SABS

DRAFT SOUTH AFRICAN STANDARD (DSS): PUBLIC ENQUIRY STAGE	
Document number: SANS 1812ED1_TC038_SC03	
Reference: SANS 1812ED1_TC038_SC03_DSS	
Date of circulation: 25 July 2019	**Closing date 25 September 2019**

Number, edition and title: SANS 1812ED1; The manufacture of washable, reusable sanitary towels

Remarks: NONE

PLEASE NOTE:

- **The technical committee, SABS TC038-SC03 responsible for the preparation of this standard has reached consensus that the attached document should become a South African standard. It is now made available by way of public enquiry to all interested and affected parties for public comment, and to the technical committee members for record purposes. Any comments should be sent by the indicated closing date, either by mail, or by fax, or by e-mail to**

SABS Standards Division
Attention: Compliance and Development department
Private Bag X191
Pretoria
0001

Fax No.: (012) 344-1568 (for attention: dsscomments)
E-mail: dsscomments@sabs.co.za

Please use the SABS Commenting template to submit comments. The hyperlink to commenting template on the SABS website for external users is:

https://isolutions.iso.org/ecom/public/sabs/Livelink?func=ll&objId=2484944&objAction=browse&viewType=1

Any comment on the draft must contain the number of the clause/sub clause to which it refers. A comment shall be well motivated and, where applicable, contain the proposed amended text.

- **The public enquiry stage will be repeated if the technical committee agrees to significant technical changes to the document as a result of public comment. Less urgent technical comments will be considered at the time of the next amendment.**

ISBN 978-0-626-

SANS 1812:2019

Edition 1

SOUTH AFRICAN NATIONAL STANDARD

The manufacture of washable, reusable sanitary towels

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

SABS – Standards Division

The objective of the SABS Standards Division is to develop, promote and maintain South African National Standards. This objective is incorporated in the Standards Act, 2008 (Act No. 8 of 2008).

The SABS continuously strives to improve the quality of its products and services and would therefore be grateful if anyone finding an inaccuracy or ambiguity while using this standard would inform the secretary of the technical committee responsible, the identity of which can be found in the foreword.

Buying Standards

Contact the Sales Office for South African and international standards, which are available in both electronic and hard copy format. Tel: +27 (0) 12 428 6883 email: sales@sabs.co.za

South African National Standards are also available online from the SABS Webstore www.store.sabs.co.za

Information on Standards

SABS Customer Services provide comprehensive standards-related information on national, regional and international standards. Tel: +27 (0) 12 428 7911 / 0861 27 7227 email: info@sabs.co.za

SANS 1812:2019
Edition 1

Table of changes

Change No.	Date	Scope

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 xxxx 2019.

Annex A forms an integral part of this document. Annex B is for information only.

Compliance with this document cannot confer immunity from legal obligations.

Contents

This page is intentionally left blank

The manufacture of washable, reusable sanitary towels

1 Scope

1.1 This standard covers the requirements and test methods for washable, reusable sanitary towels for external use.

1.2 This standard does not apply to disposable sanitary towels.

2 Normative references

The following referenced documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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.

ISO 14362-1, *Textiles – Methods for determination of certain aromatic amines derived from azo colorants – Part 1: Detection of the use of certain azo colorants accessible with and without extracting the fibres*.

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

SANS 105-C10/ISO 105-C10, *Textiles – Tests for colour fastness – Part C10: Colour fastness to washing with soap or soap and soda.*

SANS 105-X12/ISO 105-X12, *Textiles – Tests for colour fastness – Part X12: Colour fastness to rubbing.*

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

SANS 2859-1/ISO 2859-1, *Sampling procedures for inspections by attributes – Part 1: Sampling schemes induced by acceptance quality limit (AQL) for lot-by-lot inspection.*

SANS 3071/ISO 3071, *Textiles – Determination of pH of aqueous extract.*

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.*

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

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

3 Definitions

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

3.1
absorbency
quantity of fluid in millimetres that a sanitary towel can withhold for a specified period of time

3.2
acceptable
acceptable to the authority administering this standard, or to the parties concluding the purchase contract, as relevant

3.3
competent person
someone who has sufficient training and relevant experience or knowledge and other qualities that allow them to carryout a function and/or assist others properly

3.4
good manufacturing practice
concept that ensures products are consistently produced and controlled according to quality standards

3.5
odour
distinctive smell, especially an unpleasant one

3.6
package
small unit set of sanitary pads as declared by the manufacturer

3.7
reusable sanitary towel
washable sanitary towels with a porous upper layer, absorbent layer and a waterproof protective barrier that delays or prevents potential leakage and may be used again by the same person after washing, rinsing and drying

3.8
sanitary towel
feminine hygienic product made of fabric intended to absorb menstrual flow, daily vaginal discharge and post-delivery flow

4 Requirements

4.1 General

4.1.1 Sanitary towels shall be of acceptable quality and shall have been made in accordance with good manufacturing practice.

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 (free from dirt, foreign or extraneous matter; unsoiled and unstained) and commercially dry (free from moisture and not wet) condition.

4.1.4 Sanitary towels shall be odour free, both when dry or wet.

4.1.5 Chemicals shall not be added to the production of washable, reusable sanitary towels.

4.2 Construction

4.2.1 Sanitary towels shall be of an appropriate shape that is designed for comfort (with or without wings) and shall consist of an absorbent filler that is completely encased in a upper layer cover and protective barrier.

4.2.2 The upper layer cover and the protective barrier shall be so sealed or secured that it cannot unwrap from the filler during normal handling and use.

4.3 Materials

4.3.1 General

The materials shall not cause any harm (skin rashes and/or irritations) to the skin in contact as specified in annex A.

4.3.2 Colour

The colour dye of the materials shall be colourfast to washing when tested in accordance with SANS 105-C10 with a grey-scale rating of 4 and colourfast to rubbing when tested in accordance with SANS 105-X12 with a grey-scale rating of 4 when dry and 3-4 when wet. Banned, harmful and toxic dyes shall not be used. When required, banned aromatic amines used in dyes shall be determined when tested in accordance to ISO 14362-1.

NOTE Manufacturers should refrain from using dark colours for example, black, grey, blue and shades of red for the upper layer (the layer which contacts the skin).

4.3.3 Upper layer cover (the layer which contacts the skin)

The covering of the absorbent filler shall comply with 4.1 and 4.3.1. When visually inspected, the material used for the upper layer shall have an even and regular surface that is free from loose fibres, perceptible projections, lumps and indentations.

4.3.4 Absorbent filler

Absorbent filler shall comply with 4.1. Absorbency requirements of a finished product shall comply with the reguirements in table 1.

4.3.5 Protective barrier

Protective barrier shall comply with 4.1 and 4.3.1 and be such that it delays or prevents potential leakage from the absorbent layer of the sanitary towel into the underwear.

4.3.6 Fastening mechanism

Fastening device shall comply with 4.1. The mechanism shall be fitted such that it does not cause any chafing during use. Metal mechanisms shall be nickel free and anti-corrosive (rust free).

Table 1 — Absorbency requirements

1		2	3
Property		**Requirement**	**Test method subclause**
Absorbency volume mL			5.3
Types and sizes	Light flow: Small	5 min.	
	Regular flow: Medium	10 min.	
	Heavy flow: Large	15 min.	
	Very heavy flow: X-Large	20 min.	
Absorbency rate (s)		10 max.	5.4
All types and sizes			

4.4 pH

Reusable sanitary towels shall be free from acids and alkali and the pH of aqueous extract of the absorbent material shall be from pH 6 to pH 8 when tested in accordance with 5.5.

4.5 Microbiological requirements

Sanitary towels 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.

4.6 Size

Finished sizes indicated in table 2 are for guidance only and shall comply with the relevant absorbency requirements given in table 1.

4.7 Durability

Durability shall be determined by the number of times the sanitary towel can be washed without causing any defects to the products visual appearance and performance requirements as detailed in annex A.

Table 2 — Dimensions of sanitary towel

Dimensions in millimetres

1	2	3	4	5
Dimensions	**Size designation**			
	Light flow: Small	**Regular flow: Medium**	**Heavy flow: Large**	**Very heavy flow: X-large**
Length[a]	180 to 260	180 to 270	230 to 300	270 to 330
Width[a]	60 to 80	60 to 90	60 to 100	90 to 110
[a] Length and width of sanitary towel refers to the dimension of absorbent core.				

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 pH and 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 and 5.4.

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 5.5 and 5.6.

5.3 Absorbency volume

5.3.1 Test solution

Dissolve 2 g of Masson's light green stain in 1 L of water at ambient temperature.

5.3.2 Apparatus

5.3.2.1 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:

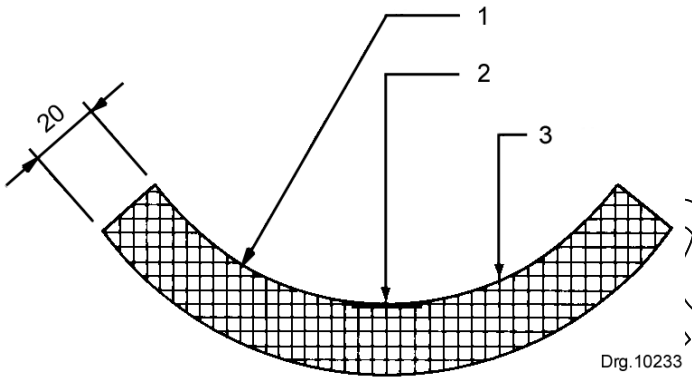
a) **electrode A**, of size (60 × 50) mm and with, cut from the centre, a square aperture with sides of length approximately 25 mm;

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 mm

Figure 1 — Electrodes D1 and D2

5.3.2.2 Cylinder

5.3.2.2.1 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.

5.3.2.2.2 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.

5.3.2.2.3 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.

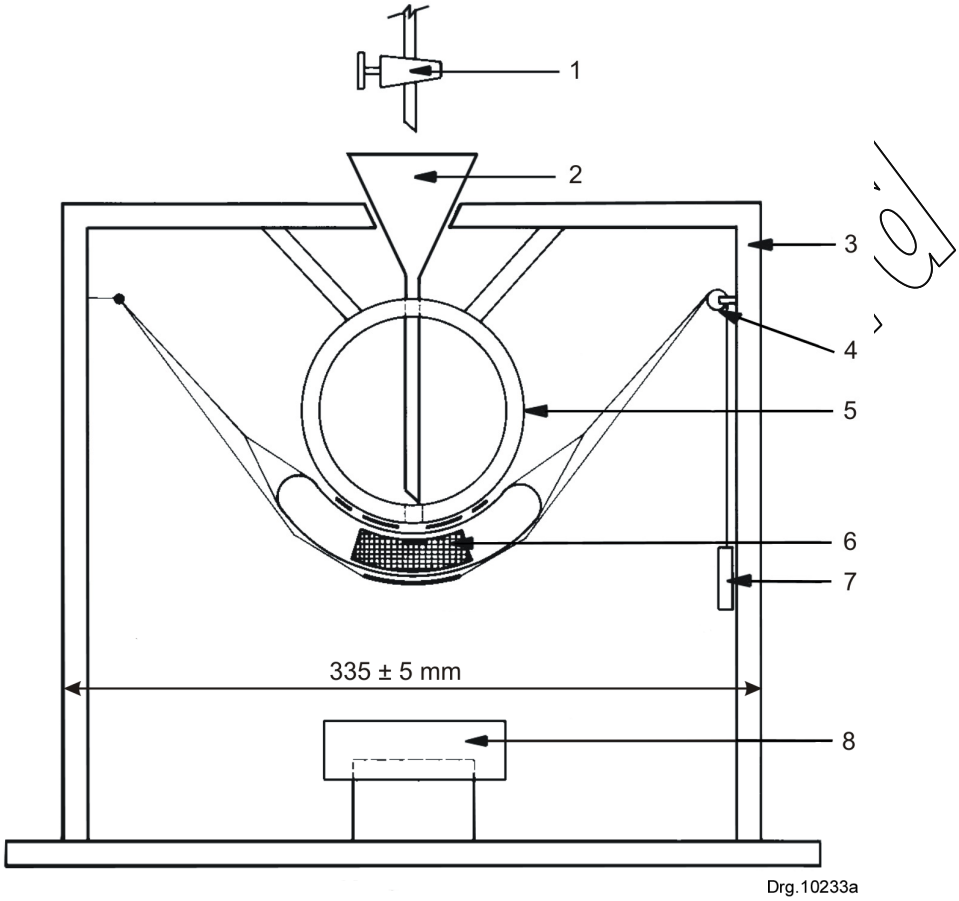
5.3.2.2.4 The cylinder is permanently mounted (see figure 2) in a suitable frame (see 5.3.2.5) with the holes in vertical alignment and the hole that is surrounded by electrode A at the bottom.

5.3.2.3 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.

5.3.2.4 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 of controlling flow
2 Glass funnel
3 Frame
4 Pulley
5 Hollow open-ended cylinder
6 Electrodes
7 Mass piece
8 Mirror

Figure 2 — Test rig

5.3.2.5 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 mass piece of approximately 250 g to apply tension to the sanitary towel;

b) a means, similar to that described in 5.3.2.5(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.

5.3.2.6 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.

5.3.2.7 Balance

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

5.3.3 Procedure

5.3.3.1 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 5.3.2.5(a).

5.3.3.2 Secure and tension electrode C as described in 5.3.2.5(b), and position electrodes D1 and D2 (with the horizontal tags away from the sanitary towel) as described in 5.3.2.5(c).

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

5.3.3.4 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.

5.3.3.5 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.

5.3.3.6 Reweigh the sanitary towel.

5.3.3.7 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.

5.3.4 Calculation

5.3.4.1 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.

5.3.4.2 Check for compliance with 4.5.

5.4 Absorbency rate

5.4.1 Apparatus

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

5.4.1.2 Stopwatch.

5.4.1.3 Forceps.

5.4.2 Preparation of test specimens

5.4.2.1 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.

5.4.2.2 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.

5.4.3 Procedure

5.4.3.1 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.

5.4.3.2 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.

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

5.4.4 Calculation

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

5.4.4.2 Check for compliance with 4.5.

5.5 pH

Use test method SANS 3071.

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.

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 4.5(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 4.5(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 4.5(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 3.

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 4.5(b).

Table 3 — 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.

6 Work environment and contamination control

6.1 Work environment

6.1.1 Sanitary towels shall be manufactured under hygienic conditions. The organization shall document the requirements for the work environment needed to achieve conformity to product requirements.

6.1.2 If the conditions for the work environment can have an adverse effect on product quality, the organization shall document the requirements for the environment and the procedures to monitor and control work environment guideline reference to standards

6.1.3 The organization shall:

a) document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect the microbiological and sterility of the product; and

b) ensure that all personnel who are required to work within the environmental conditions set out by the organization and are competent or supervised by competent person.

6.2 Contamination control

As appropriate, the organization shall plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product.

7 Packaging and marking

Sanitary towels shall be packed and stored under hygienic conditions.

7.1 Packaging

7.1.1 Sanitary towels shall be supplied in suitable packages or, when so required, shall be individually hygienically-packed.

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

7.2 Marking

7.2.1 Packages

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

a) the trade name or trademark of the manufacturer (or both);

b) the words "Washable, reusable sanitary towels";

c) the date of packaging

d) the number of sanitary towels in the package;

e) country of manufacture;

f) user and care instructions (see annex A); and

g) warning statement (see annex A).

7.2.2 Bulk containers

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

a) the information required in 7.2.1(a) to 7.2.1(c) and 7.2 1(e); and

b) the quantity of packages.

7.2.3 Additional marking

When so required, packages or bulk containers (or both) shall bear information additional to that specified in 7.2.1 and 7.2.2.

8 Sampling

Sampling shall be done in accordance with SANS 2859-1.

Annex A
(normative)

User and care instructions and warning statements

A.1 User and care instrcutions

Each package shall be marked clearly with user and care instructions or contain a separate enclosed package insert indicating both the instructions in pictograms and in words. The user shall wash the sanitary towel thoroughly and rinse until the rinsing water shows no signs of discoloration. The user and care instructions given in figure 3 is an example.

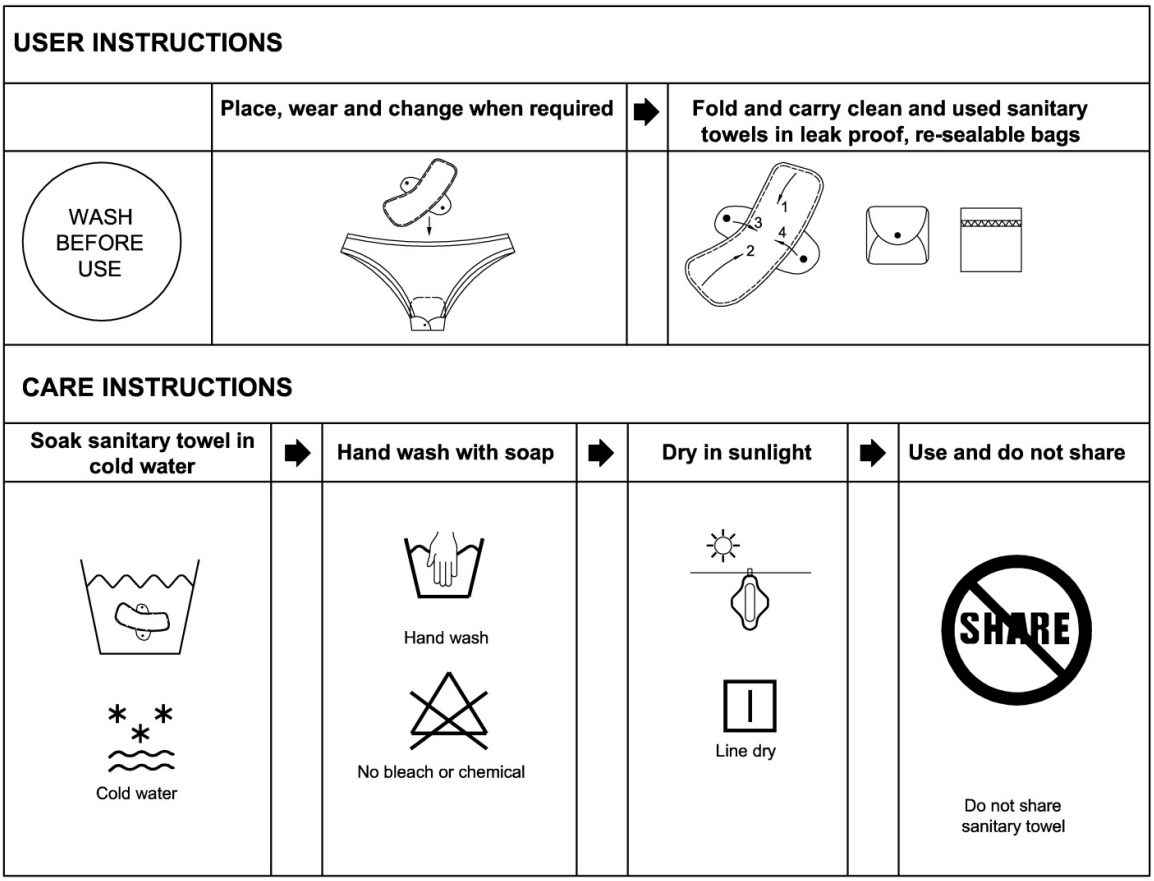


Figure 3 — Example of user and care instructions

A.2 Warning statements

A.2.1 General

The warning statements given in A.2.2 shall be included clearly marked on the package or separate insert (or both). The warning statement given in figure 4 is an example.

A.2.2 Material (see 4.3.1)

The user shall discontinue the use of the sanitary towel immediately if skin irritations or rashes (or both) are experienced.

A.2.2 Durability (see 4.7)

When defects of visual appearance (for example, blood stains, roughness, tear) or performance requirements (or both) (for example, non-absorbent) are found, the sanitary towel shall be disposed of immediately.

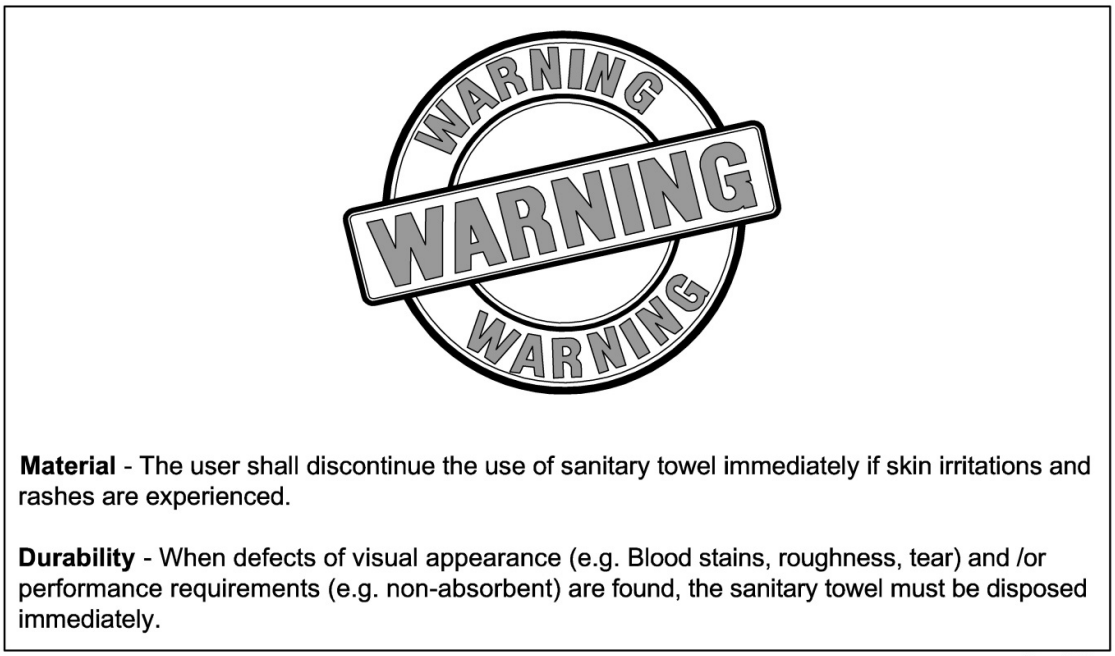


Figure 4 — Example of warning statement

Annex B
(informative)

Quality verification of washable, reusable 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 provision of an integrated quality system, and ISO 15223-1 for the labelling and information on the product.

Bibliography

Standards

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

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

SANS 15223-1/ISO 15223-1, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements.*

Other publications

United States Pharmacopoeia (USP).