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Surgical clothing — Specification - Part 1: Surgical gowns and drapes

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Foreword

Uganda National Bureau of Standards (UNBS) is a parastatal under the Ministry of Tourism, Trade and Industry established under Cap 327, of the Laws of Uganda. UNBS is mandated to co-ordinate the elaboration of standards and is

(a) a member of International Organisation for Standardisation (ISO) and

(b) a contact point for the WHO/FAO Codex Alimentarius Commission on Food Standards, and

(c) the National Enquiry Point on TBT/SPS Agreements of the World Trade Organisation (WTO).

The work of preparing Uganda Standards is carried out through Technical Committees. A Technical Committee is established to deliberate on standards in a given field or area and consists of key stakeholders including government, academia, consumer groups, private sector and other interested parties.

Draft Uganda Standards adopted by the Technical Committee are widely circulated to stakeholders and the general public for comments. The committee reviews the comments before recommending the draft standards for approval and declaration as Uganda Standards by the National Standards Council.

The committee responsible for this document is Technical Committee UNBS/TC 307, Medical devices and equipment.

This second edition cancels and replaces the first edition (US966: 2011, all parts), which has been technically revised.

Surgical clothing — Specification - Part 1: Surgical gowns and drapes

1 Scope

This Draft Uganda Standard specifies requirements, sampling and test methods for single-use and reusable surgical gowns and surgical drapes used as medical devices for patients, clinical staff and equipment intended to prevent the transmission of infective agents between patients and clinical staff during surgical and other invasive procedures.

This standard does not apply to incision drapes or films.

2 Normative references

The following referenced documents referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies

ISO 22612, *Clothing for protection against infectious agents — Test method for resistance to dry microbial penetration*

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 11737-1, *Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products*

ISO 9073-10, *Textiles — Test methods for nonwovens — Part 10: Lint and other particles generation in the dry state*

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

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

ISO 9073-3, *Textiles — Test methods for nonwovens — Part 3: Determination of tensile strength and elongation*

US ISO 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply. ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp.

3.1
surgical drape
drape covering patient or equipment to prevent transfer of infective agents

3.2
surgical gown
gown worn by a member of surgical team to prevent transfer of infective agents

3.3
colony forming unit CFU
unit by which the culturable number of microorganisms is expressed

Note 1 to entry: The culturable number is the number of microorganisms, single cells or aggregates, able to form colonies on a solid nutrient medium

3.4
cleanliness
freedom from unwanted foreign matter. Such matter can be microorganisms, organic residues or particulate matter.

3.5
cleanliness — microbial
freedom from population of viable micro-organisms on a product and/or a package. Note - In practical use, microbial cleanliness is often referred to as 'bioburden'.

3.6
critical product area
product area with a greater probability to be involved in the transfer of infective agents to or from the wound, e.g. front and sleeves of surgical gowns

3.7
infective agent
micro-organism that has been shown to cause wound infections or that might cause infection in a member of the surgical team or the patient

3.8
less critical product area
product area less likely to be involved in the transfer of infective agents to or from the wound

3.9
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

3.10
particle release
release of fibre fragments and other particles during mechanical stress simulating handling and use

3.11
performance level
discrete standard defined to classify products according to the performance requirements of this document

Note 1 to entry: With the introduction of two performance levels, this document acknowledges the fact that products are challenged to differing extents during surgical procedures, dependent upon the duration, mechanical stress and liquid challenge throughout the surgical procedure.

3.12
standard performance
classification addressing minimum performance requirements for various characteristics of products used as medical devices in invasive surgical procedures

3.13
high performance
classification addressing elevated performance requirements for various characteristics of products used as medical devices in invasive surgical procedures

Note 1 to entry: Examples of surgical procedures where elevated performance level should be considered are those where extensive exposure to liquid, mechanical stresses or longer surgical procedures can be expected.

3.14
processor
natural or legal person who processes products so that their performance complies with the requirements of this document

Note 1 to entry: A processor who places a product on the market is a manufacturer in the sense of this document.

Note 2 to entry: A processor of reusable products is often referred to as a 'reprocessor' and processing reusable products is often referred to as 'reprocessing'

3.15
resistance to liquid penetration
ability of material to withstand the penetration of liquid(s) from one side of the material through to the other

3.16
resistance to microbial penetration
ability of material(s) to withstand penetration of micro-organisms from one side of the material through to the other

3.17
dry penetration
effect of a combination of air movement and mechanical action by vibration on microbial penetration in dry condition

3.18
wet penetration
effect of combination of wetness, pressure and rubbing on microbial penetration

3.19
reusable product
product intended by the manufacturer to be reprocessed and reused

3.20
single-use product
product intended to be used once only for a single patient

3.21
sterile field
area created by sterile surgical drape material where aseptic technique is practised

Note 1 to entry: A sterile field can be practised e.g. on a back table.

3.22
surgical procedure
surgical intervention performed by a surgical team

3.23
invasive surgical procedure
surgical procedure penetrating skin or mucosa

4 Requirements

4.1 General requirement

4.1.1 The surgical gowns and surgical drapes shall be free from any damage or defects.

4.1.2 When tested in accordance with the relevant parts of ISO 10993, the surgical gowns and surgical drapes shall be evaluated and approved for acceptable risk.

4.1.3 If the manufacturer does not differentiate the product areas, all areas shall meet the requirements for critical product area.

4.2 Performance requirements

4.2.1 Surgical gowns shall conform to the requirements given in Table 1 when tested in accordance with the test methods specified therein.

Table 1 — Performance requirements for surgical gowns

S.No.	Characteristic	Requirement				Test method
		Standard performance		High performance		
		Critical product area	Less critical product area	Critical product area	Less critical product area	
i	Microbial penetration –dry, CFU	Not required	≤ 300[a]	Not required	≤ 300[a]	ISO 22612
ii	Microbial penetration – wet , I_B	≥ 2.8[b]	Not required	6.0[b c]	Not required	ISO 22610
iii	Cleanliness microbial /Bioburden (CFU/100cm^2)	≤ 300	≤ 300	≤ 300	≤ 300	ISO 11737-1
iv	Particle release ,$\log_{10}$ (lint count)	≤ 4.0	≤ 4.0	≤ 4.0	≤ 4.0	ISO 9073-10
v	Liquid Penetration cm H_20	≥ 20	≥ 10	≥ 100	≥ 10	ISO 811
vi	Bursting strength ,kpa	≥ 40	≥ 40	≥ 40	≥ 40	ISO 13938-1
vii	Tensile strength – Dry , N	≥ 20	≥ 20	≥ 20	≥ 20	ISO 9073-3
viii	Tensile strength – Wet , N	≥ 20	Not required	≥ 20	Not required	

a Test conditions: challenge concentration 10B CFU/g talc and 30 minutes vibration time

b b The least significant difference (LSD) for BI (Barrier Index) when estimated using ISO 22610 was found to be 0.98 at 98 % confidence level. This is the minimum difference needed to distinguish between two materials thought to be different. Thus materials varying by up to 0.98 BI are probably not different. Materials varying by more than 0.98 BI are probably different. (The 95 % confidence level means that an observer would be correct 19 times out of 20 to accept these alternatives)

c Barrier Index (IB) = 6.0 for the purpose of this standard means; no penetration, IB = 6.0 is the maximum achievable value.

4.2.2 Surgical drapes shall conform to the requirements given in Table 2 when tested in accordance with the test methods specified therein.

Table 2 — Performance requirements for surgical drapes

S.No.	Characteristic	Requirement				Test method
		Standard performance		High performance		
		Critical product area	Less critical product area	Critical product area	Less critical product area	
i	Microbial penetration –dry, CFU	Not required	≤ 300a	Not required	≤ 300a	ISO 22612
ii	Microbial penetration – wet , IB	≥ 2.8b	Not required	6.0b c	Not required	ISO 22610
iii	Cleanliness microbial /Bioburden (CFU/100cm^2)	≤ 300	≤ 300	≤ 300	≤ 300	ISO 11737-1
iv	Particle release ,log_{10} (lint count)	≤ 4.0	≤ 4.0	≤ 4.0	≤ 4.0	ISO 9073-10
v	Liquid Penetration cm H_20	≥ 30	≥ 10	≥ 100	≥ 10	ISO 811
vi	Bursting strength ,kpa	≥ 40	≥ 40	≥ 40	≥ 40	ISO 13938-1
vii	Tensile strength – Dry , N	≥ 15	≥ 15	≥ 20	≥ 20	ISO 9073-3
viii	Tensile strength – Wet , N	≥ 15	Not required	≥ 20	Not required	ISO 9073-3

a Test conditions: challenge concentration 108 CFU/g talc and 30 minutes vibration time

b The least significant difference (LSD) for IB (Barrier Index) when estimated using ISO 22610 was found to be 0.98 at 95 % confidence level. This is the minimum difference needed to distinguish between two materials thought to be different. Thus materials varying by up to 0.98 BI are probably not different. Materials varying by more than 0.98 BI are probably different. (The 95 % confidence level means that an observer would be correct 19 times out of 20 to accept these alternatives)

c Barrier Index (IB) = 6.0 for the purpose of this standard means; no penetration, IB = 6.0 is the maximum achievable value.

5 Packaging

5.1 The surgical gown and surgical drapes shall be packaged in suitable packaging materials, which shall protect product from contamination and damage during transportation, handling and storage.

5.2 The packages shall be packed in accordance with ISO 11607 series. Only products of the same type and nominal size shall be packed together in a package and in a bulk container. Sterile-packed packages shall be packed in separate bulk containers.

6 Labelling

6.1 The packages shall be legibly and indelibly marked with the following information:

a) name of product as “Surgical gown”, or “Surgical drape”;

b) name and physical address of manufacturer;

c) type of surgical clothing “reusable” or “single use”;

d) performance level;

e) country of origin;

f) date of manufacture;

g) date of expiry;

h) batch or lot number;

i) quantity of product;

j) size of the surgical clothing;

k) colour of surgical clothing;

l) storage conditions;

m) instruction of use; and

n) instructions for disposal after the useful life of the product

6.2 In case of single use, the surgical gown and surgical drape shall be labelled sterile.

6.3 In the case of the reusable surgical gowns and surgical drape, information on the appropriate processes to allow reuse, including cleaning, disinfection, packing and, if appropriate, the methods of sterilization of the device to be re-sterilized, the number of reuses and any restriction to the reuse;

6.4 if the surgical gown and surgical drape is supplied with the intention that it be sterilized before use, instructions for sterilization methods;

7 Sampling

Sampling shall be done in accordance with US ISO 2859-1

Annex A
(informative)

Guidance to users for selecting products

A.1 Performance levels

This document introduces two performance levels ('standard performance' and 'high performance') for surgical gowns and drapes, thereby acknowledging the fact that products are challenged to differing extents during surgical procedures, dependent upon the duration, mechanical stress and liquid challenge throughout the surgical procedure. The differentiation of 'standard performance' from 'high performance' products is based on the barrier performance of the products in critical product areas.

NOTE 1 For details of the differences in the required barrier performance, see Tables 1 and 2.

By establishing two performance classes this document facilitates the assessment of the barrier performance of products. However, this document does not include specific recommendations for selecting surgical gowns or drapes with regard to the type of surgical procedure the product is to be used with.

The user will select surgical gowns and drapes based on their performance in order to meet the anticipated challenges of the surgical procedure (e.g. in terms of duration, mechanical stress and liquids). If the classification scheme provided by this document is not considered suitable to address the anticipated challenges during use, discrete test results for the characteristics to be evaluated can be taken as a basis for selecting products.

NOTE 2 The selection and use of surgical gowns and drapes for specific surgical procedures can be covered by risk assessment and quality management carried out by the user and can be subject to local, regional or national infection prevention regime, guidelines, directives or regulation.

A.2 Functional design

A.2.1 General

This document does not include specific requirements for the functional design of surgical gowns and drapes. The impact of functional design on the performance of products is acknowledged by requiring testing on the finished product including potential weak spots.

However, the functional design – in particular critical and less critical areas, the over-all size of the product and the characteristics of accessories (if any) – and its impact on the working situation (thermophysiological comfort and ergonomics) should be considered when selecting products for use.

A.2.2 Critical and less critical areas

This document acknowledges the fact that not all areas of the product are involved in the transfer of infective agents to or from the wound to the same extent. In order to set different performance requirements and allow for different product areas this document introduces 'critical product areas' and 'less critical product areas'.

NOTE 1 In general 'critical product areas' include those areas most likely to be exposed to blood and other body liquids as, e.g. front and sleeves of surgical gowns or the parts of surgical drapes adjacent to the surgical wound. The back of a surgical gown and part of surgical drapes being far from the wound are usually considered as 'less critical product areas'.

NOTE 2 For details of the differences in the required performance of 'critical product areas' and 'less critical product areas', see Tables 1 and 2.

This document does not include provisions for the size and position of ‘critical’ or ‘less critical’ product areas. The user has to decide whether or not size and position of ‘critical’ and ‘less critical’ product areas are suitable to meet the anticipated challenges of a certain surgical procedure.

A.2.3 Size

This document does not include provisions for specifying the size of products in a standardized way. Selecting products of suitable size in order to appropriately cover persons, patients and equipment is up to the user in order to ensure the intended use of the respective product.

Note Using products of inappropriate size might lead to insufficient covering, i.e. jeopardize the aim of minimizing the transfer of infective agents, and might impact freedom or safety of movements (e.g. with gowns to small or too big for the wearer).

A.2.4 Accessories

This document does not include specific provisions for accessories such as, e.g. cuffs or buttons. As accessories do therefore not need to meet any requirements of this document, the user should assess the functional design with consideration to the placement of accessories so that the intended uses of the products are not compromised. The user should also assess the quality of any accessories in order to ensure that the intended uses of the products are not compromised.

A.2.5 Comfort

A.2.5.1 General

The functional design of products has an impact on the thermophysiological comfort.

Note 1 For more information on comfort, see B.1.

The user when selecting products for use should assess the comfort of products in order to exclude any significant limitations of the intended use of the product. Combinations of materials and design of clothing systems (including technical underwear or garments) that will minimize the physiological stress during work are to be encouraged.

NOTE 2 The comfort of surgical gowns and drapes depends on various characteristics, most of which can be evaluated using standardized test methods. More easily the overall comfort of surgical gowns and drapes can be assessed with trials (i.e. personal experience).

A.2.5.2 Surgical gowns

The overall comfort of surgical gowns can be influenced by a number of factors: design, fit, breathability, weight, surface thickness, electrostatic properties, colour, light reflectance, odour and skin sensitivity.

Other important variables that can influence comfort include undergarments, health and physical conditions, workload, mental stress and environmental conditions, such as temperature, relative humidity, and air changes in operating room.

The perception of comfort is subjective and can be influenced by one or a combination of the aforementioned factors.

A.2.5.3 Surgical drapes

Surgical drapes should be flexible so that they will cover the patient closely and smoothly, allowing placement and manipulation of instruments and draping of other related equipment, such as ring stands, back tables, and Mayo stands. Liquid control is important for surgical drapes in operations with much blood or other liquids such as saline.

Annex B
(informative)

Information on further characteristics

B.1 Comfort

The concept of comfort is based on several different factors, such as physiological comfort, ease of movement or factors that will influence and/or affect the individual's satisfaction with the product.

The thermophysiological comfort of a product depends on such properties as its thermal resistance, air permeability, water-vapour resistance, drapeability, tactile comfort and other properties like stretchability, weight, size, fit, fibres and manufacture.

Note 1 Drapeability addresses the ability of a material to conform to a given shape or object.

Note 2 Water-vapour resistance is defined as the water-vapour pressure difference between the two faces of a material divided by the resultant evaporative heat flux per unit area in the direction of the gradient. The evaporative heat flux can consist of both diffusive and convective components. EN ISO 11092 provides a test method for measuring the thermal and water-vapour resistance under steady-state conditions.

Note 3 Thermal resistance is a property of a material that can be measured by a thermal manikin in view to determine important parameters relevant to clothing thermal comfort.

Note 4 Tactile comfort also indicated as softness, is highly dependent on the fibre smoothness and the finish technologies.

Note 5 Properties such as stretchability, size fit, weight, can be measured.Discomfort properties, such as rustling tendency, softness and skin irritation are difficult to measure. Evaluation should be based on trials of the products or practical experience.

B.2 Adhesion for fixation for the purpose of wound isolation

Adhesives are used to attach materials during the preparation for an operation and to attach drapes to a patient on the operating table. Different adhesives are chosen for different materials, e.g. material to material and material to the skin. In choosing an adhesive, the following considerations should be taken into account:

a) adhesives should not cause damage to the skin.

b) when used on reusable materials, the adhesives should be removable during processing without damaging the material.

c) the adhesive should create a seal-off from liquid and secure a sterile field.

B.3 Liquid control

The control of liquids, like body liquids or other liquids used or generated close to the wound during a surgical procedure, is regarded relevant to reduce the risk of transfer of infective agents.

B.4 Flammability

Though surgical gowns and drapes do not provide ignition sources or oxidizer both products might serve as fuel, when a fire breaks out. Manufactures are required to supply information regarding fire risks in relation to the use of their products.

Bibliography

[1] EN 13795 -2:2019*, Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment – Part 2: Test methods*

[2] ISO 13485:2016, *Medical devices — Quality management systems — Requirements for regulatory purposes*

[3] US 966-1:2011*, Medical devices — Surgical gowns, drapes and clean air suits — Part 1: General requirements*

[4] US 966-2:2011, Medical devices — Surgical gowns, drapes and clean air suits, — Part 3: Test methods

[5] US_966-1_2011_78_Medical devices - Surgical gowns, drapes and clean air suits, - Part 1 General requirements

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