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Non-woven surgical dressing — Specification

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Foreword

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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 (US 706: 2011), which has been technically revised.

Non-woven surgical dressing — Specification

1 Scope

This Draft Uganda Standard specifies the requirements, sampling and methods of test for three types of non-woven surgical dressings; unpadded swabs, padded swabs and surgical pads.

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.

US ISO 1833 (all parts), *Textiles — Quantitative chemical analysis*

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*

US ISO 3071, *Textiles- Determination of pH of aqueous extract*

US ISO 10993 (all parts), *Biological evaluation of medical devices*

US ISO 13938(all parts), *Textiles — Bursting properties of fabrics*

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
bursting strength
multi-directional resistance to rupture of a circular fabric specimen

3.2
fibre
textile raw material, generally characterized by flexibility, fineness and high ratio of length to thickness

3.3
gauze
fine lightweight, open-texture fabric produced in plain weave or in a simple leno weave

3.4
non-woven fabric
fabric normally made from continuous filaments or from staple-fibre webs or batts strengthened by bonding using various techniques including adhesive bonding, mechanical interlocking by needling or fluid jet entanglement, thermal bonding and stitch bonding

3.5
swab
surgical dressing pad consisting of several layers of absorbent fabric, and used to prepare the site of an operation or a wound, to absorb and remove excess blood and body fluids from an incision, and for packing internal body cavities during an operation

3.6
wadding
lofty sheet of fibres, which might be bonded, and used for padding, stuffing, or packing

3.7
weave
pattern of interlacing of warp and weft in a woven fabric

3.8
warp
thread running lengthwise and parallel to a selvedge

3.9
weft
thread running width wise in a fabric as woven

4 Types

Non-woven surgical dressings shall be one of the following types,

a) unpadded swabs;

b) padded swabs; and

c) surgical pads.

5 Fibre composition

When determined in accordance with a relevant part of ISO 1833, the fibre composition of the components of the non-woven surgical dressings shall be as follows:

a) non-woven fabric: cotton, viscose or thermos bonding fibres (for example, polypropylene); and

b) wadding; either cotton, viscose or polyester fibres (or a mixture of two or more of these fibres) or bleached cellulose pulp.

6 Requirements

6.1 General requirements

6.1.1 Non-woven surgical dressing shall be free any spinning, weaving or processing defects and any foreign matter.

6.1.2 When tested in accordance with the relevant parts of ISO 10993, non-woven surgical dressing shall be non-toxic, hypoallergenic and non-irritating.

6.1.3 Non-woven fabric

Non-woven fabric used in surgical dressings shall comply with the requirements given in Table 1.

Table 1 — Non-woven fabric requirements

Characteristic	Requirement	Test method
Mass per unit area, g/m^2, min.	13	Annex C
Bursting strength, kPa, min.	35	US ISO 13938

6.1.4 Unpadded swabs

6.1.4.1 Construction

An unpadded swab shall have been made from a single piece of non-woven fabric that has been so folded to the appropriate size that no raw edge is visible, or so processed that the raw edge is non-linting, non-adherent and smooth.

6.1.4.2 Size, ply and mass

When determined in accordance with Annex B and C, the nominal size of, and number of plies in, a swab shall, unless otherwise specified by the purchaser, be one of the combinations given in columns 1 and 2 of Table 2, as specified, and the mass of 10 swabs of the same size and ply shall be at least equal to the appropriate minimum value given in column 3.

Table 2 — Size, ply and mass of unpadded swabs

Nominal size, mm	Number of plies	Minimum mass of 10 swabs, g
75 x 75	2	1.5
75 x 75	4	3
75 x 75	8	6
75 x 75	12	9
100 x 100	2	2.5
100 x 100	4	5
100 x 100	8	10
100 x 100	12	16

6.1.5 Padded swabs

6.1.5.1 Construction

A padded swab shall have been made from a single piece of non-woven fabric that has a thin layer of wadding at its centre and has been so folded to the appropriate size that the swab contains at least two plies and no raw edge is visible, or so processed that the raw edge is non-linting, non-adherent and smooth. Where bleached cellulose pulp is used as wadding, the wadding shall be encased in non-woven tissue, followed by encasement in non-woven fabric, so as to prevent the loss of short, loose fibres.

6.1.5.2 Size and mass

When determined in accordance with annexes B and C, the nominal size of a padded swab shall be one of those given in column 1 of Table 3, as specified by the purchaser, and the mass of 10 swabs of the same size shall be at least equal to the appropriate minimum value given in column 2.

Table 3 — Size and mass of padded swabs

Nominal size, mm	Minimum mass of 10 padded swabs, g
50 x 50	5
75 x 75	9
100 x 100	15

6.1.6 Surgical pads

6.1.6.1 Construction

A surgical pad shall consist of a thick layer of wadding enclosed in a tube (either open-ended or sealed) formed from one or more pieces of non-woven fabric, with the cut edges adequately sealed along the length of the pad. Where bleached cellulose pulp is used as wadding, the wadding shall be encased in non-woven tissue, followed by encasement in non-woven fabric, so as to prevent the loss of short, loose fibres.

6.1.6.2 Type

Surgical pads shall be of type A, B or C, as specified by the purchaser (see Table 4).

6.1.6.3 Size and mass

When determined in accordance with Annexes B and C, the nominal size of a surgical pad shall be one of those given in column 1 of table 4, as specified by the purchaser, and the mass of 10 surgical pads of the same size shall be at least equal to the appropriate minimum value given in column 2, 3 or 4, as relevant.

Table 4 — Size and mass of surgical pads

Nominal size,mm	**Minimum mass of 10 surgical pads, g**		
	Type A	Type B	Type C
100 x 100	36	29	19
100 x 200	70	57	39
200 x 200	140	109	73
200 x 400	280	219	147
400 x 400	560	-	-

7 Sterility

If sterile, the dressings shall be tested in accordance with Annex G.

8 Other requirements

All types of non-woven surgical dressings shall comply with the requirements given in Table 5.

Table 5 — Other requirements for all types of surgical dressings

S.No	Characteristic	Requirement	Test method
i)	Fluorescence	Not more than the occasional point of intense blue fluorescence	Annex C
ii)	Absorption rate, s ,max	10	Annex D
iii)	Ash content, g/kg, max.	5	Annex E
iv)	pH value of aqueous extract	7 ± 2	US ISO 3071
v)	Freedom from dyes	The percolate may show a yellow colour, but no blue or green tint shall appear	Annex F.

9 Packaging

9.1 The dressing shall be packaged in suitable packaging materials, which shall protect the product from contamination and damage during transportation, handling and storage.

9.2 Only dressings of the same type and nominal size, and in the case of unpadded swabs, number of plies, shall be packed together in a package and in a bulk container. Sealed and sterile- packed packages shall be packed in separate bulk containers.

10 Labelling

Each package shall be in legible and indelible marked or a label securely attached to the package with the following information

a) manufacturer's name, physical address and trade mark;

b) type of dressing, the nominal size (in millimetres) and, in the case of unpadded swabs, the number of plies;

c) type, in the case of surgical pads;

d) the word "sterile" in the case of a sterile-packed dressing;

e) quantity of dressings;

f) batch identification number;

g) country of origin;

h) date of manufacture

i) expiry date; and

j) and conditions of storage.

k) information on disposal after use

11 Sampling

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

Annex A
(normative)

Conditioning of textiles and standard temperate atmosphere for determining their physical and mechanical properties

A.1 Principle

Textile samples are conditioned in an atmosphere of a specified humidity and a specified temperature.

A.2 Standard temperate atmosphere for testing

An atmosphere that has a relative humidity of 65 % ± 2 % and a temperature of 20 °C ± 2 °C at the prevailing barometric pressure.

A.3 Pre-conditioning

If pre-conditioning is required, dry the textile to substantially constant mass in an atmosphere that has a relative humidity between 10 % and 25 % and a temperature not exceeding 50 °C.

A.4 Conditioning

Before a textile is tested in order to establish a physical or mechanical property, condition it in the standard atmosphere for testing. A textile is conditioned when (after having been pre-conditioned, if necessary), it has reached equilibrium with the standard atmosphere for testing. Provided that there has been a free flow of conditioned air through the textile throughout the entire period of conditioning, consider a textile to be in equilibrium with the atmosphere if the change in mass between successive weighing, carried out at interval of two hours is less than 0.25 %.

Annex B
(normative)

Determination of dimensions

B.1 Width of a textile fabric sample

The width of a textile fabric sample laid on a flat surface is measured with a steel scale.

B.1.1 Apparatus

Steel scale, of a length exceeding the width of the fabric to be measured, and is graduated in centimetres and millimetres

B.1.2 Procedures

B.1.2.1 Lay the test sample flat and full width (without subjecting it to tension) on a plane surface and condition it in that state for at least 24 h in accordance with Annex A.

B.1.2.2 Take, to the nearest 1 mm, five measurements across the overall width or between the innermost selvedge threads (as relevant) of the conditioned test sample at approximately equal intervals throughout its length.

B.1.3 Calculation

Calculate the arithmetic mean of the five measurements and record it as the width of the sample

B.2 Length of a textile fabric sample

B.2.1 Apparatus

B.2.1.1 Marking pen

B.2.1.2 Steel tape, of length greater than the length of the laboratory sample to be measured, and graduated in centimetres and millimetres

B.2.2 Preparation of test specimen

B.2.2.1 Lay the laboratory sample flat and full width (without subjecting it to tension) on a plane surface and condition it in that state for at least 24 h in accordance with Annex A.

B.2.2.2 From the conditioned laboratory sample cut a test specimen across the full width of the laboratory sample along a datum line drawn at right angles to the selvedge and as close as possible to the beginning

and the end of the laboratory sample.

B.2.3 Procedure

Take, to the nearest millimetre, five measurements (B.1.2.2) of the length of the test specimen at approximately equal intervals across its width.

B.2.4 Calculation

Calculate the arithmetic mean of the five measurements and record it as the length, in metres

Annex C
(normative)

Textiles — Mass per unit area of conditioned fabrics

C.1 General

C.1.1 This standard specifies three alternative procedures for determining the mass per unit area of woven fabrics (including those of the stretch type), knitted fabrics, non-woven fabrics, composite fabrics and narrow fabrics, that have been conditioned in the standard atmosphere for testing.

C.1.2 The three procedures apply to:

a) full-width fabrics that are of such a length that they can be conditioned and measured satisfactorily;

b) representative large cuttings that can be measured satisfactorily; or

c) a number of representative specimens cut to a constant area of 0.01 m2

Smaller areas are not considered suitable for testing.

C.1.3 Procedure 3 is not applicable to knitted fabrics and woven stretch-type fabrics.

C.1.4 If so specified in the relevant product specification, or if so agreed upon between the parties concerned, a correction for the non-fibrous material content of the fabric may be made.

C.2 Principle

The mass and the dimensions of a textile fabric specimen, that is without tension and has been conditioned in the standard test atmosphere, is determined and the mass per unit area is calculated.

C.3 Apparatus

C.3.1 Table, with a smooth flat surface and is of a size that exceeds that of the fabric to be measured

C.3.2 Pair of scissors or suitable cutter, capable of cutting a square or circular specimen of area 0.01 m2 to an accuracy of 1 % or better

C.3.3 Metal plate, is 5 mm smaller than the cutter (see C.3.2) and that has a thickness of 10 mm

C.3.4 Balance, capable of determining the mass of the specimen to an accuracy of 0.2 % or, in the case of 0.01 m^2 specimens, to an accuracy of 0.001 g

C.4 Procedure

C.4.1 General

Condition the sample in accordance with Annex A and carry out the test in the same standard atmosphere

NOTE 1 Any of the procedures can be used to determine the mass per unit area of a fabric; however, for the purpose of greater accuracy, the procedure that gives the largest test specimen(s) is preferable.

NOTE 2 In the case of narrow fabrics, a complete roll should be used, but, if this is not possible, the length of the specimen should be at least 5 m.

C.4.2 Procedure 1: Full-width specimen

C.4.2.1 Ensure that the fabric, which should preferably be selected from the middle of a piece, is not less than 0.5 m and not more than 4 m long, and lay it flat, and without tension, on the table. Cut at both ends, across the full width of the sample, along parallel lines at right angles to the selvedge. If the mass per unit area of a selvedge on a full-width piece appears to deviate appreciably from the mass per unit area of the body of the fabric, or if so agreed upon between the parties concerned, trim off the selvedge along the outermost threads of the body of the fabric and use only the body of the fabric for the determination of the mass per unit area. Measure the width and length of the specimen, using Annex B.

C.4.2.2 Use the balance to determine the mass of the specimen.

C.4.3 Procedure 2: for representative large cuttings

C.4.3.1 Ensure that the available cutting is representative of the sample. Trim the cutting into a square or rectangular specimen by cutting along parallel lines at right angles to the warp (length) direction and at right angles to the weft (width) direction.

C.4.3.2 Measure the width and length of the specimen, using Annex B.

C.4.3.3 Determine the mass of the specimen using the balance.

C.4.4 Procedure 3: for several small (0.01 m^2) specimens

NOTE On fabrics with large in-woven designs, which involve local areas of appreciably different mass per unit area, the use of Procedure 1 or Procedure 2 is preferable. If the sample size necessitates the use of Procedure 3, select specimens that contain an integral number of pattern repeats or that are representative of the pattern.

C.4.4.1 Cut at least three square pieces, of side length of approximately 150 mm, from areas of the fabric selected to represent the sample as fully as possible but not within 50 mm of the selvedge.

C.4.4.2 Lay each piece flat, and without tension, on a suitable cutting surface. Place the metal plate (see C.3.2.2) and the cutter (see C.3.3) on each piece in turn and cut out a 0.01 m^2 specimen from each piece, ensuring that no loss of threads occurs.

C.4.4.3 Use the balance to determine the mass of the 0.01 m^2 specimens, and calculate the mean mass.

C.5 Calculation

C.5.1 In the case of Procedure 1 and Procedure 2, calculate the mass per unit area M in grams per square metre, using the following formula:

$$M = \frac{m \times 1000000}{L \times W}$$

where

m is the mass, in grams, of the specimen;

L is the length, in millimetres, of the specimen; and

W is the width, in millimetres, of the specimen.

C.5.2 In the case of Procedure 3, calculate the mass per unit area (M in grams per square metre) by multiplying the mean mass (in grams) by 100.

C.5.3 If the mass per unit area free from non-fibrous material is required, correct the calculated mass per unit area (see C.5.1 and C.5.2) for the non-fibrous material content, determined (on a separate sample) using a suitable method agreed upon between the parties concerned.

C.6 Test report

State the following in the test report:

a) that the test was carried out strictly in accordance with this standard or whether any deviation was introduced;

b)

c) the test result to the nearest g/m^2; and

d) whether the test results indicate the mass per unit area free from non fibrous materials

Annex D
(normative)

Water absorption rate of textile fabrics

D.1 Principle

A prescribed number of textile fabric test specimens are saturated in accordance with a prescribed procedure and the arithmetic mean time for complete saturation of the specimens is recorded.

D.2 Applicability

D.2.1 This method is applicable to all textiles intended for use as towels, dishcloths, cleaning rags, absorbent surgical dressings and for other applications where water absorption is important.

D.2.2 Depending on the intended end use, the textile is either tested in a single layer (towels, dish cloths, cleaning rags, etc.) or in two or more layers (absorbent gauze, swabs, lint, etc.).

D.3 Apparatus

D.3.1 Container that is filled to a depth of approximately 100 mm with deionised water maintained at a temperature of 20 °C ± 2 °C and that has a surface area of adequate size to allow the specimen to float freely

D.3.2 Suitable balance having a sensitivity of 0.1 g

D.3.3 Stop-watch

D.3.4 Forceps

D.3.5 Staining agent, for example Congo-red or methylene blue

D.4 Preparation of test specimens

D.4.1 Condition the test sample in accordance with Annex A.

D.4.2 From each sample select five specimens in such a way that they fully represent the sample, but are taken from areas at least 50 mm away from the edges of the sample. Cut square test specimens each of mass 2 g ± 0.1 g and, when necessary, so lightly fold a specimen that its size does not exceed 100 mm x 100 mm.

D.4.3 Swabs are usually pre-folded. Test them in such a way that several layers of fabric will be exposed to the water.

D.4.4 In the case of gauze, fold the specimens lightly, keeping the different layers in contact with one another to ensure continuous absorption.

D.4.5 In the case of cleaning rags, where specimens usually have different fibre components, cut from increased parts of the specimens equilateral, triangular snippets of side length approximately 50 mm, and disregard the mass of the specimens

D.5 Procedure

D.5.1 By means of the forceps, place a specimen lightly and as flat as possible on the surface of the water, and simultaneously start the stop-watch. As soon as the specimen is completely saturated, stop the watch.

D.5.2 Record the time to the nearest 0.1 s but if the required time exceeds 10 s, record the time to the nearest 1.0 s.

D.5.3 Repeat the test on the remaining test specimens.

D.5.4 If, in the case of bleached or neutral coloured specimens, the saturation point is difficult to observe, add an adequate amount of staining agent to the water.

D.6 Calculation

D.6.1 Calculate, to the nearest 1 s, the arithmetic mean of the five test results.

D.6.2 In the case of cleaning rags, calculate to the nearest 1 s, the mean of the amount of different rags that are present in the sample.

Annex E
(normative)

Non-volatile matter content and ash content of non-volatile matter

E.1 General

This standard specifies a method for the determination of the non-volatile matter content and the ash content of the non-volatile matter.

E.2 Apparatus

E.2.1 Silica or porcelain evaporating dish

E.2.2 Oven, maintained at 110 °C ± 10 °C

E.2. Furnace, maintained at 900 °C ± 10 °C

E.2.4 Dessicator

E.2.5 Water-bath

E.2.6 Scale or weighing balance

E.3 Procedure

E.3.1 Heat the evaporating dish in the furnace (E.2.3) for 15 min.

NOTE If only non-volatile matter is required, heating to 110 °C in the oven will be sufficient.

E.3.2 Cool the desiccator and weigh it to the nearest 10 mg (m_1).

E.3.3 Weigh (see E.2.6), to an accuracy of 10 mg, approximately 4 g of the sample into the evaporating dish. Record the mass of the dish and the polish (m_2).

E.3.4 Heat the evaporating dish on a boiling water-bath (see E.2.5) until most of the volatile matter has evaporated.

E.3.5 Place the evaporating dish in the oven at 110 °C ± 2 °C for 16 h.

E.3.6 Remove the dish, cool it in the desiccator (see E.2.4) and then weigh it.

E.3.7 Reheat the dish in the oven for 2 h periods (weighing it between each 2 h period as in E.3.6) until the last two weighings do not differ by more than 5 mg (m_3).

E.3.8 Reserve the dish for the determination of the ash content (see E.3.9).

E.3.9 Slowly char the non-volatile matter (reserved in terms of E.3.8) over a small flame and then place the dish in the furnace for 15 min

E.3.10 Remove the dish, cool it in the desiccator then weigh it.

E.3.11 Repeat the heating and cooling until the last two masses do not differ by more than 5 mg (m_4).

E.4 Calculation

E.4.1 Calculate the percentage by mass of the non-volatile matter content (NV) of the sample as follows:

$$NV = \frac{m_3 - m_1}{m_3 - m_2} \times 100$$

where

m_1 is the mass, in grams, of the evaporating dish (see E.3.2);

m_2 is the mass, in grams, of the evaporating dish and polish (see E.3.3); and

m_3 is the mass, in grams, of the evaporating dish and non-volatile matter (see E.3.6);

E.4.2 Calculate the percentage by mass of the ash content (A) of non-volatile matter of the sample as follows:

$$A = \frac{m_4 - m_1}{m_3 - m_1} \times 100$$

where

m_1 is the mass, in grams, of the evaporating dish, (see E.3.2);

m_3 is the mass, in grams, of the evaporating dish and the non-volatile matter (see E.3.6); and

m_4 is the mass, in grams, of the evaporating dish and ash (see E.3.10)

Annex F
(normative)

Presence of dyes in absorbent textile fabrics

F.1 Apparatus

F.1.1 Funnel, an open-top cylindrical dropping funnel with a capacity of 400 mL and so positioned that the percolate drips into the Nessler-tube

F.1.2 Nessler-tube, with a capacity of 50 mL

F.2 Reagent

Ethanol, absolute

F.3 Preparation of test specimen

F.3.1 Condition the test sample in accordance with Annex A.

F.3.2 From the conditioned sample prepare a test specimen in the form of a wad with a mass of approximately 10 g. Pack the test specimen tightly into the funnel (see F.1.1).

F.4 Procedure

Slowly pour the ethanol (see F.2) on to the test specimen, and close the tap of the funnel as soon as the level of the percolate has reached the 50 ml mark in the Nessler-tube (see F.1.2).

F.5 Evaluation

Examine the percolate in the Nessler-tube by viewing it downwards against a white background, and deem the textile fabrics to contain a dye if the percolate has a blue or a green tint.

F.6 Test report

Report the following information:

a) all the data needed to identify the sample tested;

b) that the test was carried out in accordance with this standard;

c) any deviation from this standard;

d) the test results, as positive or negative for the presence of dyes.

Annex G
(normative)

G.1 Introduction

The test for sterility is carried out under aseptic conditions. In order to achieve such conditions, the test environment has to be adapted to the way in which the sterility test is performed. The precautions taken to avoid contamination are such that they do not affect any microorganisms that are to be revealed in the test. The working conditions in which the tests are performed are monitored regularly by appropriate sampling of the working area and by carrying out appropriate controls. The following culture media have been found to be suitable for the test for sterility: fluid thioglycollate medium is primarily intended for the culture of anaerobic bacteria; however, it will also detect aerobic bacteria. Soya-bean casein digest medium is suitable for the culture of both fungi and aerobic bacteria.

Media for the test may be prepared as described below or equivalent commercial media may be used provided that they comply with the requirements of the growth promotion test of aerobes, anaerobes, and fungi. The following culture media have been found to be suitable for the test for sterility: fluid thioglycollate medium is primarily intended for the culture of anaerobic bacteria; however, it will also detect aerobic bacteria, soybean-casein digest medium is suitable for the culture of both fungi and aerobic bacteria.

G.2 Fluid thioglycollate medium

L-Cystine	0.5 g
Sodium Chloride	2.5 g
Dextrose Monohydrate/Anhydrous	5.5/5.0 g
Agar	0.75 g
Yeast Extract (water-soluble)	5.0 g
Pancreatic Digest of Casein	15.0 g
Sodium Thioglycollate	0.5 g
or Thioglycolic Acid	0.3 ml
Resazurin Sodium Solution (1 g/L of resazurin sodium), freshly prepared	1.0 ml
Purified Water mL	1000
pH after sterilization	7.1±0.2.

G.2.2 Mix the L-cystine, agar, sodium chloride, glucose, water-soluble yeast extract and pancreatic digest of casein with the water R and heat until solution is effected.

G.2.3 Dissolve the sodium thioglycollate or thioglycollic acid in the solution and, if necessary, add 1 M sodium hydroxide so that, after sterilization, the solution will have a pH of 7.1 ± 0.2. If filtration is necessary, heat the solution again without boiling and filter while hot through moistened filter paper.

G.2.4 Add the resazurin sodium solution, mix and place the medium in suitable vessels which provide a ratio of surface to depth of medium such that not more than the upper half of the medium has undergone a colour change indicative of oxygen uptake at the end of the incubation period. Sterilize using a validated process. If the medium is stored, store at a temperature between 2 °C and 25 °C in a sterile, airtight container.

G.2.5 If more than the upper one-third of the medium has acquired a pink colour, the medium may be restored once by heating the containers in a water-bath or in free-flowing steam until the pink colour disappears and cooling quickly, taking care to prevent the introduction of non-sterile air into the container. Do not use the medium for a longer storage period than has been validated. Fluid thioglycollate medium is to be incubated at 30 °C - 35 °C.

D.2.6 For products containing a mercurial preservative that cannot be tested by the membrane-filtration method, fluid thioglycollate medium incubated at 20 °C - 25 °C may be used instead of soya-bean casein digest medium provided that it has been validated as described in growth promotion test.

G.3 Alternative thioglycollate medium

Where prescribed, justified and authorized, the following alternative thioglycollate medium may be used: prepare a mixture having the same composition as that of the fluid thioglycollate medium, but omitting the agar and the resazurin sodium solution, sterilize as in accordance with G.2. The pH after sterilization is 7.1 ± 0.2. Heat in a water-bath prior to use and incubate at 30 °C - 35 °C under anaerobic conditions.

G.4 Soya-bean casein digest medium

Pancreatic Digest of Casein	17.0 g
Papaic Digest of Soybean Meal	3.0 g
Sodium Chloride	5.0 g
Dibasic Potassium Phosphate	2.5 g
Dextrose Monohydrate/Anhydrous	2.5/2.3 g
Puried Water	1000 ml
pH after sterilization	7.3±0.2.

G.4.1 Dissolve the solids in water R, warming slightly to effect solution. Cool the solution to room temperature. Add 1 M sodium hydroxide, if necessary, so that after sterilization the solution will have a pH of 7.3 ± 0.2.

G.4.2 Filter, if necessary, to clarify, distribute into suitable vessels and sterilize using a validated process. Store at a temperature between 2 °C and 25 °C in a sterile well-closed container, unless it is intended for immediate use. Do not use the medium for a longer storage period than has been validated. Soya-bean casein digest medium is to be incubated at 20 °C - 25 °C.

G. 4.3 The media used shall comply with G.6, carried out before or in parallel with the test on the product to be examined.

G.5 Sterility

Incubate portions of the media for 14 days. No growth of micro-organisms occurs.

G.6 Growth promotion test of aerobes, anaerobes, and fungi

G.6.1 Test each lot of ready-prepared medium and each batch of medium prepared either from dehydrated medium or from ingredients. Suitable strains of microorganisms are indicated in Table G.1.

G.6.2 Inoculate portions of fluid thioglycollate medium with a small number (not more than 100 cfu) of the following microorganisms: using a separate portion of medium for each of the following species of microorganism, *Clostridium sporogenes*, *Pseudomonas aeruginosa*, and *Staphylococcus aureus.* Inoculate portions of alternative thioglycollate medium with a small number (not more than 100 cfu) of *Clostridium sporogenes*.F. Inoculate portions of soy-bean casein.

G.6.3 Digest the medium with a small number (not more than 100 cfu) of the following microorganisms, using a separate portion of medium for each of the following species of microorganism, *Aspergillus brasiliensis*, *Bacillus subtilis,* and *Candida albicans*. Incubate for not more than three days in the case of bacteria and not more than five days in the case of fungi.

G.6.4 Seed lot culture maintenance techniques (seed-lot systems) are used so that the viable microorganisms used for inoculation are not more than five passages removed from the original master seed lot. The media are suitable if a clearly visible growth of the microorganisms occurs.

Table G.1 —Strains of the test microorganisms suitable for use in the growth promotion test

Test microorganisms		
Aerobic bacteria	**Fungi**	**Anaerobic bacterium**
• *Staphylococcus aureus* ATCC 6538, CIP 4.83, NCTC10788, NCIMB 9518, NBRC 13276 • *Bacillus subtilis* ATCC 6633, CIP 52.62, NCIMB 8054, NBRC 3134 • *Pseudomonas aeruginosa*[a] ATCC 9027, NCIMB 8626, CIP 82.118, NBRC 13275	*Candida albicans* ATCC 10231, IP 48.72, NCPF 3179, NBRC 1594	*Clostridium sporogenes*[b] ATCC 19404, CIP 79.3, NCTC 532 or ATCC 11437, NBRC 14293
[a] An alternative microorganism is *Kocuria rhizophila* (*Micrococcus luteus*) ATCC 9341. [b] An alternative to *Clostridium sporogenes*, when a nonspore-forming microorganism is desired, is *Bacteroides vulgatus* (ATCC 8482).		

Bibliography

[1] US 706: 2011, *Non-woven surgical dressings — Specification*

[2] US 2276:2020, Medical cotton swabs- Specification

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