ISBN 978-0-626-40301-0

SANS 1043:2021

Edition 3.1

SOUTH AFRICAN NATIONAL STANDARD

The manufacture of disposable sanitary towels

Amdt 1

WARNING
This document references other documents normatively.

Published by the South African Bureau of Standards
1 Dr Lategan Road Groenkloof ✉ Private Bag X191 Pretoria 0001
Tel: +27 12 428 7911 Fax: +27 12 344 1568
www.sabs.co.za

This page has been left blank intentionally

COPYRIGHT PROTECTED DOCUMENT

SANS 1043:2021
Edition 3.1

Table of changes

Change No.	Date	Scope
Amdt 1	2021	Amended to update the title of the standard, referenced standards, requirements, the table on dimensions of filler components, the table on performance requirements, the clauses on inspection and methods of test, and on packing and marking, and to delete an annex on notes to purchasers.

Foreword

This South African standard was prepared by National Committee SABS/TC 038/SC 03, *Textiles – Medical textiles*, in accordance with procedures of the South African Bureau of Standards, in compliance with annex 3 of the WTO/TBT agreement.

This document was approved for publication in xxxxx 2021.

This document supersedes SANS 1043:2010 (edition 3).

A vertical line in the margin shows where the text has been technically modified by amendment No. 1.

Compliance with this document cannot confer immunity from legal obligations.

Contents

This page is intentionally left blank

The manufacture of disposable sanitary towels

Amdt 1

1 Scope

This standard covers the manufacturing and performance requirements for four types of sanitary towels for external use.

2 Normative references

The following referenced documents are indispensable for the application 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. Information on currently valid national and international standards can be obtained from the South African Bureau of Standards.

2.1 Standards

SANS 70, *Conditioning of textiles and standard temperate atmosphere for determing their physical and mechanical properties.*

SANS 81, *Width of a textile fabric sample.*

SANS 83, *Length of a textile fabric sample.*

SANS 171, *Glassware and equipment for microbiological tests.*

SANS 4833-2/ISO 4833-2, *Microbiology of the food chain – Horizontal method for the enumeration of microorganisms – Part 2: Colony count at 30 degrees C by the surface plating technique.* **Amdt 1**

SANS 5553, *Media and reagents for microbiological tests.*

SANS 6888-2/ISO 6888-2, *Microbiology of the food chain – Horizontal method for the enumeration of coagulase-positive staphylococci (*Staphylococcus aureus *and other species) –Part 2: method using rabbit plasma fribinogen agar medium.*

2.2 Other publications

United States Pharmacopoeia (USP).

3 Definitions

For the purposes of this standard, the following definitions apply.

3.1
acceptable
acceptable to the authority administering this standard, or to the parties concluding the purchase contract, as relevant

3.2
extraneous dust
atmospheric particulate matter that is produced from a source or sources other than any of the components used in the manufacture of sanitary towels

3.3
mechanical pulp
papermaking pulp made entirely by mechanical means from various raw materials but usually from wood

4 Requirements

4.1 General

4.1.1 Sanitary towels shall have been made in accordance with sound manufacturing practice, and shall be of an acceptable uniform make, shape and finish.

4.1.2 All sanitary towels shall be free from lumps, oil spots, streaks of dirt, and similar foreign matter that might affect their appearance or impair their serviceability (or both).

4.1.3 Sanitary towels shall be delivered in a clean and commercially dry condition and shall, when so required, be capable of withstanding sterilization in an autoclave, or shall be individually sterile-packed.

4.2 Construction

4.2.1 Sanitary towels shall be rectangular in shape and shall consist of a filler (which may incorporate a non-absorbent layer) that is completely encased in a cover of a woven gauze or of a non-woven material or of a tubular knitted fabric (with or without a seam). **Amdt 1**

4.2.2 The cover in all sanitary towels shall be so sealed or secured that it cannot unwrap from the filler during normal handling and use.

4.2.3 If a sanitary towel has a non-absorbent face, this face shall be clearly indicated.

4.2.4 Type 1, 2 and 3 sanitary towels shall be with or without loops, with or without wings or shall have adhesive backing strips on the cover, as required. **Amdt 1**

4.2.5 Type 4 sanitary towels shall be with or without loops or with or without wings, as required.

4.2.6 Sanitary towels may be produced with or without a scent, and labelled appropriately. **Amdt 1**

4.3 Dimensions of filler components

The average length and width of the filler components, determined in accordance with 5.3, shall fall within the range of values given in table 1, appropriate to the size designation of sanitary towels. Each size designation (type) may be named appropriately for commercial and retail purposes. The following naming are examples:

a) Type 1 – Thins, Light flow or Small;

b) Type 2 – Regular, Regular flow or Medium;

c) Type 3 – Matermity, Heavy flow or Large; and

d) Type4 – Delivery, Very heavy flow or X(Extra)-Large. **Amdt 1**

Table 1 — Dimensions of filler components

Dimensions in millimetres

1	2	3	4	5
Dimensions	**Size designation**			
	Type 1	**Type 2**	**Type 3**	**Type 4**
Length[a]	180 to 260	180 to 270	230 to 300	270 to 330
Width (of filler) min.	60			
[a] The length of the absorbent component intended to be nearest to the body and excluding any non-absorbent or tissue wrappings.				

Amdt 1

4.4 Sanitary towel filler composition

4.4.1 Sanitary towels shall be of one filler composition given in table 2. **Amdt 1**

4.4.2 When determined in accordance with 5.3.2, the filler composition shall comply with the appropriate requirements given in table 2. **Amdt 1**

4.4.3 No component of the filler shall contain unprocessed waste paper or mechanical pulp.

NOTE The filler may contain absorbent gelling agents.

Table 2 — Designation and filler composition

1	2
Designation	**Filler composition**
COM	A combination of cellulose pulp and cellulose tissue or cotton wool (or both) (or similar material(s))
CP	Cellulose pulp

4.5 Performance requirements

Sanitary towels shall comply with the requirements given in table 3.

Table 3 — Performance requirements

1	2	3
Property	**Requirement**	**Test method subclause**
Absorbency volume (mL) min.		5.4
Type 1	5 mL	
Type 2	10 mL	
Type 3	15 mL	
Type 4	20 mL	
Absorbency rate (s) max.	10 s	5.5
All size designation (type)		

Amdt 1

4.6 Microbiological requirements

Sanitary towels that have not been sterile-packed (see 4.1.3) shall be such that

a) the total viable bacterial count, determined in accordance with 5.6.4.1, does not exceed 1 000 per gram of sanitary towel, and

b) when tested in accordance with 5.6.4.2, 5.6.4.3 and 5.6.4.4, they shall be free from *Enterobacteriaceae, Staphylococcus aureus* and *Pseudomonas aeruginosa*, respectively.

4.7 Sterility

When sanitary towels are sterile-packed, they shall pass the test for sterility given in 5.7. **Amdt 1**

4.8 Autoclavability

When so required, the sanitary towel when tested in accordance with 5.8, sanitary towels shall be able to withstand steam sterilization without showing any appreciable deterioration in handle or appearance. **Amdt 1**

5 Inspection and methods of test

5.1 Inspection

After checking each package in the sample for compliance with the relevant requirements of clause 6, retain enough unopened packages for the microbiological tests, and then visually examine the contents of the remaining packages for compliance with the requirements given in 4.1 and 4.2.

5.2 Test specimens

5.2.1 Physical tests

Condition the test samples in accordance with SANS 70 and then take, at random, sufficient sanitary towels for each of the tests given in 5.3 to 5.5 (inclusive) and, when relevant, 5.8.

5.2.2 Microbiological tests

From the packages retained in terms of 5.1, aseptically draw, at random, sufficient sanitary towels for the tests given in 5.6 and, when relevant, 5.7.

5.3 Filler

5.3.1 Dimensions of filler components

5.3.1.1 Remove the cover from the sanitary towel under test.

5.3.1.2 Measure the width of the filler and the length of the appropriate absorbent component in accordance with SANS 81 and SANS 83, respectively, but take only one measurement in each direction (see table 1).

5.3.1.3 Record as the average length and average width the arithmetic mean of the corresponding results on at least 10 sanitary towels.

5.3.1.4 Check for compliance with 4.3.

5.3.2 Filler composition

5.3.2.1 Determine the composition of the filler by microscopical examination and chemical analysis.

5.3.2.2 Check for compliance with 4.4.

5.4 Absorbency volume

5.4.1 Test solution

Dissolve 2 g of colour stain in 1 L of water at an acceptable room temperature. **Amdt 1**

5.4.2 Apparatus

5.4.2.1 Electrodes

The following electrodes made from woven copper wire gauze of aperture size approximately (2 × 2) mm, with each electrode having all cut edges so soldered as to cover the ends of the wires and with, soldered to an edge or corner, an insulated single-core conductor that has a jack plug connection at the free end:

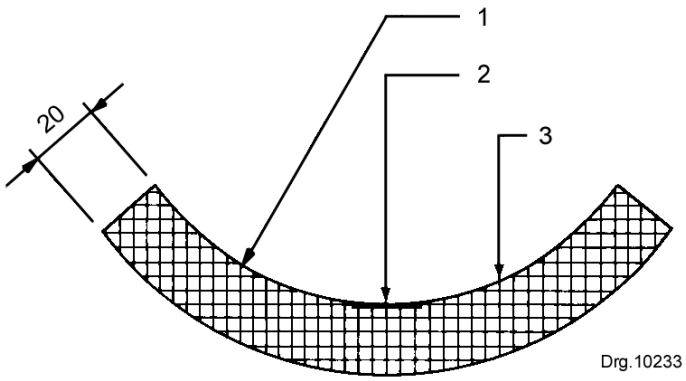
a) **electrode A**, of size (60 × 50) mm and with, cut from the centre, a square aperture with sides of length approximately 25 mm;

b) **electrodes B1 and B2**, each of size (90 × 30) mm;

c) **electrode C**, of size (100 × 50) mm; and

d) **electrodes D1 and D2**, each of the shape and dimensions given in figure 1 and with, at the centre of the upper edge, a tag of size (20 × 15) mm that is perpendicular to the 20 mm wide surface of the electrode.

Dimensions in millimetres



Key

1 R 50
2 tag
3 length of arc: 60

Figure 1 — Electrodes D1 and D2

5.4.2.2 Cylinder

5.4.2.2.1 A hollow open-ended cylinder of a clear plastics material, with a nominal external diameter of 100 mm, a length of at least 120 mm, and two diametrically opposite holes, each of diameter approximately 20 mm, at the midpoint of the length of the cylinder.

5.4.2.2.2 Electrode A is so attached to the cylinder that the square aperture is centred over one of the holes and the longer sides are parallel to the circumference of the cylinder.

5.4.2.2.3 Electrodes B1 and B2 are also attached to the cylinder, each one 10 mm away from each end of the electrode A and with the longer sides parallel to the longitudinal axis of the cylinder.

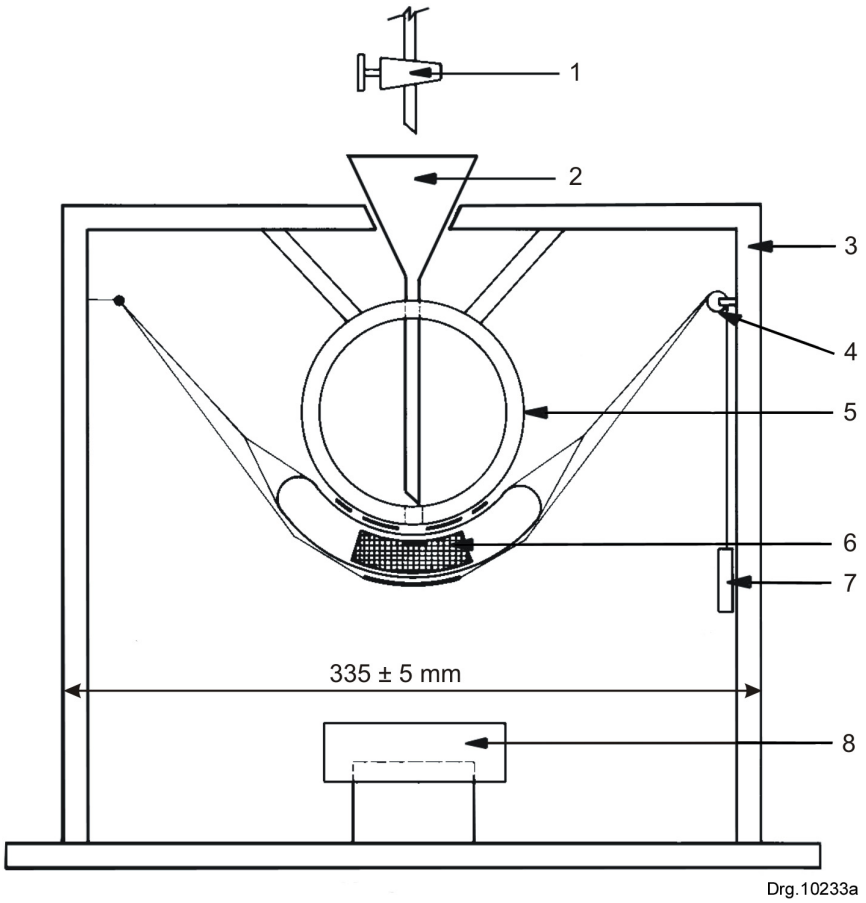
5.4.2.2.4 The cylinder is permanently mounted (see figure 2) in a suitable frame (see 5.4.2.5) with the holes in vertical alignment and the hole that is surrounded by electrode A at the bottom.

5.4.2.3 Funnel

A small glass funnel with a stem of length at least 100 mm and an internal bore of approximately 4 mm, and so suspended through the upper hole in the cylinder that the end of the stem just reaches the lower hole.

5.4.2.4 Reservoir

A suitable reservoir (preferably of the constant-head type) mounted above the funnel, containing the test solution (see 5.4.1), and equipped with a tap or other suitable means for controlling the outflow of the solution into the funnel at a rate of (10 ± 0,1) mL/min.



Key

1 Tap or other suitable means
2 Glass funnel
3 Frame
4 Pulley
5 Hollow open-ended cylinder
6 Electrodes
7 Mass piece
8 Mirror

Figure 2 — Test rig

5.4.2.5 Supporting frame

The frame is equipped with

a) a means for wrapping the sanitary towel under test around the underside of the cylinder (with the sanitary towel centred below the lower hole) by attaching one end of the sanitary towel to a suitable anchor that is fixed to the side of the frame at a level not below the upper surface of the cylinder, and the other end of the sanitary towel to a cord that passes over a pulley that is secured to the other side of the frame (at the same level as the anchor), and that carries a masspiece of approximately 250 g to apply tension to the sanitary towel;

b) a means, similar to that described in 5.4.2.5(a), for holding the ends of electrode C so that its midpoint is in vertical alignment with the lower hole in the cylinder, its upper surface is in full contact with the lower surface of the sanitary towel under test, and that it is under the same tension as the sanitary towel;

c) a means for holding each of electrodes D1 and D2 against each edge of the sanitary towel under test and centred on its transverse centre-line; and

d) a mirror, so positioned and fixed to the base of the frame below the lower hole of the cylinder as to reflect the lower surface of the sanitary towel under test.

5.4.2.6 Relay box

A suitable electrical relay box with a built-in transformer and rectifier (for reducing voltage to 1 mV DC), that is connected to a mains supply, and that has six interconnected jack plug sockets to accommodate the connections from the electrodes, and is such that an electrical circuit made between any two of the electrodes by means of electrical conductance through the test solution, is registered by a suitable signal lamp connected to each socket.

5.4.2.7 Balance

A balance with a sensitivity of at least 0,1 g.

5.4.3 Procedure

5.4.3.1 Fill the reservoir with the test solution, weigh the sanitary towel under test to the nearest 0,1 g, and secure and tension it as described in 5.4.2.5(a).

5.4.3.2 Secure and tension electrode C as described in 5.4.2.5(b), and position electrodes D1 and D2 (with the horizontal tags away from the sanitary towel) as described in 5.4.2.5(c).

5.4.3.3 Connect the jack plug from each electrode to the corresponding socket of the relay box and switch on the mains supply.

5.4.3.4 Run the test solution through the funnel at a rate of (10 ± 0,1) mL/min until a signal lamp indicates that an electrical circuit has been made between two of the electrodes.

5.4.3.5 Close the tap from the reservoir, disconnect the mains supply to the electrodes, remove the sanitary towel and, using the dye in the test solution as an indicator, check the correct functioning of the electrode.

5.4.3.6 Reweigh the sanitary towel.

5.4.3.7 Repeat the test on at least a further nine sanitary towels.

NOTE It is essential to ensure that all electrodes are always kept free from non-conductive matter.

5.4.4 Calculation

5.4.4.1 Calculate the mean gain in mass (in grams) of the sanitary towels tested and report this as the absorbency volume, in millilitres, of the sanitary towels.

5.4.4.2 Check for compliance with 4.5.

5.5 Absorbency rate

5.5.1 Apparatus

5.5.1.1 Waterbath, of depth at least 100 mm and maintained at a temperature of (30 ± 1) °C.

5.5.1.2 Stopwatch.

5.5.1.3 Forceps.

5.5.2 Preparation of test specimens

5.5.2.1 From each of at least 10 sanitary towels, carefully remove and discard the cover on the side of the sanitary towel that is not intended to be in contact with the body, the loops (when relevant) and any non-absorbent layer(s) or layer(s) that do not contribute to the absorbency of the sanitary towel.

5.5.2.2 Cut a test specimen of area 42 cm^2 from across the full width of the remaining filler in each sanitary towel and staple or tack the specimen at each corner.

5.5.3 Procedure

5.5.3.1 By means of the forceps, place a specimen lightly on the surface of the water, ensuring that the side of the sanitary towel that is intended to be in contact with the body is in full contact with the water surface and start the stopwatch simultaneously.

5.5.3.2 As soon as the specimen sinks below the surface of the water, stop the stopwatch and record the absorption period to the nearest 0,1 s.

5.5.3.3 Repeat the test on each of the remaining test specimens.

5.5.4 Calculation

5.5.4.1 Calculate the arithmetic mean of the absorbency rate of the fillers tested.

5.5.4.2 Check for compliance with 4.5.

5.6 Microbiological examination

5.6.1 Apparatus and equipment

Use apparatus and equipment that comply with the relevant requirements of SANS 171.

5.6.2 Media and reagents

5.6.2.1 General

Ensure compliance with the general requirements for the ingredients and for the preparation of media and reagents given in SANS 5553.

5.6.2.2 Bacteriological peptone

5.6.2.2.1 Ingredients

Peptone: .....10 g
Disodium hydrogen phosphate dodecahydrate
($Na_2HPO_4 \cdot 12H_2O$): ..... 9 g
Sodium chloride: ..... 5 g
Monobasic potassium phosphate (KH_2PO_4): .....1,5 g

5.6.2.2.2 Preparation

Prepare the bacteriological peptone medium as follows:

a) Dissolve the ingredients in distilled water and make up to 1 L with water.

b) Adjust the pH value so that it will be 7,0 ± 0,1 after sterilization.

c) Dispense 300 mL volumes into flasks of 500 mL capacity and sterilize by autoclaving at (121 ± 2) °C for 20 min.

5.6.2.3 Plate count agar

5.6.2.3.1 Ingredients

Agar: .....15 g
Glucose: ..... 1 g
Tryptone: ..... 5 g
Yeast extract: .....2,5 g

5.6.2.3.2 Preparation

Prepare the plate count agar medium as follows:

a) Dissolve the ingredients in distilled water and make up to 1 L with water.

b) Adjust the pH value to 7,2.

c) Dispense 15 mL volumes into bottles and sterilize by autoclaving at (121 ± 2) °C for 20 min.

5.6.2.4 Neutral red-bile salt peptone glucose medium

5.6.2.4.1 Ingredients

Peptone: .....20 g
Glucose: .....10 g
Bile salts No. 3: .....1,5 g
Sodium chloride: .....5 g
Neutral red: .....0,03 g
Crystal violet: ..... 0,002 g

5.6.2.4.2 Preparation

Prepare the neutral red-bile salt peptone glucose medium as follows:

a) Dissolve the ingredients in 400 mL of distilled water and make up to 500 mL with water, boiling to aid solution.

b) Adjust the pH value to 7,4, and filter to obtain a clear solution.

c) Dispense 10 mL volumes into bottles each containing a Durham tube and sterilize by autoclaving at (121 ± 2) °C for 20 min.

5.6.2.5 Fluid soybean-casein digest medium

5.6.2.5.1 Ingredients

Pancreatic digest of casein: .....17 g
Papaic digest of soybean meal: .....3 g
Sodium chloride: .....5 g
Dibasic potassium phosphate (K_2HPO_4): .....2,5 g
Dextrose: .....2,5 g

5.6.2.5.2 Preparation

Prepare the fluid soybean-casein digest medium as follows:

a) Dissolve the ingredients in distilled water, warming slightly to aid solution, and make up to 1 L with water.

b) Cool the solution to room temperature.

c) Adjust the pH value so that it will be 7,3 ± 0,2 after sterilization, and filter to obtain a clear solution, if necessary.

d) Dispense into suitable containers and sterilize by autoclaving at (121 ± 2) °C for 20 min.

5.6.2.6 Cetrimide agar medium

5.6.2.6.1 Ingredients

Pancreatic digest of gelatin: .....20 g
Magnesium chloride: .....1,4 g
Potassium sulfate (K_2SO_4): .....10 g
Agar: .....13,6 g
Cetyl trimethylammonium bromide
(Cetrimide): .....0,3 g
Glycerin: ..... 10 mL

5.6.2.6.2 Preparation

Prepare the Cetrimide agar medium as follows:

a) Dissolve all the solid ingredients in distilled water, make up to 1 L with water, and then add the glycerin.

b) Heat, agitating frequently, and boil for 1 min.

c) Adjust the pH value so that it will be 7,2 ± 0,2 after sterilization.

d) Dispense into suitable containers and sterilize by autoclaving at (121 ± 2) °C for 20 min.

5.6.2.7 Pseudomonas agar medium for the detection of fluorescein

5.6.2.7.1 Ingredients

Pancreatic digest of casein: .....10 g
Peptic digest of animal tissue: .....10 g
Dibasic potassium phosphate (K_2HPO_4): .....1,5 g
Magnesium sulfate ($MgSO_4 \cdot 7H_20$): .....1,5 g
Glycerin: ..... 10 mL
Agar: .....15 g

5.6.2.7.2 Preparation

Prepare the Pseudomonas agar medium for the detection of fluorescein as follows:

a) Dissolve all the solid ingredients in distilled water, make up to 1 L with water, and then add the glycerin.

b) Heat, agitating frequently, and boil for 1 min.

c) Adjust the pH value so that it will be 7,2 ± 0,2 after sterilization.

d) Dispense into suitable containers and sterilize by autoclaving at (121 ± 2) °C for 20 min.

5.6.2.8 Pseudomonas agar medium for the detection of pyocyanin

5.6.2.8.1 Ingredients

Pancreatic digest of gelatin: .....20 g
Anhydrous magnesium chloride: .....1,4 g
Potassium sulfate (K_2SO_4): .....10 g
Agar: .....15 g
Glycerin: ..... 10 mL

5.6.2.8.2 Preparation

Prepare the Pseudomonas agar medium for the detection of pyocyanin as follows:

a) Dissolve all the solid ingredients in distilled water, make up to 1 L with water, and then add the glycerin.

b) Heat, agitating frequently, and boil for 1 min.

c) Adjust the pH value so that it will be 7,2 ± 0,2 after sterilization.

d) Dispense into suitable containers and sterilize by autoclaving at (121 ± 2) °C for 20 min.

5.6.3 Preparation of test suspension

5.6.3.1 Transfer 300 mL of the sterile solution of bacteriological peptone (see 5.6.2.2) to a sterile wide-mouthed jar of capacity not less than 1 L and not more than 2 L, with a mouth of diameter not less than 150 mm and not more than 250 mm, and that is fitted with a hermetically closing glass or metal-and-glass lid.

5.6.3.2 Aseptically determine the mass of the sanitary towel under test to the nearest 0,1 g, place the sanitary towel in the solution in the jar, fit the lid, agitate the contents of the jar for 2 min and then allow the jar to stand for 10 min.

5.6.3.3 Repeat this agitating and standing procedure twice more.

5.6.3.4 Aseptically remove about 100 mL of the test suspension for testing in accordance with 5.6.4.

5.6.4 Procedure

5.6.4.1 Total viable bacterial count

5.6.4.1.1 Aseptically pipette a 1 mL portion of the test suspension into each of three sterile Petri dishes.

5.6.4.1.2 Add 15 mL of freshly melted plate count agar (see 5.6.2.3) that has been cooled to 45 °C to each dish, and mix well.

5.6.4.1.3 Incubate, count and calculate the total count as described in SANS 4833-2. **Amdt 1**

5.6.4.1.4 From the total viable bacterial count and the mass of the sanitary towel (see 5.6.3.2), calculate the total viable bacterial count per gram of sanitary towel.

5.6.4.1.5 Check for compliance with 4.6(a).

5.6.4.2 Examination for the presence of *Enterobacteriaceae*

5.6.4.2.1 Aseptically add 10 mL of the test suspension to a bottle that contains neutral red-bile salt peptone glucose medium (see 5.6.2.4).

5.6.4.2.2 Incubate the bottle for (24 to 36) h at (37 ± 0,5) °C and examine for the presence of *Enterobacteriaceae* as evidenced by the formation of acid and gas.

5.6.4.2.3 Check for compliance with 4.6(b).

5.6.4.3 Examination for the presence of *Staphylococcus aureus*

5.6.4.3.1 Use the media, reagents and procedure in accordance with SANS 6888-2 to examine the test suspension (see 5.6.3).

5.6.4.3.2 Pipette 0,1 mL of a 1:1 000 dilution of an (18 to 24) h culture of *Staphylococcus aureus* medium as a control, and proceed as with the test suspension.

5.6.4.3.3 Check for compliance with 4.6(b).

5.6.4.4 Examination for the presence of *Pseudomonas aeruginosa*

5.6.4.4.1 Aseptically pipette 10 mL of the test suspension into 90 mL of fluid soybean-casein digest medium (see 5.6.2.5) and mix well.

5.6.4.4.2 Incubate for 24 h at (30 to 35) °C.

5.6.4.4.3 By means of an inoculating loop, transfer a portion from the 24 h incubated sample tube of fluid soybean-casein digest medium to the dry surface of Petri dishes each containing approximately 20 mL of Cetrimide agar medium (see 5.6.2.6).

5.6.4.4.4 Incubate at (30 to 35) °C and examine, after 24 h and again after 48 h incubation, for suspect colonies, bearing in mind that in general, greenish fluorescent colonies are typical of *Pseudomonas aeruginosa* and that, in its presence, a gram stain examined microscopically will reveal gram-negative slender rod-shaped cells.

5.6.4.4.5 Add 0,1 mL of a 1:1 000 dilution of an (18 to 24) h culture of *Pseudomonas aeruginosa* to 100 mL of fluid soybean-casein digest medium (see 5.6.2.5) as a control, and proceed as with the test suspension.

5.6.4.4.6 If none of the colonies obtained from the test suspension conform to the description given in 5.6.4.4.4 and the control culture has been satisfactorily recovered, deem the test sample to be free from *Pseudomonas aeruginosa*.

5.6.4.4.7 If colonies conforming to the description given in 5.6.4.4.4 are found, so streak representative suspect colonies from the Cetrimide agar onto the surfaces of Pseudomonas agar medium for the detection of fluorescein (see 5.6.2.7) and Pseudomonas agar medium for the detection of pyocyanin (see 5.6.2.8) to obtain isolated colonies.

5.6.4.4.8 Cover and invert the Petri dishes and incubate at (30 to 35) °C for at least 3 d.

5.6.4.4.9 Examine the streaked surfaces under ultraviolet light for suspect colonies in accordance with table 4.

5.6.4.4.10 If any further doubt exists as to the identity of the colonies, obtain final confirmation by inoculating the suspect colonies to the wells on commercially available diagnostic kits in accordance with the manufacturer's instructions.

5.6.4.4.11 Check for compliance with 4.6(b).

Table 4 — Description of colonies

1	2
Medium	**Description of colonies**
Pseudomonas agar for the detection of fluorescein	Generally colourless to yellowish. Yellowish fluorescence in ultra-violet light.
Pseudomonas agar for the detection of pyocyanin	Generally greenish. Blue fluorescence in ultraviolet light.

5.7 Sterility

5.7.1 Use the method "Sterility tests" given in the USP.

5.7.2 Check for compliance with 4.7.

5.8 Autoclavability

5.8.1 Steam sterilize at least three test specimens at a temperature of 134 ºC for a period of 3 min.

5.8.2 Condition the test specimens in accordance with SANS 70, then visually and physically examine the specimens for signs of deterioration and compare with untreated specimens.

5.8.3 Examples of deterioration include:

– harshness of handle;

– lumpiness;

– linting of cover;

– shrinkage;

– melting of adhesive backing strips;

– brittleness or hardness of strike-through barrier; and

– tackiness of any adhesive.

5.8.4 When there is appreciable deterioration in handle or appearance, reject the test specimen.

5.8.5 If there is any doubt as to the degree of deterioration (for example, slight deterioration), conduct performance tests in accordance with 5.3, 5.4 and 5.5. Accept the test specimens if they pass, but reject the specimens is they fail any of the performance tests.

6 Packing and marking

6.1 Packing

6.1.1 Sanitary towels shall be sterile-packed in suitable packages or, when so required, shall be individually sterile-packed. **Amdt 1**

6.1.2 The packages shall be packed in bulk containers that will protect the contents from damage and contamination during normal handling, transportation and storage.

6.1.3 Only packages bearing the same date of manufacture (or other batch identification) and containing sanitary towels of the same construction, size designation, and type shall be packed together in a bulk container.

6.2 Marking

6.2.1 Packages

The following information shall appear in legible and indelible marking on the outside of each package in at least English:

a) the trading name (trademark) or the name of the manufacturer (both if not the same organization); **Amdt 1**

b) the words "Sanitary towels";

c) the size designation (type) and filler composition ; **Amdt 1**

d) the description e.g. whether with or without loops, with or without wings, with adhesive backing strips, scented or scent free; **Amdt 1**

e) the number of sanitary towels in the package; **Amdt 1**

f) the date of manufacture or other suitable batch identification; and **Amdt 1**

g) the words "Sterile packed" or “Individually sterile packed”. **Amdt 1**

6.2.2 Bulk containers

The following information shall appear in legible and indelible marking on the outside of each bulk container:

a) the information required in 6.2.1(a) to 6.2.1(g); **Amdt 1**

b) the words “sterile packed” or "individually sterile-packed"; and **Amdt 1**

c) the quantity of packages.

6.2.3 Additional marking

When so required, packages or bulk containers (or both) shall bear information additional to that specified in 6.2.1 and 6.2.2.

Annex A

Deleted by amendment No. 1.

Annex B
(informative)

Quality verification of sanitary towels

When a purchaser requires ongoing verification of the quality of sanitary towels, it is suggested that, instead of concentrating solely on evaluation of the final product, he also direct his attention to the manufacturer's quality system. In this connection it should be noted that SANS 9001 and SANS 13485 cover the provisions of an integrated quality system.

Bibliography

SANS 9001/ISO 9001, *Quality management systems – Requirements.*

SANS 13485/ISO 13485, *Medical devices – Quality management systems – Requirements for regulatory purposes.*