DUS 966-2

# DRAFT UGANDA STANDARD

**Second Edition**
**2021-mm-dd**

## Surgical clothing — Specification - Part 2: Clean air suits



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**Compliance with this standard does not, of itself confer immunity from legal obligations**

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The Executive Director
Uganda National Bureau of Standards
P.O. Box 6329
Kampala
Uganda
Tel: 256 414 505 995
Fax: 256 414 286 123
E-mail: unbs@infocom.co.ug
Web: www.unbs.go.ug

 

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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.



 

## Introduction

Clean air suits are used to minimize the spread of infective agents to patients' surgical sites and equipment, through prevention of dispersal of bacteria-carrying skin scales from the operating room staff, thereby helping to prevent post-operative surgical site infections.

The performance required of working clothes for clinical staff varies with, for example, the type and duration of the procedure, and the susceptibility of the patient to infection. In infection-prone invasive operations, a clean air suit can contribute to reduction of infection risks, in conjunction with ventilation and correct working methods.

# Surgical clothing — Specification - Part 2: Clean air suits

## 1 Scope

This Draft Uganda Standard specifies requirements, sampling and test methods for single-use and reusable surgical clean air suits 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.

It does not apply to scrub suits.

## 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

ISO 11607 (all parts), Packaging for terminally sterilized medical devices

US ISO 10993, Biological evaluation of medical devices

## 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**
**clean air suit**
suit used as working garment intended and shown to minimize contamination of operating room air from skin scales originating on the skin of persons wearing it.

**3.2**
**critical product area**
product area with a greater probability to be involved in the transfer of infective agent to or from the wound.

**3.3**
**performance level**
discrete standard defined to classify products according to the performance requirements of this standard

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 microbial cleanliness of the operating room required for the procedure

**3.3.1**
**standard performance**
classification addressing minimum performance requirements for various characteristics of products used as medical devices in invasive surgical procedures

**3.3.2**
**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 high performance level might be considered are infection prone clean surgical procedures where air counts in the operating room of ≤ 10 CFU/m3 are required.

**3.4**
**processor**
natural or legal person who processes products so that their performance complies with the requirements of this standard

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’

**3.5**
**processor**
natural or legal person who processes reusable product items so that their performance complies with the requirements of this standard

**3.6**
**resistance to microbial penetration**
ability of material(s) to withstand penetration of micro-organisms from one side through to the other

**3.6**
**dry penetration**
effect of a combination of air movement and mechanical action by vibration on microbial penetration in dry condition

**3.8**
**wet penetration**
effect of combination of wetness, pressure and rubbing on microbial penetration



 

**3.9**
**reusable product**
clean air suit intended by the manufacturer to be reprocessed and reused

**3.10**
**single-use product**
clean air suit intended by the manufacturer to be used for only one surgical procedure before disposal

**3.11**
**surgical procedure**
surgical intervention penetrating skin or mucosa, performed by a surgical team

**3.12**
**invasive surgical procedure**
procedure that reaches the inside of the body through the body surface

**3.1.3**
**cleanliness**
freedom from unwanted foreign matter

NOTE Such matter can be micro-organisms, organic residues or particulate matter.

**3.4**
**cleanliness — microbial**
freedom from population of viable micro-organisms on a product and/or a package

**3.15**
**fixation**
adhesion of a surgical drape to the patient for the purpose of wound isolation

**3.16**
**infective agent**
micro-organism that has been shown to cause a wound infection or that might cause infection in a member of the surgical team or the patient

**3.17**
**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

**3.18**
**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



## 4 Requirements

### 4.1 General requirement

**4.1.1** The clean air suit shall be free from any damage or defects.

 

**4.1.2** The biocompatibility of the clean air suits shall be evaluated and approved for acceptable risk in accordance to the relevant part of US ISO 10993.

**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

Clean air suits shall conform to the requirements given in Table 1 when tested in accordance with the test methods specified therein.

**Table 1 — Performance requirements for clean air suits**

| S.No | Characteristic | Requirement | | Test method |
|---|---|---|---|---|
| | | Standard performance | High performance | |
| i | Microbial penetration –dry, CFU | ≤ 100[a] | ≤ 50[a] | ISO 22612 |
| ii | Cleanliness microbial /Bioburden (CFU/100cm$^2$) | ≤ 100 | ≤ 100 | ISO 11737-1 |
| iii | Particle release ,$\log_{10}$ (lint count) | ≤ 4.0 | ≤ 4.0 | ISO 9073-10 |
| iv | Bursting strength ,kpa, dry | ≥ 40 | ≥ 40 | ISO 13938-1 |
| v | Tensile strength – Dry , N | ≥ 20 | ≥ 20 | ISO 9073-3 |
| | a Test conditions: challenge concentration $10^8$ CFU/g talcum and 30 minutes vibration time | | | |

## 5 packaging

**5.1** The surgical clean air suits 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 “Clean air suit”;

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 clean air suits shall be labelled sterile.

**6.3** In the case of the reusable clean air suits, 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 clean air suit 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 General

The selection and use of clean air suits for specific surgical procedures should be covered by risk assessment and quality management and can be subject to local, regional or national infection prevention regime, guidelines, directives or regulations.

## A.2 Performance levels

This standard introduces two performance levels ('standard performance' and 'high performance') for clean air suits, thereby acknowledging the fact that different products may be required depending on the microbial cleanliness of the operating room required for the procedure. The differentiation of 'standard performance' from 'high performance' products is based on the barrier performance of the products. For infection-prone clean surgery, air counts in the operation room of less than 10 CFU/$m^3$ are recommended. To achieve that level, standard performance clean air suits can be used in operating rooms with high air flow rates, but in operating rooms with average ventilation, e.g. 0,56 $m^3/s$ (equalling 17 air changes/h in an average operating room), high performance clean air suits are needed, particularly when the operation requires a high number of persons present.

Note 1 For details of the differences in the required barrier performance, see Table 1.

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

The user should select clean air suits based on their performance levels in order to meet the anticipated challenges of the surgical procedure (e.g. in terms of duration, mechanical stress and temperature) and the microbial cleanliness of the operating room required for the procedure.

Note 2 In clean-room clothing systems, not primarily intended for operating room use, the suit has long sleeves, is designed as a coverall, and is worn with a hood and textile boots. Such clothing systems have practical drawbacks, such as difficulty in performing hand disinfection. In addition, garments made from tight materials can impair the comfort of the wearer, particularly when performing physically heavy and stressful work such as large surgical procedures. When a high performance clean air suit is required, e.g. in operating rooms with a low air- flow where the clinician considers the patient to be particularly infection-prone, a complete clean-room clothing system can be considered.

## A.3 Functional design aspects

### A.3.1 Size

This standard does not include provisions for specifying the size of products in a standardized way. Products should have suitable size and construction to fulfil the intended use of the clean air suit, and to ensure safety and freedom of moments. Selecting products of suitable size to appropriately cover persons is up to the user.



 

### A.3.2 Accessories

This standard does not include specific provisions for accessories like e.g. cuffs or buttons. Therefore, accessories need not to meet any requirements of this document, and 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.4 Comfort

### A.4.1 General

**A.4.1.1** 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 work performance and satisfaction with the product. Garments made from tight materials can impair the comfort of the wearer, particularly when performing physically heavy and stressful work such as large surgical procedures.

**A.4.1.2** The 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 31092 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.

**A.4.1.3** 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. 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.

### A.4.2 Clean air suits

The overall comfort of clean air suits can be influenced by a number of factors mentioned in A.4.1. 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.



 

# Annex B
(informative)

## Adhesion for fixation and wound isolation

Adhesives are used to attach fabrics during the preparation for an operation and to attach drapes to a patient on the operating table. Different adhesives are chosen for different materials, for example, 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 reprocessing without damaging the fabric.

# Bibliography

[1] EN13795-2_2019, Surgical clothing and drapes — Requirements and test methods — Part 2 Clean air suits

[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 2: Test methods

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



 

## Certification marking

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