Lot size**	**Non-destructive testing**		**Destructive testing**	
	Number	No of pad to be selected	Acceptance Number	No of pad to be selected	Acceptance number
i.	Up to 280	13	1	8	0
ii.	281-500	20	2	8	0
iii.	501-200	32	3	13	0
iv.	1201-3200	50	5	13	0
v.	3201-10000	80	7	20	1
Or lot size when less than 13					

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ANNEX A

(Normative)

Test Method for Absorbance

A.1 Apparatus

A dry, cylindrical copper wire basket, 80 mm high and 50 mm in diameter fabricated from wire of diameter 0.4 mm and having a mesh aperture of 15 to 20 mm; the basket shall weigh 2.4 to 3.0 g.

A.2 Sinking Time

A.2.1 Method I

Weigh the basket to the nearest 10 mg. Take five samples, each of approximately 1 g, from different places in the material being examined, pack loosely in the basket and weigh the packed basket to the nearest 10 mg. Hold the basket with its long axis in the horizontal position and drop it from a height of about 10 mm into water at 20 °C contained in a beaker at least 12 cm in diameter and filled to a depth of 10 cm. Measure with a stopwatch, the time taken by the basket to sink below the surface of the water. Repeat the procedure on two further samples and calculate the average value

A.2.2 Method 11

Using forceps, fold a sample of the material, weighing 1 g, four times (that is, into 16-ply) and smooth the surface. For narrow ribbon gauze, fold as many times as is necessary to obtain a length not greater than 8 cm. Allow the material to drop lightly on to the surface of water at 20 °C contained in a beaker at least 12 cm in diameter and filled to a depth of 10 cm. Measure with a stopwatch, the time taken for the sample to sink below the surface of the water. Repeat the procedure on two further samples and calculate the average value.

A 3 Water Holding Capacity

After the sinking time has been recorded in *Method I*, remove the basket from water, allow it to drain for 30 s with its long axis in the horizontal position, transfer it to a tared beaker and weight to the nearest 10 mg. Calculate the weight of water retained by the sample. Repeat the procedure on two further samples and calculate the average value

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ANNEX B

(Normative)

Test Method for water soluble substance

(Use *Method I*, unless specified otherwise in the standard.)

B.1 Method I

Boil 7 g with 700 ml of water for 3 min, stirring frequently, and replace the water lost by evaporation Decant the liquid into a breaker, squeeze the residual liquid from the material carefully with a glass rod, mix the liquids and filter the extract whilst hot. Evaporate 400 ml and dry the residue to constant weight at 100 to 105 °C.

B.2 Method II

Dry 5 g to constant weight at 105 °C and determine the loss of weight. Heat slowly with 400 ml of water and boil for 1 min, cool by adding about the same quantity of water and decant the liquid through a sieve with a nominal mesh aperture of 106 µm, wringing the material by hand to remove as much of the liquid as possible; return the material to the vessel and repeat the washing process with five 400 ml quantities of water.

B.2.1 Method II

Place the washed material and any loose threads or fibres from the sieve in a breaker, cover with a 0.5 percent solution of diastase and maintain at 70 °C, or if the material being examined contains wool, 45 to 50 °C, until free from starch. Decant the liquid through the sieve, return any loose fibres or threads retained on the sieve to the bulk material in the vessel, repeat the washing process with boiling water and again return any loose fibres or threads retained on the sieve to the bulk material. Dry the material and determine the loss in weight.

B.2.2 Method II

For cotton crepe, cotton stretch, cotton and rubber elastic, heavy cotton and rubber elastic and elastic net bandages, and unbleached calico that has not been dyed, subtract from the loss in weight, 3 percent of the weight of the final dry sample; if the materials have been dyed, subtract 1 percent; for crepe bandage and Donette bandage, subtract 2 percent. Calculate the percentage of water-soluble substances with reference to the material dried to constant weight at 105 °C.

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ANNEX C

(Normative)

Test Method for Ether Soluble substances

C .1 Method I

Extract 5 g with ether in a Soxhlet apparatus for 4 h, operating the apparatus in such a manner that the rate is at least four extractions per hour. Evaporate the ether extract and dry the residue to constant weight at 100 to 105 °C, unless specified otherwise in the standard.

C.2 Method II

Evaporate the ether solution reserved in the test for weight per unit area of fabric and dry the residue to constant weight at 105 °C. Divide the weight of the residue by the area taken for the test.

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