KENYA STANDARD

KS 2636:2021

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ICS 13.340.30

Second Edition

Medical face masks — Specification

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REVISION OF KENYA STANDARDS

In order to keep abreast of progress in industry, Kenya Standards shall be regularly reviewed. Suggestions for improvements to published standards, addressed to the Managing Director, Kenya Bureau of Standards, are welcome.

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Foreword

This Kenya Standard was prepared 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.

Medical face 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.

This standard has been revised in the following areas:

- The types of mask to be covered by this standard have been classified into three types (Type I, Type II and Type II R) according to bacterial filtration efficiency and splash resistance.
- Provisions for dimensions of children's mask introduced.
- Test method for determining Bacterial filtration efficiency (BFE) in Annex A revised.
- The requirements for strap revised.

This Second edition cancels and replaces the First edition (KS 2636:2016) which has been technically revised.

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

BS EN 14683, Medical face masks — Requirements and test methods.

SANS 1866:2008 Edition 1.1, Medical 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.

Medical face masks — Specification

1 Scope

This Kenya Standard specifies construction, design, performance requirements and test methods for medical face masks intended to prevent the transmission of infective agents from one person to another in medical settings and other settings.

2 Normative references

The following referenced documents are 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.

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

KS ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

KS ISO 11737-1, *Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products*

KS ISO 22609, *Clothing for protection against infectious agents — Medical face masks — Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)*

3 Terms and definitions

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

3.1
medical face mask
medical device covering the mouth, nose and chin and providing a barrier to minimize the direct transmission of infectious agents

3.2
aerosol
gaseous suspension of solid and/or liquid particles

3.3
bacterial filtration efficiency
efficiency of the medical face mask material(s) as a barrier to bacterial penetration

3.4
biocompatibility
quality of being accepted in a specific living environment without adverse or unwanted side effects

3.5
microbial cleanliness
freedom from population of viable micro-organisms on a product and/or a package in practical use, microbial cleanliness is often referred to as “bioburden”

3.6
differential pressure
air permeability of the mask, measured by determining the difference of pressure across the mask under specific conditions of air flow, temperature and humidity

NOTE The differential pressure is an indicator of the “breathability” of the mask.

3.7
filter
material used for mechanical and physical separation or deposition of aerosol particles (liquid or solid) from the inhaled and exhaled air

3.8
infective agent
microorganism that has been shown to cause medical face wound infections or that might cause infection

3.9
splash resistance
ability of a medical face mask to withstand penetration of synthetic blood projected at a given pressure

3.10
surgical procedure
surgical intervention penetrating the skin or mucosa, performed by a surgical team under controlled environmental conditions

3.11
strap
narrow strip or a flexible material used for securing the mask on to the person wearing the mask

4 General requirements

4.1 Classification

Medical face masks specified in this standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant. The 'R' signifies splash resistance.

4.2 Materials and construction

4.2.1 Construction

The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric. The medical face mask shall not disintegrate, split or tear during intended use. In the selection of the filter and layer materials, attention shall be paid to cleanliness.

4.2.2 Strap

The mask shall have a tape spun bonded polypropylene or elastic tape sewn to the mask. The tensile strength of the attachment of the tape to the mask shall be at least 20 N when tested in accordance with Annex C. The elastic shall be a synthetic elastomeric material of diameter of 2.5 mm to 3 mm, while the flat strap shall have a width of 4 mm to 5 mm. The length shall be such that it fits comfortably around the head of the wearer.

4.2.3 Nose bridge

The mask shall have a nose bridge made of a flexible strip of aluminum, plastics or similar material of nominal width 3 mm which enables the mask to be shaped comfortably around the nose and face. The bridge shall retain the shape for at least 10 min.

4.2.4 Reinforcing strip

The reinforcing strip may be made from synthetic spun laced, melt blow or stitch bonded material.

4.2.5 Workmanship

The masks shall be free from defects and contaminants that affect their appearance and/or serviceability.

4.3 Design and size

4.3.1 The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.

4.3.2 Medical face masks may have additional features such as a face shield (to protect the wearer against splashes and droplets) and with or without anti-fog function.

4.3.3 The masks shall have a minimum of three pleats with a depth of 10 mm to 15 mm and the edges ultrasonically sealed with minimum depth of 10 mm.

4.3.4 The rectangular shaped mask shall be of finished dimensions as specified in Table 1.

Table 1 — Finished dimensions for medical face masks

Characteristic	Young children (2 – 5 years)	Children (6 – 12 years)	Teens, adults
Width, mm	min. 150	min. 160	170 - 195
Depth, mm	min. 80	min. 85	90 - 100

5 Specific requirements

5.1 Bacterial Filtration Efficiency (BFE)

The BFE of the medical face mask shall conform to the minimum value given for the relevant type in Table 2 when tested in accordance with Annex A. When a mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually. The lowest performing panel or area shall determine the BFE value of the complete mask.

For thick and rigid masks such as rigid duckbill or cup masks, the test method may not be suitable as a proper seal cannot be maintained in the cascade impactor. In these cases, another valid equivalent method shall be used to determine the BFE.

5.2 Differential pressure (breathability)

The differential pressure of the medical face mask shall be as specified in Table 2 when tested in accordance with Annex B.

5.3 Splash resistance

The resistance of each of the type of medical face mask to penetration of liquid shall comply with the requirements given in Table 2 when tested in accordance with KS ISO 22609.

5.4 Microbial cleanliness (Bioburden)

The bioburden of the medical mask shall be as specified in Table 2 when tested in accordance with KS ISO 11737-1: procedure described in Annex D. The number of masks that shall be tested is minimum 5 of the same batch/lot. Other test conditions as described in KS ISO 11737-1 may be applied. The total bioburden per individual mask and based on the mask weight shall be reported which is the total bioburden per gram.

5.5 Biocompatibility

According to the definition and classification in KS ISO 10993-1, a medical face mask is a surface device with limited contact. The medical mask shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants. The manufacturer shall complete the evaluation of the medical face mask according to KS ISO 10993-1 and determine the applicable toxicology testing regime. The results of testing should be documented according to the applicable parts of the KS ISO 10993 series. The test results shall be available upon request.

Table 2 — Performance requirements for medical face masks

S/N	Property	Type I[a]	Type II	Type IIR
i.	Bacterial filtration efficiency(BFE), %, min.	95	98	98
ii.	Differential pressure, Pa/cm^2, max.	40	40	60
iii.	Splash resistance (kPa), min.	Not required	Not required	16
iv.	Microbial cleanliness (Bioburden) (cfu/g) max.	30	30	30

[a] Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

6 Packaging

The following packaging requirements shall apply for the medical face masks:

6.1 The packaging shall allow for ease of dispensing, whether upright or inverted.

6.2 The standard weight of the packaging shall not exceed 30 kg.

6.3 The pack shall have a barrier to moisture and or contaminants.

7 Labelling

The following information shall be legibly and indelibly marked in English on the secondary packaging in which the medical face mask is supplied:

a) the manufacturers name and address;
b) date of manufacture and expiry date;
c) the country of manufacture;
d) type of the mask (as indicated in Table 2);
e) number of units;
f) instructions for storage, use and disposal;
g) Color of the mask; and
h) Batch number.

Annex A
(normative)

Method for in vitro determination of bacterial filtration efficiency (BFE)

A.1 General

WARNING — *Staphylococcus aureus* is a pathogen. The relevant national provisions by law and hygienic instructions when dealing with pathogens shall be complied with.

A.2 Principle

A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber. An aerosol of *Staphylococcus aureus* is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency (BFE) of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol. For test apparatus see Figure A.3.

A.3 Reagents and materials

A.3.1 General

A.3.2 and A 3.3 describe commercially available solutions of tryptic soy agar and tryptic soy broth. Other variants may be suitable.

A.3.2 Tryptic soy agar

uFormula/litre

Enzymatic digest of casein 15 g

aEnzymatic digest of soybean meal 5 g

eSodium chloride 5 g

iAgar 15 g

Final pH 7.3 ± 0.2 at 25 °C

A.3.3 Tryptic soy broth

Formula/litre

eEnzymatic digest of casein 17 g

vEnzymatic digest of soybean meal 3 g

Sodium chloride 5 g

Dipotassium phosphate 2.5 g

Dextrose 2.5 g

Final pH 7.3 ± 0.2 at 25 °C

A.3.4 Peptone water

Formula/litre

Peptone 10 g

Sodium chloride 5 g

Final pH 7.2 ± 0.2 at 25 °C

A.3.5 Culture of *staphylococcus aureus* ATCC 6538, growing on tryptic soy agar slants

A.4 Test apparatus

A.4.1 Six stage cascade impactor, the arrangement is specified in Table A.1.

A.4.2 Nebulizer, capable of delivering particles with a mean size of (3,0 ± 0,3) µm when in contact with the cascade impactor.

A.4.3 Aerosol chamber, glass, 600 mm long and 80 mm in external diameter.

A.4.4 Flow meters, capable of measuring a flow rate of 28.3 l/min.

A.4.5 Pressure gauge, capable of measuring a pressure of 35 kPa to an accuracy of ± 1 kPa.

A.4.6 Erlenmeyer flasks, 250 ml and 500 ml capacity.

A.4.7 Peristaltic or syringe pump, capable of delivering 0,01 ml/min.

A.4.8 Vacuum pump, capable of maintaining a flow rate of 57 l/min.

A.5 Test specimens

Test specimens shall be cut from complete masks. A complete mask may be used in place of a cut specimen, as long as the extremities are removed, the mask is laid flat and all layers are incorporated (in case of folded masks unfold the mask in order to test a surface as flat as possible). Each specimen shall be minimum 100 mm x 100 mm and shall include all layers of the mask in the order in which they are placed in the complete mask. The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL (Acceptable Quality Level) of 4 %. All specimens tested shall be taken from representative areas to incorporate all/any variation in construction. Unless otherwise specified, the testing shall be performed with the inside of the medical face mask in contact with the bacterial challenge.

Each test specimen shall be conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for a minimum of 4 h to bring them into equilibrium with atmosphere prior to testing.

A.6 Preparation of bacterial challenge

Staphylococcus aureus (see A.3.5) shall be inoculated into 30 ml tryptic soy broth in an Erlenmeyer flask and incubated with mild shaking at a temperature of (37 ± 2) °C for (24 ± 2) h. The culture shall then be diluted in peptone water to give a concentration of approximately 5 x 10^5 CFU/ml.

The bacterial challenge shall be maintained at 1.7×10^3 to 3.0×10^3 CFU per test. The bacterial challenge shall be determined on the basis of experience and previous positive control plates (see A.7.3) and the dilution of the challenge suspension adjusted accordingly. The mean particle size (MPS) in the bacterial challenge shall be maintained at (3.0 ± 0.3) µm (see A.7.9).

Table A.1 — Cascade impactor stage arrangement

Stage number	1	2	3	4	5	6
Size of particle	P1	P2	P3	P4	P5	P6
Viable "particle" plate count	C1	C2	C3	C4	C5	C6

where

P1 = 7.00 µm

P2 = 4.70 µm

P3 = 3.30 µm

P4 = 2.10 µm

P5 = 1.10 µm

P6 = 0.65 µm

$$\text{MPS}=\frac{(P1X\ C1)+(P2\ X\ C2)+(P3X\ C3)+\ (P4X\ C4)+\ (P5\ XC5)+\ (P6\ XC6)}{C1+C2+C3+C4+C5+C6}$$

The viable "particles" plate count values used for MPS calculations are the converted "probable hit" counts calculated using the positive hole conversion chart from the cascade impactor manual. The MPS value above is the 50 % effective cut-off diameter calculated for each stage using the equation and information from the cascade compactor manual.

A.7 Procedure

A.7.1 Assemble the test apparatus in accordance with the flow chart shown in Figure A.1 or Figure A.3.

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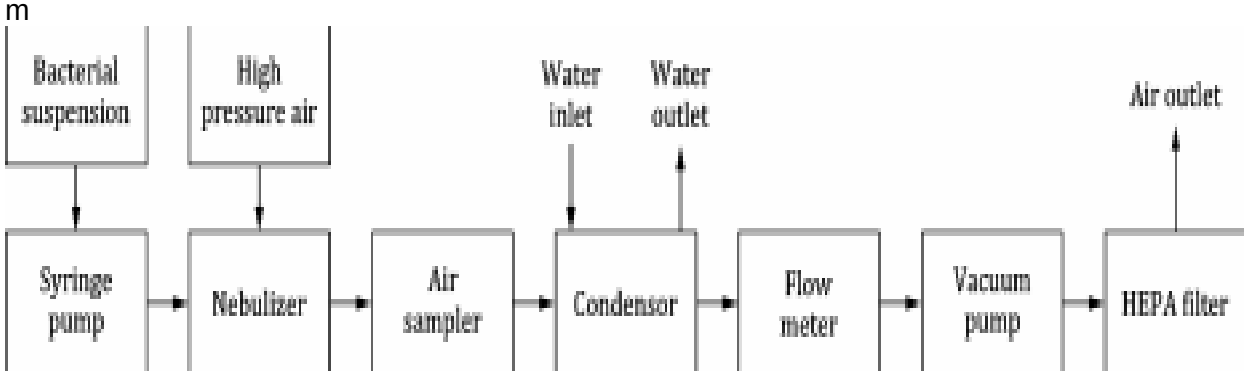


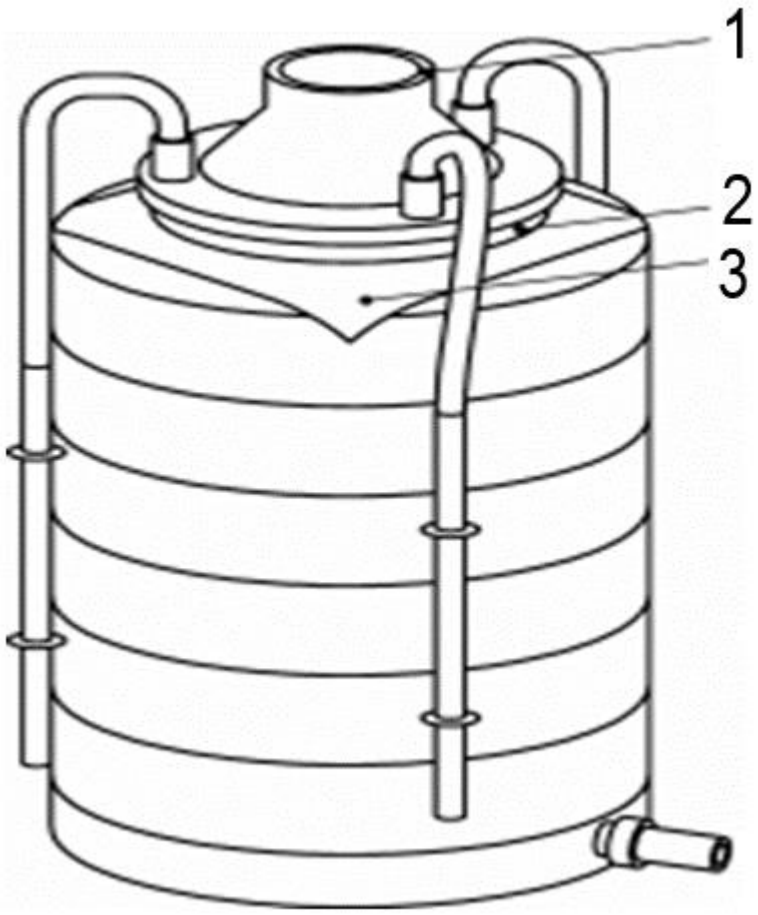
Figure A.1 — Principle of BFE test apparatus

A.7.2 Deliver the bacterial challenge to the nebulizer using the peristaltic or syringe pump.

A.7.3 Perform a positive control run without a test specimen. Initiate the bacterial challenge by turning on the vacuum pump and adjust the flow rate through the cascade impactor to 28.3 l/min. Deliver the bacterial challenge for 1 min. Maintain the airflow through the cascade impactor one additional minute (total test time is 2 min). Then remove the plates from the cascade impactor. Ensure that each plate is numbered to indicate its position in the cascade impactor.

A.7.4 Place fresh plates in the cascade impactor, clamp the test specimen in place between the first stage of the cascade impactor and the inlet cone (see Figure A.2) and repeat the procedure described in A.7.3.

B.7.3 The test area shall be minimum 49 cm^2. Alternative means to position the sample may be appropriate, but, if deviated from the procedure, this shall be documented in the test report.



Key

1 inlet cone
2 o'ring inlet cone
3 cloth / mask

Figure A.2 — Placement of test specimen on the cascade impactor

A.7.5 Repeat this procedure for each test specimen.

A.7.6 After the last test specimen has been tested, perform a further positive control run.

A.7.7 Perform a negative control run by passing air, without addition of the bacterial challenge, through the cascade impactor for 2 min.

A.7.8 Incubate all the plates at (37 ± 2) °C for (20 to 52) h.

A.7.9 For each specimen and control run, count the number of colonies on each plate and add up the counts to give the total number of CFU collected by the cascade impactor. Use the "positive hole conversion table[1)] in accordance with the instructions of the cascade impactor manufacturer for stages 3 to 6. For the two positive control runs, take the mean of the two totals. From the positive control plates calculate the mean particle size (MPS) of bacterial challenge aerosol using the formula given in B.6.

A.8 Calculation of Bacterial Filtration Efficiency (BFE)

For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the following formula:

NOTE 1 See the positive hole conversion table found in the cascade impactor manual.

$$B=(C-T)/CX100$$

where

C is the mean of the total plate counts for the two positive control runs; and

T is the total plate count for the test specimen.

A.9 Test report

The following information shall be given in the test report:

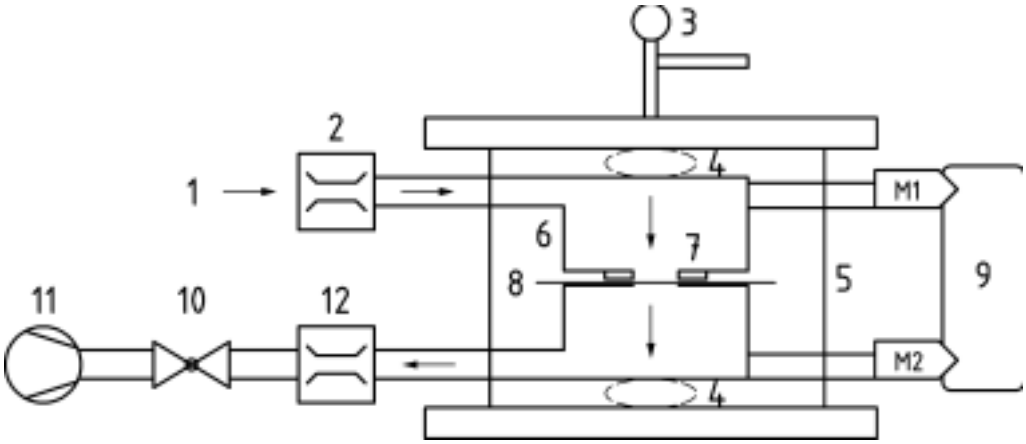
a) dimensions of the test specimens and the size of the area tested;
b) which side of the test specimen was facing towards the challenge aerosol;
c) flow rate during testing;
d) mean of the total plate counts of the two positive controls;
e) mean plate count of the negative controls; and
f) bacterial filtration efficiency (BFE).

Annex B
(normative)

Method for determination of differential pressure (breathability)

B.1 Principle

A device which measures the differential pressure required to draw air through a measured surface area at a constant air flow rate is used to measure the air exchange pressure of the medical face mask material, as shown in Figure B.1. A water-filled (or digital) differential manometer is used to measure the differential pressure. A mass flow meter is used for measurement of the airflow. An electric vacuum pump draws air through the test apparatus and a needle valve is used to adjust the airflow rate.



Key

1 air inlet
2 mass flow meter
3 lever for mechanical clamping
4 systems for final adjustment of the pressure of the sample holder (either at the top or the bottom)
5 system ensuring optimal alignment of the 2 parts of the sample holder
6 sample holder with a metal sealing mechanism (optional)
7 metallic ring (3 mm thick)
8 filter material
9 differential manometer or M1 and M2 manometers
10 valve
11 vacuum pump including a pressure buffer tank
12 mass flow meter for checking leaks

Figure B 1— Test apparatus for measuring differential pressure

B.2 Test apparatus

B.2.1 Mass flow meter(s), capable of measuring an airflow of 8 l/min.

B.2.2 Manometer, a differential manometer (water or digital). Individual manometers can also be used. M1 is for the upstream pressure measurement and M2 is for the downstream pressure measurement.

B.2.3 Electric vacuum pump including a pressure buffer tank

B.2.4 Valve permitting the adjustment of the flow rate

B.2.5 Sample holder

B.2.5.1 The sample holder shall consist of a mechanical clamping system and alignment of the top and bottom holder.

B.2.5.2 The sample holder shall consist of a mechanism to adjust the clamping pressure. A system with thread of screw can be used either at the bottom or top part of the sample holder.

B.2.5.3 The internal diameter of the top holder and the bottom holder in the contact are with the filter material shall be (25 ± 1) mm.

B.2.5.4 The seal of the top and bottom holder onto the filter material shall consist of a metal-metal contact. A metallic ring of internal diameter of (25 ± 1) mm and ca. 3 mm thick will be fixed to the top holder. The bottom holder will consist of a completely flat metallic surface with an internal diameter of (25 ± 1) mm and a 3 mm area around the open diameter. Materials such as rubber or poly foam do not provide a sufficient seal and may deform into the test area.

B.2.5.5 Validation of the test apparatus shall consist of a leak test. A second flow meter (12) immediately before the valve (10) will allow for evaluation of an air leak within the test apparatus. With the sample holder closed, start the pump and adjust the flow meter to read 8 l/min on the first flow meter (2). If no leaks are present both flow meters should read 8. Another check shall consist of stopping inlet air when both flow meters give 8 l/min. After a few seconds both flow meters should indicate 0 l/min if no leaks.

B.3 Test specimens

Test specimens are complete masks or shall be cut from complete masks. If a complete mask is used, remove extremities and lay the mask flat with all layers incorporated. Each specimen shall be able to provide different circular test areas of 25 mm in diameter. If one specimen cannot provide 5 test areas of 25 mm diameter, the number of test areas retrieved should be representative for the entire mask. For thick and rigid masks, the test method may not be suitable as a proper seal cannot be maintained in the sample holder. The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL of 4 %. All specimens tested shall be taken from areas representative from the mask to incorporate all/any variation in construction. Unless otherwise specified, the testing shall be performed with the airflow direction from the inside of the mask to the outside of the mask. Each test specimen shall be conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for a minimum of 4 h.

B.4 Procedure

B.4.1 Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump is started and the flow of air adjusted to 8 l/min.

B.4.2 The holder is opened and the test specimen is placed across the 25 mmameter orifice (total area $_{4.9}$ $_{cm^2}$) between the top and bottom parts of the holder. Then it is clamped in place using a mechanical clamp with sufficient pressure to avoid air leaks. Due to the presence of an alignment system the tested area of the specimen should be perfectly in line and across the flow of air\With the specimen in place the flow rate should be 8 l/min as previously set in B.4.1. If the flow rate is not at 8 l/min, a leak may be present. Try to increase the pressure if possible to avoid this problem. In such case the use of a second flow meter during testing is also indicated.

B.4.3 The differential pressure is read directly if using a differential pressure manometer. If using manometers M1 and M2 read and record each pressure.

B.4.4 The procedure described in steps B.4.1 to B.4.3 is carried out on 5 (or appropriate number) different areas of the mask and the readings averaged.

If the mask comprises different material types in different areas, test an even number of the different areas. For example, the average should consist of 3 readings on the top portion of the mask with material type A and 3 readings on the bottom portion of the mask with material type B.

B.5 Calculation of differential pressure

For each test specimen calculate the differential pressure ΔP/cm^2 of each tested area as follows:

$$\Delta P = (X_{m1} - X_{m2})/4.9$$

where

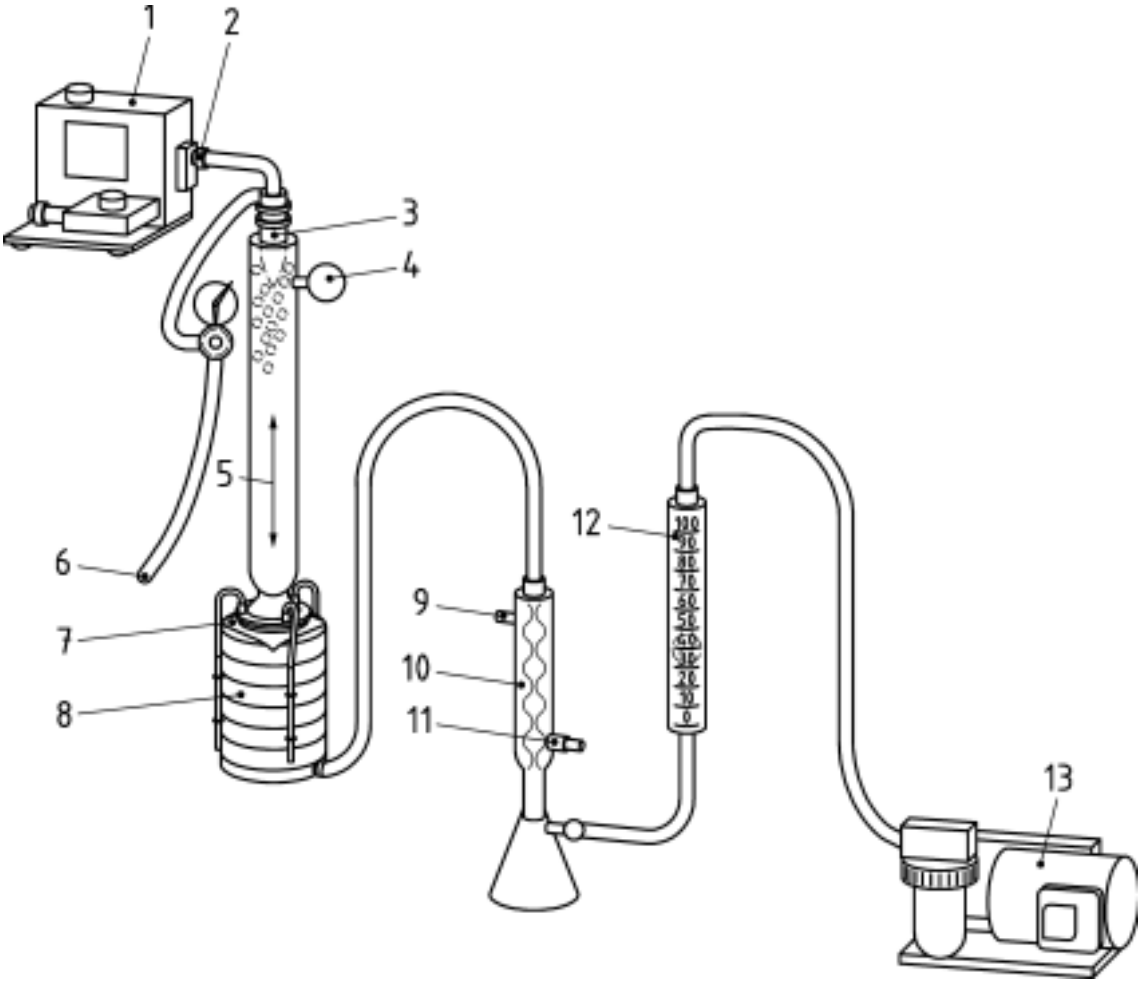
X_{m1} is the pressure in Pa, measured by manometer M1 – low pressure side of the material;

X_{m2} is the pressure in Pa, measured by manometer M2 – high pressure side of the material;

4.9 is the area (in cm^2) of the test material; and

ΔP is the differential pressure per cm^2 of test material expressed in Pa.

NOTE If a differential manometer is used the differential pressure ($X_{m1} – X_{m2}$) is directly obtained.



Key
1 drive mechanism
2 bacterial suspension
3 nebulizers
4 filter 5 aerosol chamber
6 high pressure air source
7 test material
8 cascade impactor
9 outlets to sink
10 condenser
11 cold water inlet
12 calibrated flow meter
13 compressors (vacuum pump)

Figure A.3 — Example of real BFE test apparatus

Annex C
(normative)

Determination of strap attachment force

C.1 Examine the way the straps are fixed onto the body of the mask note their positions.

C.2 From the body of the mask, at the point at which the strap is fixed, cut out an inline specimen of at least 50 mm x 100 mm.

C.3 Cut off the strap, leaving out a length of 200 mm attached to the test specimen (*see* Figure C.1).

C.4 The strap attachment strength is tested using a constant-rate-of-extension (CRE) tensile machine as described in KS ISO13934-1.

C.5 Set the gauge length of the tensile-testing machine to 50 mm ± 1 mm. With a pretension of 1 N, mount the test specimen centrally so that the strap center-line passes through the center point of the front edges of the jaws.

C.6 Operate the tensile machine at a constant rate of extension of 200 mm per minute, and record the maximum force required to break off the strap from the mask.

C.7 Repeat the procedure for at least four other specimens randomly selected.

C.8 Report the Arithmetic mean of the maximum force to the nearest 1 N.

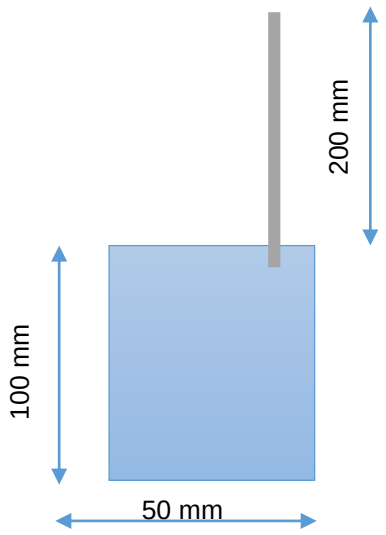


Figure A.1 —Attachment of the strap to test specimen(mask) after cut off

Annex D
(normative)

Microbial cleanliness

D.1 Sampling

Mask samples for testing should be provided in the original primary packaging (dispenser box or an equivalent) as offered to the end user. When 5 samples are selected take the top, bottom and 3 randomly chosen masks. If the mask contains a visor or other accessories it should be included in the testing.

D.2 Testing

Weigh each mask prior to testing. The full mask is aseptically removed from the packaging and placed in a sterile 500 ml-bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl and 2 g/l polysorbate surfactant 20 [e.g. Tween 20, Alkest TW 20]).

The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0.45 µm filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) with chloramphenicol for fungi enumeration. The plates are incubated for 3 days at 30 °C and 7 days at (20 to 25) °C for TSA and SDA plates respectively. An alternative and equivalent extraction method may be used. If this is the case, the chosen extraction method shall be documented in the test report.

The total bioburden is expressed by addition of the TSA and SDA counts.

KS 2923-1:2021