KENYA STANDARD

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Surgical masks — Specification

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Foreword

This Kenya Standard has been developed by the Technical Committee on Towels, Medical and Hygienic Textile Products under the guidance of the Standards Projects Committee, and it is in accordance with the procedures of the Kenya Bureau of Standards.

Surgical masks act as an effective means to reduce risk of infectious disease transmission between infected and non-infected persons during health care procedures.

One releases smaller or larger amounts of droplets or secretions from the mucous membranes in the mouth and nose. Those droplets quickly disseminate and leave nuclei suspended in the air which can subsequently spread through the air to a susceptible site such as an open operating wound or sterile equipment. The masks are designed to protect the working environment and the wearer when breathing, speaking, coughing, sneezing etc.

The degree of protection offered by a mask depends on a number of factors such as the filtration capacity and efficiency of the material, capacity to absorb moisture and the fit of the mask on the wearer's face.

During the preparation of this standard, reference was made to the following documents:

SANS 1866:2008 Edition 1.1, Surgical face masks.

SANS 5263, Water absorption rate of textile fabrics.

SANS 5637, Determination of tearing strength.

SANS 6163, Water vapor transfer through a textile fabric.

Acknowledgement is hereby made for the assistance derived from these sources.

Surgical masks — Specification

1 Scope

This Kenya Standard specifies materials, composition, type, workmanship, design, size, test methods, labeling, and packaging of surgical masks.

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.

KS ISO 1833-1, *Textiles — Quantitative chemical analysis Part 1: General principles of testing*

KS ISO 3081, *Determination of mass per unit area*

SANS 79, *Textiles - Mass per unit area of conditioned fabrics*

SANS 5637, *Determination of tearing strength*

SANS 5263, *Water absorption rate of textile fabrics*

SANS 6163, *Water-vapour transfer through a textile fabric*

3 Definitions

For the purposes of this standard, the following definitions shall apply:

3.1
protective clothing
any material or combination of materials used in an item of clothing for the purpose of isolation of parts of the body from contact with potential hazard

3.2
surgical mask
a medical device covering the mouth, nose and chin and providing a barrier to minimize the direct transmission of infectious agents

3.3
non-woven
a fabric-like material made from long fibers, bonded together by chemical, mechanical, heat or solvent treatment. The term is used in the textile manufacturing industry to denote fabrics, such as felt, which are neither woven nor knitted.

3.4
types
3.4.1 type 1 mask
fluid shield mask with or without eye shield

3.4.2 type 2 mask
particulate filtration respirator for use by patients with diseases such as tuberculosis

3.4.3 type 3 mask
fog free mask for use with spectacles

3.4.4 type 4 mask
mask for use by persons with sensitive skin

3.4.5 type 5 mask
standard mask

4 Requirements

4.1 Materials

4.1.1 General

All materials used in the composition of a mask shall be free from latex and glass.

4.1.2 Mask layers

The requirements for the different layers of material for each type of mask shall be as shown in Table 1.

4.1.3 Tape

The tape shall be spun bonded polypropylene tape ultrasonically sewn to the mask. The tensile strength of the attaching of the tape to the mask shall be at least 20 N when tested in accordance with SANS 13934-1.

4.1.4 Elastic

The elastic shall be a synthetic elastomeric material of approximate width of 5 mm. The length shall be such that the elastic fits comfortably around the head of the wearer.

4.1.5 Nose piece

The nose piece shall be a flexible strip of aluminum, plastics or similar material of normal width 3 mm which enables the mask to be shaped comfortably around the nose and face.

4.1.6 Reinforcing strip

The reinforcing strip shall be a strip of a synthetic spun bonded material.

4.1.7 Foam strip

The foam strip shall be a polyurethane foam strip of width of 25 mm and normal thickness of 1 mm.

4.1.8 Eye shield

The eye shield shall be a clear PVC sheet of thickness 0.1 mm with a light transmittance of at least 89 %, the design and shape of the eye shield shall be as shown in Figure 3.

4.2 Workmanship

The masks shall be made with first class workmanship throughout and shall be free from defects that affect their appearance or may affect their serviceability (or both), and free from marks spots or stains incurred in the making up.

4.3 Design and size

The masks types 1, 3, 4, and 5 shall be rectangular in shape and shall be of finished width 180 mm and finished depth 95 mm (see Figure 6). The masks shall be pleated horizontally and the edges ultrasonically sealed with tape. The type 2 design shall be of the design and dimensions shown in Figures 4 and 5

4.4 Composition

4.4.1 Type 1 mask

The mask shall be made from four layers of fabric in accordance with requirements of Table 1. These layers comprise an outer layer, filter layer, a unidirectional moisture layer and an absorption layer, in that order. All four layers shall be pleated horizontally with three pleats finished depth 15 mm and at the front of the mask (the outer layer side) the top pleat shall face upwards and the other two shall face downwards. The top edge of the mask shall be bound with tape (see 4.1.3) to a depth of 15 mm, enclosing, on the front side, an aluminum strip (see 4.1.5) and the top edge shall also be bound with a reinforcing strip (see 4.1.6) to a depth of 20mm at the front of the mask and 10 mm at the back of the mask. A foam strip (see 4.1.7) shall be attached to the top edge of the mask at the back, across the full width and over the reinforcing strip. The bottom of the mask shall be bound with tape to a depth of 10 mm. Each side of the mask shall also be bound with tape to a depth of 10 mm and this tape shall then be folded and shall continue in each direction beyond the mask to give a tie of nominal length 380 mm. The binding of the tape to the mask and the folding of the tape on the free sections shall be ultrasonically sealed. If required (see annex b), an eye shield (see 4.1.8) can be glued to the side tape binding at the front of the mask (see Figure 2).

4.4.2 Type 2 mask

The mask shall be made in two sections, each consisting of four layers of fabric in accordance with the requirements in Table 1. These layers comprise an outer layer, a filter layer, a unidirectional moisture layer and an absorption layer in that order. The two sections shall be ultrasonically sealed together, to a depth of 8 mm, at the bottom and the sides. At the top edge, the front and back sections shall each be ultrasonically bound with tape (see 4.1.3) to a depth of 10 mm and the front top edge shall enclose a nose piece (see 4.1.5). Two lengths of elastic (see 4.1.4) shall be secured in the binding at each end of the top edge of the mask.

4.4.3 Type 3 mask

The mask shall be made from three layers of fabric in accordance with the requirements in Table 1. These layers comprise an outer layer, a filter layer and an absorption layer, in that order. All three layers shall be pleated horizontally with three pleats of finished depth 15 mm and at the front of the mask (the outer layer side) the pleats shall face downwards. The top mask shall be bound with tape (see 4.1.3) to a depth of 15 mm, enclosing, on the front side, a nose piece (see 4.1.5). A foam strip (see 4.1.7) shall be attached at the back, across the full width, to the top edge of the mask. The bottom of the mask shall also be bound with the tape to the depth of 10 mm and this tape shall then be folded and shall continue in each direction beyond the mask to give a tie of normal length 380 mm. The binding of the tape to the mask, and the folding of the tape on the free sections, shall be ultrasonically sealed.

4.4.4 Type 4 mask

The mask shall be made from the three layers of fabric in accordance with the requirements in Table 1. These layers comprise an outer layer, a filter layer and an absorption layer, in that order. All three layers shall be pleated horizontally with three pleats of finished depth 15 mm and at the front of the mask (the outer layer side) the pleats shall face downwards. The top of the mask shall be bound with tape (See 4.1.3) to a depth of 15 mm, enclosing on the front side, a nose piece see (4.1.5). A foam strip (see 4.1.7) shall be attached to the back, across the full width, to the top edge of the mask. The bottom of the mask shall also be bound with tape to a depth of 10 mm. Each side of the mask shall be bound with tape to a depth of 10 mm and this tape shall then be folded and shall continue in each direction beyond the mask to give a tie of nominal length 380 mm. The binding of the tape to the mask, and the folding of the tape on the free sections shall be ultrasonically sealed.

4.4.5 Type 5 mask

The mask shall be made from three layers of fabric in accordance with requirements in Table 1. These layers comprise an outer layer, a filter layer and an absorption layer in that order. All three layers shall be pleated horizontally with three pleats of finished depth 15 mm and at the front of the mask (the outer layer side) the pleats shall face downwards. The top of the mask shall be bound with a tape (see 4.1.3) to a depth of 15 mm, enclosing, on the front side, a nose piece (see 4.1.5). The bottom of the mask shall also be bound with tape to a depth of 10 mm. Each side of the mask shall be bound with tape to a depth of 10 mm and this tape shall then be folded and shall continue in each direction beyond the mask to give a tie of nominal length 380 mm. The binding of the tape to the mask, and the folding of the tape on the free sections, shall be ultrasonically sealed.

5 Test methods

5.1 Determination of penetration percentage and differential pressure

5.1.1 Apparatus

5.1.1.1 Automated filter tester

5.1.2 Procedure

Place the sample between two discs, each with a hole of diameter 76 mm, with the sample so positioned that the filtering material covers the hole with no seams visible in this area. Leave the filtering material folded as supplied and not straightened for testing.

Place the assembly in the test area of the filter tester and set the airflow rate at 30 L/min.

The test apparatus generates a sodium chloride aerosol of approximately 4 mg/m^3, which is passed through the sample. Take air samples before and after each specimen and compare the concentrations as a percentage.

During this process measure the difference in pressure between the upstream and downstream sides of the filter.

Check for compliance with the relevant requirements in Table 1.

5.2 Aerosolized bacterial filtration efficiency

5.2.1 General

Ensure that all glassware is resistant to repeated heat sterilization, and that the glass is free from inhibiting substances such as heavy metals and free alkalis. The use of borosilicate glass with an expansion coefficient of less than 6 $x10^{-6}K^{-1}$ is recommended. All glassware and disposable plastic pipettes, if the last-mentioned are used, shall be sterile.

5.2.2 Apparatus

5.2.2.1 Erlenmeyer flasks, of nominal capacity 250 mL.

5.2.2.2 Wide-mouthed bottles, of nominal capacity 500 mL, of diameter 80 mm, of height 180 mm and that have plastic screw caps.

5.2.2.3 Universal bottles, of capacity 30 mL, and that have screw caps.

5.2.2.4 Pipettes, that are either total delivery glass pipettes, or suitable disposable total delivery plastic pipettes, of nominal capacity 20 mL.

5.2.2.5 Petri dishes, that are made of glass of wettable polystyrene, that are of diameter 65 mm and of height 14 mm.

5.2.2.6 Autoclave, that is capable of producing steam or that is connected to a central steam source and capable of withstanding a temperature of 121 ^{o}C within 15 min from the inception of sterilization.

5.2.2.7 Incubator, that is a thermostatically controlled heating device capable of maintaining a temperature of 37 ^{o}C, and that is so fitted with means of circulation that the temperature of the total enclosed space is maintained to within 1 ^{o}C of the thermostat setting.

5.2.2.8 Hot air oven, that is thermostatically controlled and heated by electricity or gas and capable of maintaining the temperature of the total enclosed space at 170 ^{o}C ± 5 ^{o}C, the heat supply being such that the working temperature is regained within 10 min after opening and closing the oven door momentarily.

NOTE 1 The hot air oven is intended for sterilization by means of dry heat.

5.2.2.9 UV – Vis spectrophotometer

5.2.2.10 Bacteria colony counter

5.2.2.11 pH meter, that is accurate to ± 0.1 pH unit at 25 ^{o}C.

5.2.2.12 Nebulizer, that is a six-jet nebulizer with outlet of diameter 14 mm.

5.2.2.13 Sieve type bacterial air sampling system, that operates at 180 L/min for 5 min (such as pbi surface air system (SAS).

NOTE 2 This information is given for users of this standard and does not constitute and endorsement of the product named. Equivalent products may be used if they can be shown lead to the same results.

5.2.2.14 Nitrogen gas cylinder

5.2.2.15 Neopropene pressure tubing, of internal diameter 3 mm.

5.2.2.16 Membrane filter holders, of diameter 300 mm

5.2.2.17 Clamp

5.2.2.18 Timer

5.2.3 Media and reagents

5.2.3.1 General

5.2.3.1.1 Water

Use only glass-distilled water, or demineralized water of equivalent purity, that is clear, colorless and free from visible suspended matter and of which the pH value, measured at 25^{o}C, is in the range 5.0 to 7.5.

5.2.3.1.2 Quality of ingredients

In the preparation of the media and reagents, use only ingredients of a quality acceptable for microbiological purposes. Use anhydrous salts, unless otherwise specified.

5.2.3.1.3 Accuracy

Except where otherwise specified, allow the following tolerances:

a) on temperatures ± 1 ^{o}C

b)	on masses	± 1.0%
c)	on volumes	± 1.0%
d)	on pH value	± 0.1 pH unit

5.2.3.1.4 Dehydrated media

Many of the media required are obtainable in dehydrated form and, for uniformity of results, the use of such media is recommended. If these are used, strictly follow the manufacturer's instructions regarding the reconstitution and sterilization.

5.2.3.1.5 Filtration of media

Whenever it is necessary to filter a medium in the course of its preparation, proceed as follows:

Filter a medium that contains a solidifying agent (for example agar) through a layer of pre-wetted absorbent cotton wool of thickness 10 mm to 15 mm. To prevent solidification of the medium during filtration, use a steam-jacketed funnel. Alternatively, carry out the filtration in a steam chamber.

5.2.3.1.6 Adjustment of the pH value of media

Where the final pH value of a medium or reagent is specified, in the case of media, adjust the pH value before sterilization, if necessary, so that after sterilization the required pH value, measured at 25 ^{o}C ,is obtained. Unless otherwise specified, use a solution of hydrochloric acid (c(HCL) = 1mol/L) or sodium hydroxide, (c(NaOH)=1 mol/L), as required to adjust the pH values.

5.2.3.1.7 Sterilization

When sterilization by autoclaving is specified, and unless otherwise directed, autoclave the media at 121 ^{o}C for 15 min.

5.2.3.1.8 Control of prepared media

Ensure, by suitable incubation tests, that prepared media are sterile.

5.2.3.1.9 Storage of media

Ensure that prepared media are carefully protected from exposure to heat and sunlight and have not evaporated or changed in concentration or in pH value, and that, unless otherwise specified, they are used within two weeks of preparation.

5.2.3.2 Diluent

The diluent consists of sterile water in 500-mL bottles (see 5.2.2.2).

5.2.3.3 Nutrient medium

5.2.3.3.1 Ingredients

Peptone	5.0 g
Sodium chloride	5.0 g
Yeast extract	2.0 g
Beef extract	1.0 g
Water (see 5.2.3.1.1)	1000 mL

5.2.3.3.2 Preparation

Dissolve the ingredients in the water and adjust the pH value to 7.1. Dispense 10 mL volumes into 30-mL universal bottles (see 5.2.2.3),and sterilize by autoclaving.

5.2.3.4 Solid medium nutrient agar

5.2.3.4.1 Ingredients

Beef extract	1 g
Peptone	5 g
Sodium Chloride	5 g
Yeast extract	2 g
Agar	15 g
Water (see 5.2.3.1.1)	1000 mL

5.2.3.4.2 Preparation

5.2.3.4.2.1 Bring some of the water to boil. Add ingredients and heat to boiling point while stirring frequently until completely dissolved. Adjust the pH value so that, after sterilization, the pH value is 7.1 ± 0.1 and dilute the solution to 1 L with the remaining water. Dispense 10 mL volumes into 30 mL-universal bottles (see 5.2.2.3), and sterilize by autoclaving.

5.2.3.4.2.2 Cool the agar to 45 ^{o}C and pour 10 mL volumes into the required number of petri dishes.

5.2.3.4.2.3 Allow the agar in the remaining bottles to solidify in a sloped position.

5.2.4 Test organism (Staphylococcus aureus)

5.2.4.1 Maintenance of the test organism

5.2.4.1.1 From a newly opened freeze dried culture or recently received agar culture, subculture the test organism into bottles of nutrient medium (see 5.2.3.3).

5.2.4.1.2 Incubate the bottles at 37 ^{o}C for 24 h. Make subcultures from the cultures in the bottles on slopes of nutrient agar (see 5.2.3.4) incubate the slopes at 37 ^{o}C for 24 h.

5.2.4.1.3 From each of these slope cultures, prepare four subcultures (stock cultures) of the test organism on slopes of nutrient agar (see 5.2.3.4). Incubate the stock cultures at 37 ^{o}C for 24 h and then store them in a refrigerator maintained at 4 ^{o}C.

NOTE Not more than six serial subcultures should be made from each stock culture before resorting to a new freeze-dried culture.

5.2.4.2 Preparation of the culture for test suspension

5.2.4.2.1 Make a subculture of *S. aureus* from a stock culture kept at 4 ^{o}C on a nutrient agar slope (see 5.2.3.4) and incubate at 37 ^{o}C for 24 h.

5.2.4.2.2 For the test, use a 24 h culture which has been sub cultured for at least two successive days.

5.2.4.2.3 Using 10 mL of diluent (see 5.2.3.2), wash the resulting bacterial growth from the 24 h slope, scraping the agar surface if necessary. Carefully decant the suspended growth into a sterile screw-top glass bottle and shake vigorously to suspend all the growth in the water. Standardize the suspension by using the

UV-Vis spectrophotometer in conjunction with a turbidimetric calibration curve for *S. Aureus* or by any other suitable means, such as a haemocytometer or a Petroff Hauser counting chamber so that the suspension contains 1000 (10^3) organisms per milliliter. Use the suspension within 3 h of preparation.

5.2.5 Principle

Compressed nitrogen is used to propel droplets of a suspension of *S. aureus* from a nebulizer towards the test specimen. The droplets are impinged against the face side of the test specimen at a constant flow rate of 0.2 mL/min for the remaining 2.5 min. The pressure of the nitrogen is manually adjusted to maintain this constant flow.

Those particles that are not retained by the test specimen are directed towards the SAS that is operating at180 L/min for 5 min (see Figure 1). The number of colonies on the test plate captured by the SAS with the test specimen in position is compared with the number of colonies captured on the control plate by the SAS without a test specimen.

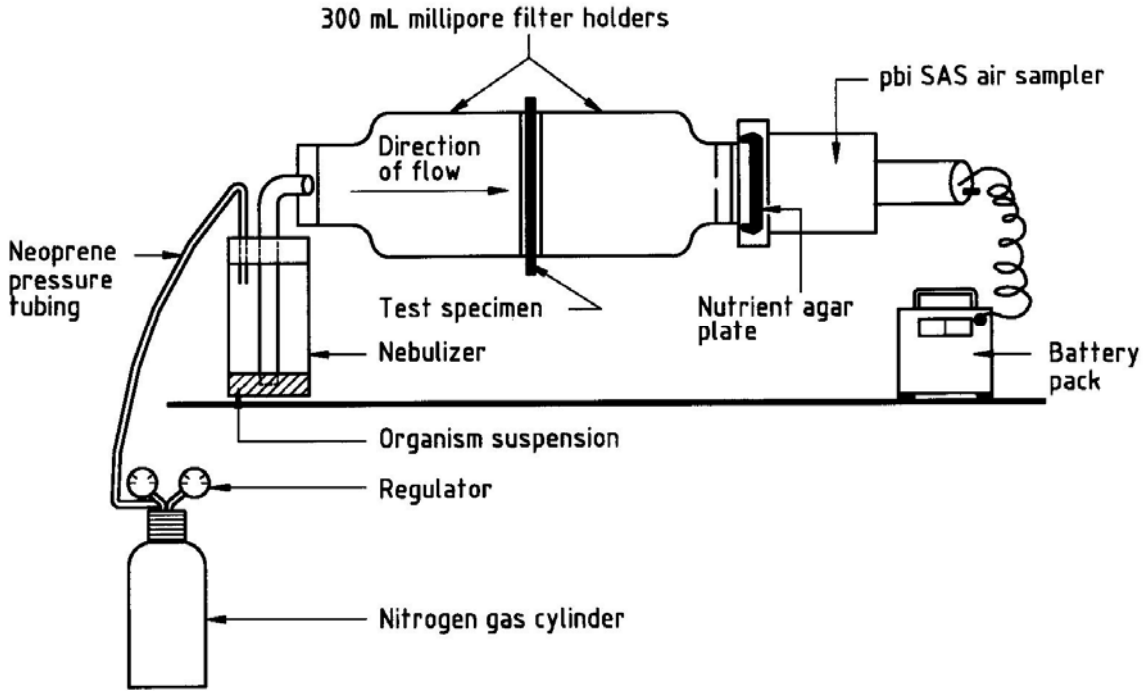

Figure 1 — Test apparatus

5.2.6 Procedure

5.2.6.1 Cut four square test specimens, each of side length 100 mm, from areas of the fabric selected to represent the sample as fully as possible but not within 50 mm of the outer edge.

5.2.6.2 Pipette 20 mL of the test suspension (see 5.2.4.2) into the nebulizer.

5.2.6.3 Insert a nutrient agar plate (control plate) into the SAS and set the system on 15 units (5 min).

5.2.6.4 Using the neoprene pressure tubing (see 5.2.2.15), direct the nitrogen flow into the nebulizer, set the timer for 5 min then start the SAS.

5.2.6.5 At the end of 5 min, turn off the nitrogen flow.

5.2.6.6 Remove the agar plate from the SAS and insert a fresh agar plate (the test plate).

5.2.6.7 Place the test specimen between the wide ends of two membrane filter holders and clamp the holder's securely together (see Figure 1).

5.2.6.8 Repeat the steps given in 5.2.6.2 to 5.2.6.5 (inclusive). Remove the agar plate from the SAS. Remove the test specimen from the apparatus.

5.2.6.9 Test three more specimens in the same way and then run another control as described in 5.2.6.2 to 5.2.6.5, removing the agar plate at the end of 5 min.

5.2.6.10 Periodically replenish the test suspension in the nebulizer. Do not allow the volume to fall below 10 mL.

5.2.6.11 Incubate all the agar plates at 37 ^{o}C for 24 h.

5.2.7 Expression of results

Count the colonies on the control plates. If the average number of colonies per control plate is between 100 and 300, use a colony counter to count the colonies on each test plate. If fewer than 100 or more than 300 colonies per control plate are observed, regard the test as invalid and repeat it.

If the aerosolized bacterial filtration efficiency of the specimens is below 90 % or above 99 %, repeat the test.

Calculate the percentage aerosolized bacterial efficiency (A) of the test specimens as a percentage, using the following equation:

Insert formula

$$A = \frac{(c-m)}{c} \times 100$$

where

A is the percentage aerosolized bacterial filtration efficiency;

c is the average control plate count; and

m is the average test plate count.

Check for compliance with the relevant requirements in Table 1.

6 Packaging

The following packaging requirements shall apply for the surgical masks:

6.1 Surgical masks shall be packed 50 pieces in a box.

6.2 The boxes shall allow for ease of dispensing, whether upright or inverted.

6.3 The standard weight of the carton shall be 15 kg to 30 kg.

6.4 The pack shall be free of contaminants.

7 Labelling

The following labelling requirements shall apply for the surgical masks:

a) Labeling shall be legible.

b) Labeling shall be in English imprinted in indelible ink with bold block letters.

c) Labeling shall have the manufacturers name and address.

d) Labeling shall have the date of manufacture and expiry date.

e) Labeling shall have the country of origin stated clearly.

f) Each box and carton shall be clearly labelled with the name and characteristics (type) of the article and production batch number.

g) Each box & carton shall indicate number of units per carton and weight.

h) Each package shall have the quality mark on the primary and secondary packaging.

All dimensions in mm

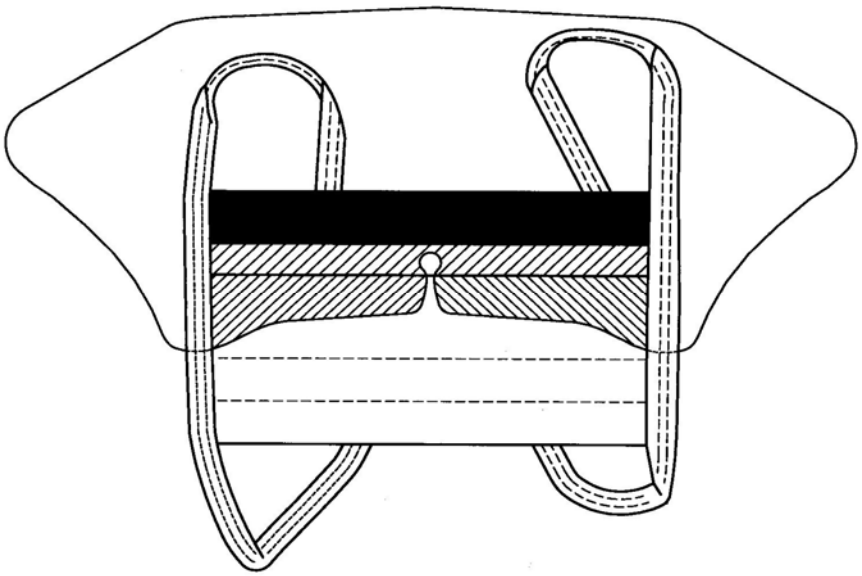

Figure 2 — Type 1 mask (with eye shield)

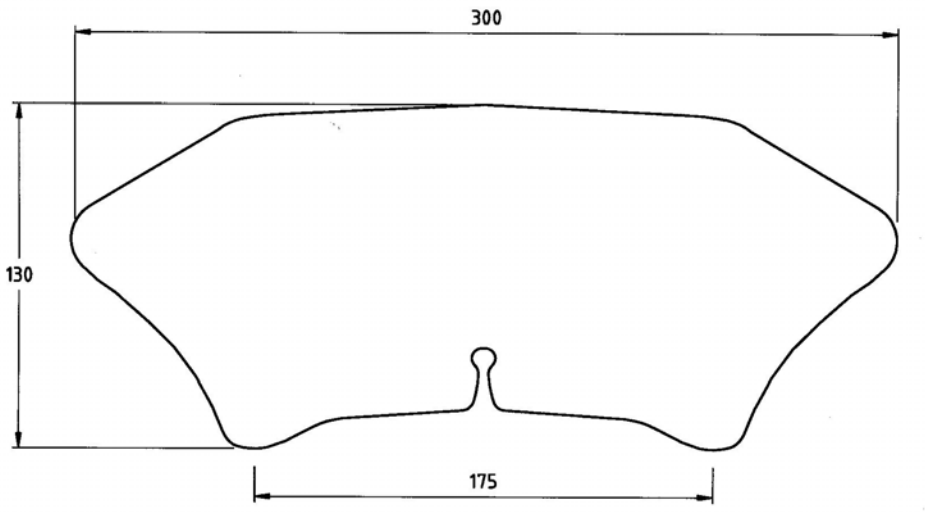

Figure 3 — Eye shield, dimensions

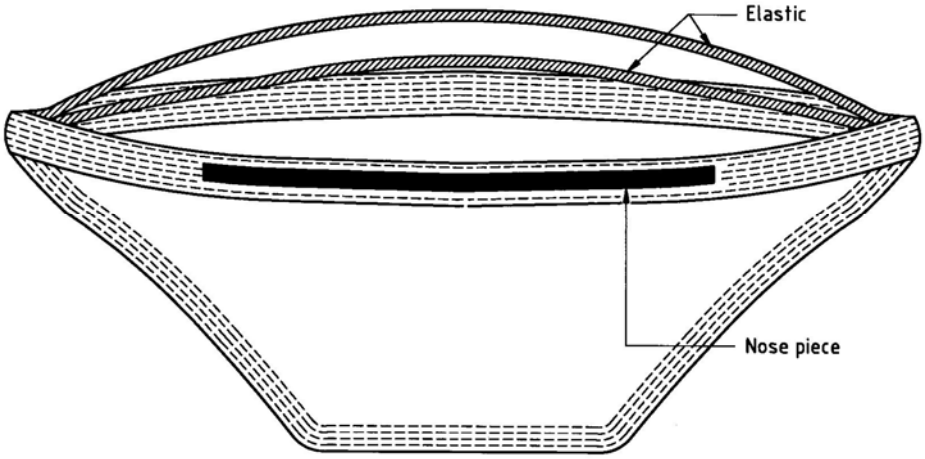

Figure 4 — Type 2 mask

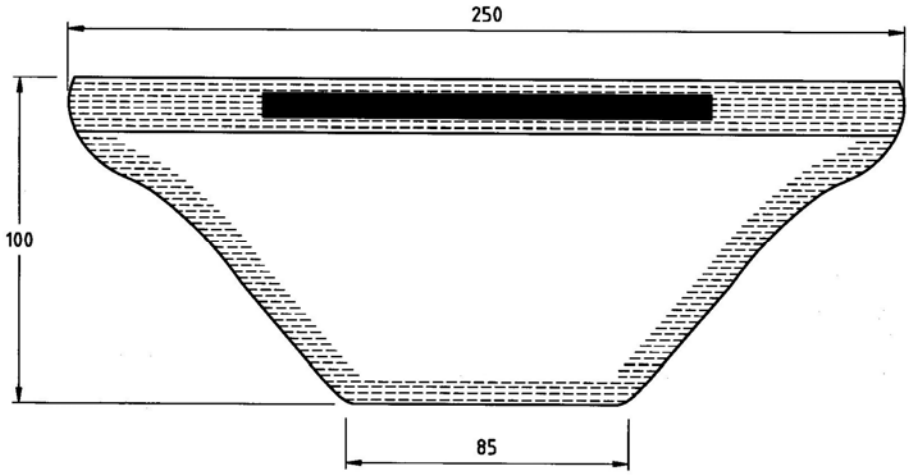

Figure 5 — Type 2 mask dimensions

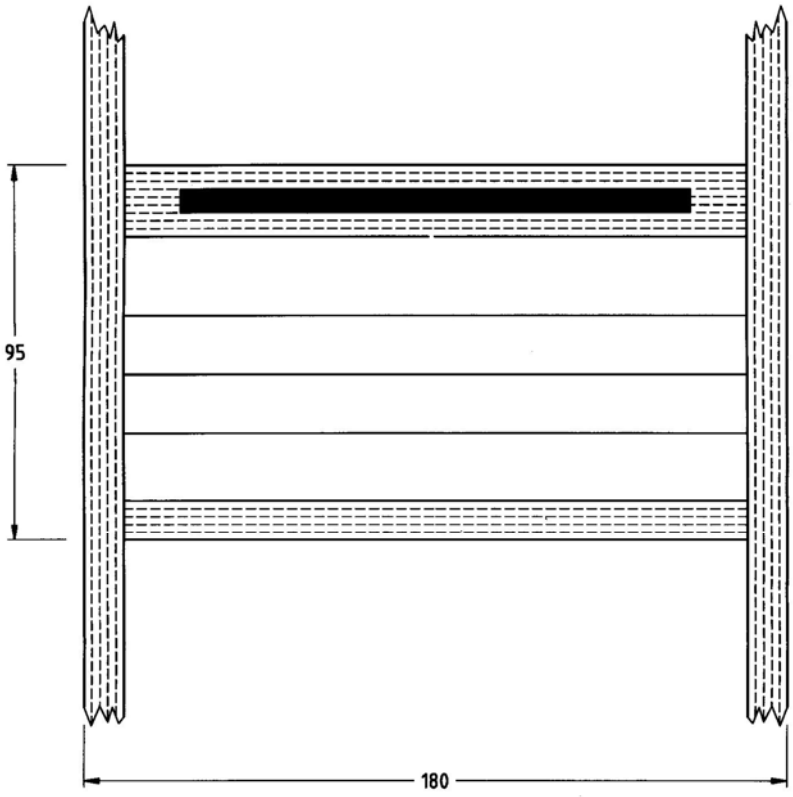

Figure 6 — Rectangular mask dimensions

Table 1 – Material requirements for surgical masks

SL No	1	2	3	4	5	6	7
	Property	Requirement					Test method
		Type of mask					
		Type 1	Type 2	Type 3	Type 4	Type 5	
i)	**Fibre composition. min.**						AATCC test method 20/ KS ISO 1833
	1st layer (outermost)	Cotton and polyester	Polypropylene	Polypropylene	Cotton and Polyester	Cotton and Polyester	
	2nd layer	Polypropylene	Polypropylene	Polypropylene	Polypropylene	Polypropylene	
	3rd layer	Polypropylene	Polypropylene	Cotton and polyester	Cotton and polyester	Cotton and polyester	
	4th layer	Cotton and polyester	Polyester and Polypropylene				
ii)	**Mass per unit area, g/m2, min.**						SANS 79/ KS ISO 3081
	1st layer (outermost)	19	35	24	20	20	
	2nd layer	18	87	22	15	15	
	3rd layer	29	32	19	19	19	
	4th layer	19	20				
iii)	**Tensile Strength, N min.**						SANS 5637
	1st layer (outermost)	1.7	5.7				
	2nd layer	1.0	3.4	5.4	1.7	1.7	
	3rd layer	1.8	1.5	1.0	1.0	1.0	
	4th layer	1.9	2.9	1.4	1.4	1.4	
iv)	**Absorption rate**, s, min, 1st layer	>60[a]	>60[a]	>60[a]	>60[a]	>60[a]	SANS 5263
v)	**Water vapour transfer**, g/m2/24h, min.	3767[b]	4040[b]	3872[b]	3767[b]	3767[b]	SANS 6163
vi)	**Penetration**, %, min.	30	4	24	26	26	5.1
vii)	**Differential pressure**, Pa, min.	56	357	40	30	35	5.1
viii)	**Aerosolized bacterial filtration efficiency**, %, min.	98	98	98	98	98	5.2

[a] Sample does not absorb water.
[b] Tested as a composite.