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DRAFT TANZANIA STANDARD

Textiles — Surgical Gowns and Surgical Drapes — Specification

TANZANIA BUREAU OF STANDARDS

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Textiles – Textiles — Surgical Gowns and Surgical Drapes — Specification – Specification

0 Foreword

This 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 Tanzania Standard, assistance was derived from:

IS 17334, *Medical Textiles — Surgical Gowns and Surgical Drapes — 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

1.1 This Draft Tanzania Standard specifies requirements for single use and reusable surgical gowns and surgical drapes intended for medical use.

1.2 This Draft Tanzania Standard is intended to be used primarily by manufacturers of surgical gowns and surgical drapes in qualifying, classifying, packaging, labelling, and sterilization of surgical gowns and surgical drapes, so that healthcare workers can make more informed decisions in selection of right surgical gown and surgical drape in accordance with the protection level and risk involved in the procedure.

1.3 This Draft Tanzania Standard does not include universal procedure packs designed for specific procedures; however, contents of customized procedure packs shall be manufactured in accordance with this standard.

2 Normative references

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

TZS 22, Textiles – Woven fabrics –Determination of breaking load and extension

TZS 2584-3/ISO 9073-3, Textiles – Test methods for nonwovens – Part 3- Determination of tensile strength and elongation.

TZS 2584-10/ISO 9073-10, Textiles - Test Methods for Nonwovens Part 10 Lint and Other Particle Generation in the Dry State

ISO 811:2018 Textiles — Determination of resistance to water penetration — Hydrostatic pressure test

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

ISO 10993-10:2021 Biological evaluation of medical devices Part 10: Tests for skin sensitization

ISO 18695, Textiles — Determination of resistance to water penetration — Impact penetration test

ISO 11737 – 1, Sterilization of health care products — Microbiological Methods Part 1: Determination of a population of micro-organisms on products

ISO 13938 – 1, Bursting properties of fabrics — Part 1: Hydraulic method for determination of bursting strength and bursting distension

ISO 16603, Clothing for protection against contact with blood and body fluids — Determination of the resistance of protective clothing materials to penetration by blood and body fluids — Test method using synthetic blood

ISO 16604, Clothing for protection against contact with blood and body fluids — Determination of resistance of protective clothing materials to penetration by blood-borne pathogens — Test method using Phi-X 174 bacteriophage

ISO 22610, Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Test method to determine the resistance to wet bacterial penetration

ISO 11607-1:2019 Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems

ISO 11607-2:2019 Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes

ISO 11135:2014 Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices

ISO 11137-2:2013 Sterilization of health care products — Radiation Part 2: Establishing the sterilization dose

ISO 11138-7:2019 Sterilization of health care products — Biological indicators Part 7: Guidance for the selection, use and interpretation of results

ISO 10993-13:2010 Biological evaluation of medical devices Part 13: Identification and quantification of degradation products from polymeric medical devices

3 Terms and Definition

For the purposes of this standard, the following terms and definitions shall apply:

3.1 Barrier Properties

ability of a protective material to resist the penetration of liquids and resistance to airborne and liquid borne micro-organisms at different states (*see* **3.9** and **3.24**).

3.2 Biocompatibility

the ability to be in contact with a living system without producing an adverse effect.

3.3 Blood-borne Pathogen

infectious micro-organisms including pathogens carried in blood or other body fluids.

3.4 Body Fluids

any liquid produced (secreted/ excreted) by body.

3.5 Colony Forming Unit (CFU)

unit by which culturable number of micro-organisms is expressed

3.6 Cleanliness–microbial

freedom from population of viable micro-organism on a product and/ or a package.

3.7 Cleanliness–particulate Matter

freedom from particles that are contaminating a material and can be released but are not generated by mechanical impact.

3.8 Critical Product Area

product area with a greater probability to be involved in the transfer of infective agents to or from the wound, for example, front and sleeves of surgical gowns.

3.9 Dry Microbial Penetration

migration of microorganisms through a barrier material in dry state.

3.10 Infective Agent

micro-organism that has been shown to potentially cause infections.

3.11 Invasive Surgical Procedure

surgical procedure penetrating skin or mucosa or through body orifices

3.12 Less Critical Product Area

product area where direct contact with blood, body fluids, and other potentially infectious materials (OPIMs) is less likely to occur.

3.13 Liquid Penetration

migration of liquid(s) through the material.

3.14 Manufacturing

means processing of raw material or inputs in any manner that results in a new product having a distinct name, character and use.

3.15 Microbial Penetration

migration of micro-organisms, from one side of the material through the other.

3.16 Particle Release

release of fiber fragments and other particles during mechanical stress.

3.17 Performance Level

discrete standard defined to classify products according to the performance requirements of this standard.

3.18 Reusable Product

product intended by the manufacturer to be reprocessed and reused.

3.19 Single-use Product

product intended by the manufacturer to be used only once.

3.20 Sterile Field

an area created by placing sterile surgical drapes around the patient's surgical site and on the stand that will hold sterile instruments and other items needed during surgery.

3.21 Surgical Gown

protective clothing that is intended to be worn by healthcare workers during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of micro-organisms, body fluids and particulate matter.

3.22 Surgical Drape

covering for the patient for the prevention of transfer of infective agents, such as micro-organisms, body fluids and particulate matter

“Surgical drapes are used during surgery to prevent contact with unprepared surfaces and to maintain the sterility of environmental surfaces, equipment and the patient’s surroundings”.

3.23 Synthetic Blood

mixture of an amaranth dye, surfactant, thickening agent, inorganic salts, and distilled water having a surface tension and viscosity representative of blood and some other body fluids

NOTE 1:

The synthetic blood in this Draft Tanzania Standard does not simulate all of the characteristics of real blood or body fluids, for example, colour, coagulation and content of cell matter.

3.24 Wet Microbial Penetration

migration of micro-organisms through a barrier material in wet state.

3.25 Manufacturer

an organization that produces and assembles products from raw materials and/or purchased parts and subassemblies.

4 Requirements

4.1 General Requirements

4.1.1 Product (s) shall meet all the requirements specified in this standard throughout their useful life. If the manufacturer does not specify critical and/or non-critical area of a product, the product shall meet at least level “0” performance requirements as given in Table 1 and Table 2.

4.2 Manufacturing, Processing Requirements and Documentation

4.2.1 The manufacturer shall establish, document, implement and maintain a formal quality management system, which includes risk management and maintain its effectiveness. This quality management system shall include requirements through out product realization, including development, design, manufacture, testing, packaging, labelling, distribution and for reusable products, processing and life-cycle control.

4.2.2 A clinical evaluation for surgical drapes and gowns shall be carried out and shall consider the performance of the full draping and gowning system to establish fitness for purpose. The evaluation shall include the critical review of the applicable clinical literature and the results of post market surveillance and vigilance**.**

4.2.3 For reusable products, processing and lifecycle control shall be included in the quality management system. The requirements specified in this Draft Tanzania Standard shall be met and documented that the fitness for the intended purpose has been established for each use, both for single-use and reusable surgical gowns and surgical drapes.

4.2.4 Microbiological monitoring (as per ISO 14698-1), air monitoring of clean room (as per ISO 14644-1), sterilization (as per IS/ISO 11135), packaging [as per IS/ISO 11607 (Part 1 and Part 2)], validation

[as per IS/ISO 11137 (Part 1 and 2), ISO 11138-t 7] and residual sterility (IS/ISO 10993-7) shall be maintained by the manufacture.

4.3 Barrier Properties

4.3.1 The final performance requirement level shall be based on the performance of the critical zone component. The classification of the product shall indicate the performance of the critical zone component having the lowest barrier performance.

4.3.2 The information for principle of critical area for guidance has been given in Annex B.

4.3.3 The performance of seams between and within critical zones shall meet the requirements of this Draft Tanzania Standard. The performance of seams between critical and less critical zones shall meet at least the requirements of the adjacent less critical zone.

4.3.4 Less-critical areas of the surgical gowns and surgical drapes can have one level less as compared to the standard earmarked for the surgical gowns and surgical drapes.

4.3.5 The performance requirements of reusable products shall have to be met after declared wash cycle.

4.4 Workmanship and Finish

4.4.1 A manufacturing and processing specification shall be designed and validated for the product, including visual and hygienic cleanliness. The validation shall include all steps involved in manufacturing and processing.

4.4.2 The key manufacturing and processing variables shall be identified, monitored and recorded. The type and frequency of routine monitoring shall be documented.

4.4.3 During manufacturing and processing, the control of decontamination, disinfection procedures and the traceability of sterilization shall be maintained.

4.5 Performance Requirements

4.5.1 The manufacturer shall ensure the maintenance of required performance level after sterilization of the material and testing shall be performed on the finished product. If the product is intended to be used after sterilization, testing shall be carried out on products after sterilization.

4.5.2 Test specimens shall be taken from different Units of the same lot. If multiple tests are to be performed (for example, the critical zone consists of more than one component, such as the base material, a seam, and a point of attachment), then test specimens for each component may be taken from the same product.

4.5.3 If the test area of the finished product is too small to perform the test, a representative sample of the same material may be used. The representative sample shall be treated in the same way as the finished product.

4.5.4 During manufacture and processing, testing shall be carried out within a formal quality system.

4.5.5 Surgical gowns and surgical drapes shall conform to the requirements specified when tested according to the method given in Table 1 and Table 2 respectively.

4.5.6 The general guidelines/recommendations to use different levels of surgical gown/surgical drape for healthcare applications and surgeries in hospitals have been given in Table 3.

Table 1 – Performance requirements for surgical gowns

SN	Parameter	Level 0	Level 1	Level 2	Level 3	Test Method
1	Water Penetration Resistance (Impact Penetration test)	≤4.5	NA	NA	NA	ISO 18695
2	Water Penetration Resistance (Hydrostatic Pressure test)	NA	≥20	≥50	NA	TZS 3115:2021/ ISO 811
3	Resistance to penetration by blood and body fluid (synthetic blood penetration resistance), procedure d (see note 2)	NA	NA	NA	Pass	ISO 16603
4	Resistance to penetration by blood borne pathogens (resistance to viral penetration), procedure d (see note 2)	-	-	-	Pass	ISO 16604
5	Particle release in dry state (log 10(lint count)	≤4.0	≤4.0	≤4.0	≤4.0	TZS 2584-10/ISO 9073-10
6	Tensile Strength, N, (dry and wet)	≥20	≥20	≥20	≥20	Nonwoven: TZS 2584-3/ISO 9073-3
7	Bursting strength (dry and wet)	≥40	≥40	≥40	≥40	ISO 13938 - 1
8	Population of micro-organism on products (CFU/100	≤300	≤300	≤300	≤300	ISO 11737 -1
9	Resistance to wet bacteria penetration (I_g),	NA	NA	6 (for critical zone)	-	ISO 22610
10	Biocompatibility and Evaluation					
	Vitro cytotoxicity	None				ISO 10993-5
	Skin Irritation and Sensitization	None Irritant and non-sensitizer				ISO 10993-10
12	Thermal and water vapour resistance under steady state condition	NA	NA	NA	40 m^2 Pa/W	ISO 11092

Table 2 – Performance Requirements for Surgical Drapes

SN	Parameter	Level 0	Level 1	Level 2	Level 3	Test Method
1	Water Penetration Resistance (Impact Penetration test)	≤4.5	NA	NA	NA	ISO 18695
2	Water Penetration Resistance (Hydrostatic Pressure test)	NA	≥20	≥50	≥100	TZS 3115:2021/ ISO 811
3	Resistance to penetration by blood and body fluid (synthetic blood penetration resistance), procedure d (see note 2)	NA	NA	NA	Pass	ISO 16603
4	Particle release in dry state	≤4.0	≤4.0	≤4.0	≤4.0	TZS 2584-

	(log 10(lint count)					10/ISO 9073-10
5	Tensile Strength, N, (dry and wet)	≥20	≥20	≥20	≥20	Nonwoven: TZS 2584-3/ISO 9073-3
6	Bursting strength (dry and wet)	≥40	≥40	≥40	≥40	ISO 13938 - 1
7	Population of micro-organism on products (CFU/100	≤300	≤300	≤300	≤300	ISO 11737 -1
8	Resistance to wet bacteria penetration (I_g),	NA	NA	6 (for critical zone)	-	ISO 22610
9	Biocompatibility and Evaluation					
	Vitro cytotoxicity	None				ISO 10993-5
	Skin Irritation and Sensitization	None Irritant and non-sensitizer				ISO 10993-10

Note 2:

a) Moisture water vapor transmission test (Optional test for surgical gown): Moisture vapor transmission is the ability of water vapor to pass through a material. This attribute has a significant effect on comfort, because materials without the ability to allow moisture transmission are generally uncomfortable. This test is recommended to be performed for level 3 surgical gowns as given in Table 1, as level 3 gowns are being used in high-risk surgeries with prolonged duration where the doctors/healthcare personnel are subjected to heat stress due to which they may feel uncomfortable

b) Confirm the biocompatibility of raw material at designed stage for all levels. 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 for manufacturing the product

Table 3 General Guidelines/Recommendations for Use of Different Levels of Surgical Gowns/Surgical Drapes

Performance Level	Examples of Procedures with Anticipated Exposure Risks
Level 0	Simple excisional biopsies Excision of “lumps and bumps” Ophthalmological procedures Simple ear, nose and throat (ENT) procedures
Level 1	Tonsillectomies adenoidectomies Endoscopic gastrointestinal procedures Simple orthopedic procedures with tourniquets Open hernia repair Minimally invasive surgery Interventional radiology or catheter lab procedures
Level 2	Mastectomies Arthroscopic orthopedic procedures Endoscopic urological procedures (for example, transurethral prostate

	resections) Open gastrointestinal and Genito-urinary procedures
Level 3	Any procedure in which the surgeon's hands and arms are in a body cavity Orthopedic procedures without a tourniquet Open cardiovascular or thoracic procedures Trauma procedures Caesarean sections

5 Marking, Packing and Sterilization

5.1 Marking

5.1.1 Each pack of surgical gown/surgical drape shall be legibly and indelibly marked with following information:

a) Name of the product;
b) Dimension /size of the product;
c) Manufacturer's name, initials or trade-mark, Manufacturing site if any;
d) Month and year of manufacture and expiry
e) Batch /lot number;
f) Sterilized or un-sterilized (or) it can be sterile or unsterile;
g) Method of sterilization and necessary instructions in the event of damage to sterile packaging and, where appropriate, description of methods of re-sterilization;
h) An indication that the products has been specified by the manufacturer for single-use only;
i) If the product is multiple uses, information on the appropriate processes to allow reuse, including cleaning, disinfecting, packaging and, where appropriate, the method of re-sterilization and
j) Performance level; and
k) Any other statutory requirement as required by the law in force.

5.1.2 Each package containing surgical gowns, surgical drapes, having a critical area shall be prominently labeled identifying the areas with different performance levels and the performance level of the relevant area(s).

5.1.3 Labeling and marking requirements shall be followed as per medical device rules and regulation.

5.2 Packing and Sterilization

5.2.1 For packaging of the products, requirements as per ISO 11607-1 and 2 shall be followed**.**

5.2.2 For packaging and sterilization, the medical device rules and regulation shall be followed.

5.2.3 Validation of sterilization process shall be done as per ISO 11135, ISO 11137 -1 and 2, ISO 11138-7 and, ISO 10993-7 standards.

6 Sampling and Criteria for Conformity

6.1 Lot

All the surgical gowns or surgical drapes of the same material and dimensions produced under similar conditions of manufacture and sterilization shall constitute a lot.

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

NOTES 3:

a) For level 0, 1, 2 and 3 surgical gowns, the conformance of the performance requirements as given in Table 1 may be accepted at fabric stage (except cleanliness microbial, resistance to blood and resistance to viral) for a product if desired by buyer/user. In such cases, the traceability certificate for conformance of the performance requirement of fabric shall be maintained by the product manufacturer for each lot.

b) Similarly, for level 0, 1, 2 and 3 surgical drapes, the conformance of the performance requirements as given in Table 2 may be accepted at fabric stage (except cleanliness microbial and resistance to blood) for a product if desired by buyer/user. In such cases, the traceability certificate for conformance of the performance requirement of fabric shall be maintained by the product manufacturer for each lot.

6.1.2 The number of surgical gowns or surgical drapes to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 1, 2 and 4 of Table 4.

6.1.3 These surgical gowns/surgical drapes shall be selected at random from the lot.

6.2 Number of Tests and Criteria for Conformity

6.2.1 All the surgical gowns/surgical drapes as per column 2 of Table 4 shall be examined for workmanship and finish (**clause 4.4**).

6.2.1.1 Any surgical gowns/surgical drapes 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 3 of Table 4. 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 4 of Table 4 shall be taken. This sub-sample shall be further tested for the remaining requirements as given in Table 1 and Table 2.

6.2.3 The lot shall be considered as conforming to the requirements of the specification if the total number of defective surgical gowns/ surgical drapes found in the sample (as per **6.2.2**) is less than or equal to the acceptance number as given in column 5 of Table 4.

Table 4 Number of Surgical Gown/ Surgical Drape to be Selected

Lot Size	**Non-destructive Testing**		**Destructive Testing**	
	No. of Gown/Drape to be Selected	Acceptance Number	No. of Gown/Drape to be Selected	Acceptance Number
N	N	a	n1	a1
~~Column 1~~	~~Column 2~~	~~Column 3~~	~~Column 4~~	~~Column 5~~
Up to 50	5	0	2	0

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51 to 150	8	0	3	0
151 to 280	13	1	3	0
281 to 500	20	2	3	0
501 to 1 200	32	3	5	0
1 201 to 3 200	50	5	5	0
3 201 and above	80	7	5	0

ANNEX A

(NORMATIVE)

Manufacturer Information on Performance Levels and Critical Areas

A-1 The manufacturer may provide technical information and/or training explaining the performance level classification system and its implications for the end-user. Thereafter, the end-user is responsible for making judicious selections of products according to:

a) the performance level of the product, and
b) the anticipated degree of exposure of health care personnel to blood, body fluids, and OPIM during a given procedure or activity.

A-2 The manufacturer shall differentiate between the critical and less critical areas of the product, if applicable, and identify the different areas.

ANNEX B(Normative)

Critical Zone

B-1 Principles of the Critical Zone

B-1.1 The critical zone can be described as an area approximately 12 inches around the fenestration of a drape where it is thought that reinforcement is needed to resist the penetration and strike through of fluids. Additionally, the critical zone (see Fig. 1) on surgical gown encompasses the front area from mid-chest to waist and the sleeves to 2 inches above the elbows.

B-1.2 However, there are two important factors as related to the critical zone. Fluid is often not always contained in the proximity of the critical zone. For example, during an arthroscopic procedure a large amount of fluid can be used during the procedure and is not contained within the critical zone of the arthroscopic drape.

B-1.3 Specialty drapes, such as extremity drapes, may have a reinforced critical zone (see Fig. 2). However, due to the amount of fluids that may be encountered and/or manipulation of the body parts the surgical team should consider draping reinforcement of the areas outside of the critical zone. For example, during a hip arthroplasty, the leg is placed through several maneuvers to initially dislocate the joint, facilitate bone excision and placement of the prostheses, put the joint back into place, and further maneuvers to test the prostheses prior to closing the surgical wound. This calls for draping reinforcement of the entire leg and foot in order to prevent an SSI.

B-1.4 In this situation, it may be considered that the critical zone should be further expanded outside of the manufacturer's region of reinforcement around the fenestration, thus further suggesting that the critical zone is a fluctuating zone that dependent on the procedure to be performed.

B-1.5 The final performance requirement level of the product shall be based on the performance of the critical zone component.

A and B – Critical Zones
C and D – Less Critical
Fig 1 – Surgical Gown