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DRAFT TANZANIA STANDARD

Textiles — Underpad — Specification

TANZANIA BUREAU OF STANDARDS

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TDC 9 (3173) DTZS

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 17786, *Medical Textiles – Under pad - Specification*

For the purpose of deciding whether a particular requirement of this 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 requirement of underpad used to cover beds, mattress or furniture to prevent soiling by bedridden patient suffering from incontinence or any other condition resulting in leakage of body fluids. Underpad may also be used in operation theaters. They may be of single use or re-useable as per the requirement of buyer.

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

TZS 1823/ISO 21149, Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria.

TZS 1825, Cosmetics — Microbiology — Detection of Escherichia coli.

TZS 1826/ISO 22717, Cosmetics — Microbiology — Detection of pseudomonas aeruginosa.

TZS 1827/ISO 22718, Cosmetics — Microbiology — Detection of staphylococcus aureus.

TZS 1830/ISO 18416, Cosmetics — Microbiology — Detection of candida albicans.

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

ISO 11737 – 1, Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products.

ISO 10993 – 5, Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity

ISO 10993 – 10, Biological evaluation of medical devices Part 10: Tests for skin sensitization

ISO 10993 – 12, Biological evaluation of medical devices Part 12: Sample preparation and reference materials

ISO 11948 – 1, Urine-absorbing aids Part 1: Whole-product testing

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

3 Terms and definitions

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

3.1 Manufacturer

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

3.2 Reusable Product

product intended by the manufacturer to be re used after cleaning as per care instruction provided.

3.3 Single-use Product

product intended by the manufacturer to be used only once.

3.4 Underpad

flat pad with absorbent filler and waterproof backing, designed to absorb bodily fluids resulting from incontinence, surgical procedure or other reasons and to prevent soiling of bedding, furniture and medical equipment.

4 General Requirements

4.1 Material and Manufacture

The material used for manufacture of under pad shall not have harmful effect during normal use. The under pads shall mainly constitute of:

a) Top cover or the top sheet;

b) Absorbent core;

c) Outer protective barrier or back sheet; and

d) Adhesive.

4.2 Top Cover or Top Sheet

4.2.1 The top cover/top sheet is the material which comes under skin contact during use and allows liquid to pass through. It shall cover the absorbent filler completely and prevent the filler from reaching the user’s skin or his/her clothes under normal handling.

4.2.2 The top sheet shall be of good quality hydrophilic nonwoven/woven fabric or any other suitable materials with sufficient porosity to permit the assembled pad to meet the absorbency requirements.

4.3 Absorbent core

4.3.1 An absorbent core forming the middle layer(s) with filler materials also known as Super Absorbent Polymer (SAP)

4.3.2 The absorbent core shall have good ability to absorb the liquid, and formed into suitable shape rectangular or square and must be free from lumps, oil spots, dirt or foreign materials. It shall be arranged in a manner that will speed up the liquid absorption and helps in avoiding the bed to get wet.

4.4 Outer Protective Barrier or Back Sheet

The barrier shall be made from suitable material that is not prohibited for use for the purpose under any applicable law/regulation in force. It shall not allow the passage of absorbed fluid through it, thus preventing liquid leakage out of the underpad.

4.5 Adhesive

The construction of the underpad shall be done using different kinds of hot melt adhesive or any other method of suitable quality for fixation of the various components of the underpad.

4.6 Type and sizes

4.6.1 The under pads may be classified on the basis of their sizes; small, medium, large and extra large or as per agreement between buyer and seller.

4.6.2 The underpad shall be rectangular, square shape or any other shape as per agreement between buyer and seller.

4.6.3 The dimension may vary between different types and sizes of the under pad or as per the agreement between buyer and seller. The recommended Dimensions of the under pad with respective to their types are given in Table 3.

4.7 Workmanship and finish

The absorbent filler of the underpad shall be arranged and neatly cut to the required size and shape without any wrinkles and distortion. The material used for under pad shall be free from Oduor, harmful dyes, oils, fragrance and all sorts of unwanted material. The under pad shall have sealed edges to prevent leakage.

4.8 Washing, drying and handling instruction

The manufacturer shall provide the washing, drying, handling and storage instructions on every package of reusable under pad to ensure proper use and care for the user.

4.9 Hygiene Testing Requirement

4.9.1 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.

4.9.2 Bacterial and Fungal Bioburden

The under 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

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

4.10.1 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.

4.10.2 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.

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

5 Performance Requirement

The performance requirements shall be as specified in Table1.

Table 1 Performance Requirements for the Under pad

SN	Parameter	Requirement	Test Method
i.	pH	6.0 – 8.0	TZS 26
ii.	Absorbency rate (sinking time), sec, Max	10	Annex A
iii.	Absorbency Capacity, min, ml		ISO 11948 - 1
	Small	150	
	Medium	200	
	Large	300	
	Extra Large	400	
iv.	Retention Capacity, g, min	7.5 times of initial weight	Annex D

Note 1 – Sinking Time is 10 seconds (maximum) and Retention Time of 30 seconds (minimum)

Table 2 – Hygiene Testing Requirements for Under 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

Table 3 - Dimensions of Under pad (mm) (For reference only)

Size	Underpad Length (mm)	Underpad Width (mm)	Absorbent core Length (mm)	Absorbent Core Width (mm)
Small	400 ± 10	600 ± 10	340 ± 10	550 ± 10
Medium	600 ± 10	600 ± 10	510 ± 10	550 ± 10
Large	900 ± 10	600 ± 10	770 ± 10	550 ± 10
X Large	1 500 ± 20	600 ± 10	1280 ± 30	550 ± 10

6. Marking and Packing

6.1 Marking

6.1.1 Each pack of the under pads shall be legibly and indelibly marked with following information:

a) Name of the product;

b) Dimension/size of the product;

c) Manufacturer's name and address, initials, or trademark, if any;

d) Month and year of manufacture, batch/lot number and expiry

e) An indication that the product has been specified by the manufacturer for single-use only;

f) Instruction for safe disposal for single-use product;

g) Washing, drying and care instruction, if the product is reusable;

h) Declared life cycle/maximum wash cycle, if the product is reusable;

i) Country of origin;

j) If the product is reusable, information on the appropriate processes to allow reuse; and medical devices symbol as per ISO 15223-1

6.2 Packing

The under pad 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 shall be, such as to maintain the integrity of the product throughout its shelf life.

7 Sampling and Criteria for Conformity

7.1 Lot

All the under pads of the same material 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 under pads to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 2, 3 and 5 of Table 4.

7.1.3 These under pads shall be selected at random from the lot.

7.2 Number of Tests and Criteria for Conformity

7.2.1 All the under pads selected as per column 3 of Table 3 shall be examined for workmanship and finish

7.2.1.1 Any under pad 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 4. 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 column 5 of Table 4 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 products found in the sample (as per 7.2.2) is less than, or equal to the acceptance number as given in column 6 of Table 4.

7.2.4 The manufacturer shall perform the hygiene testing for the final product every quarter for monitoring purpose and whenever there is a change in the raw material, manufacturing premises, and the supplier of the raw material.

Table 4 - Number of Under pad to be Selected

Sl No	Lot size	Non – Destructive Testing		Destryctuve Testing	
		No. of pad to be selected	*Acceptance Number*	*No. of pad to be selected*	*Acceptance Number*
	N	*n*	*A*	n_1	a_1
(1)	(2)	(3)	(4)	(5)	(6)
i)	Up to 280	13[1]	1	8	0
ii)	281 to 500	20	2	8	0
iii)	501 to 1200	32	3	13	0
iv)	1201 to 3200	50	5	13	0
v)	3201 and above	80	7	20	1

Note 2 — for hygiene testing and biocompatibility evaluation refer *clause* **7.2.4** *and* **7.2.5** respectively.

7.2.5 The biocompatibility evaluation shall be carried out once for existing raw material and whenever there is a change in the raw material or source of supply of raw material for manufacturing the product

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

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.

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.

ANNEX D

(Normative)

Determination of Retention Capacity

D-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

D-2 Procedure

D-2.1 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.

D-2.2 Hold the basket with its long axis in the horizontal position and drop it from a height of about 10 mm into water at 27 °C contained in a beaker at least 12 cm in diameter and filled to a depth of 10 cm.

D-2.3 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.

D-2.4 After the sinking time has been recorded in C-2.1, 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.

D-2.5 Repeat the procedure on two further samples and calculate the average value.