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DRAFT KENYAN STANDARD

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First [Edition]

Personal Protective Equipment - Face Masks – Masks for public use - Requirements and Test Methods

Technical Committee Representation

The following organizations were represented on the Technical Committee

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Association of Medical Engineers of Kenya(AMEK)
Christian Health Association of Kenya(CHAK)
Diverse Management Consultancy Ltd
Equra Health Kenya
Gertrude's Children's Hospital
Jads Diagnostics EA Ltd
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Kenya Accreditation Service (KENAS)
Kenya National Chamber of Commerce and Industry (KNCCI)
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Ministry of Health
Physicist Society of Kenya
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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.

Personal Protective Equipment - Face Masks – Masks for public use - Requirements and Test Methods

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P R E F A C E

This Kenya Standard was prepared by the Technical Committee on Towels, Hygienic and Medical Textile Products under the guidance of the Project Standards Committee and in accordance with standards development procedure.

Kenyans have expressed confusion on whether or not to wear face masks in the advent of the Covid-19 pandemic. Advice on the matter has been inconsistent, with health experts and the World Health Organization earlier advising that people leave the masks to medics and others on the Covid-19 frontline.

However, unfolding research findings points to the contrary. It is now clear that wearing a mask is crucial in protecting oneself from a virus that has infected more than one million people worldwide and killed more than three people in Kenya alone-including a six-year-old. The Ministry of health recently announced that wearing of masks shall be mandatory for all travelers, signaling a major policy shift. This position was also pinned by a meeting convened by the Kenya Bureau of Standards and the Kenya Association of Manufacturers, where a section of participants made very strong case on the use of woven material in the manufacturing of face masks.

Center for Disease Control (CDC), citing new data that shows high rates of transmission from people who are infected but show no symptoms, now advises that the earlier guidance on mask-wearing is “being critically re-reviewed to see if there’s potential additional value for individuals that are infected or individuals that may be asymptomatically infected”.

Kenya’s guidelines are limited to passenger service vehicles, boda-bodas and tuktuks, but it still brings to the public domain a major tool in the war against the coronavirus that has been previously ignored, and which could prove a game changer in the coming days. The current standard, KS 2636 does not address the woven materials and other materials for use by the public inundating the development of this edition.

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

KS 2636, Surgical Masks – Specification
BS EN 14683, Medical face masks – requirements and test methods
ASTM-

Acknowledgement is made for the assistance received from these sources.

KENYAN DRAFT STANDARD

Personal Protective Equipment - Face Masks – Masks for public use - Requirements and Test Methods

1. SCOPE

This Draft Kenya Standard specifies the requirements for masks for general use as prevention of aerosolized emissions from person to person in the general public. A face mask with appropriate microbial barrier can be effective in reducing emission of the infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms.

2. Normative references

The following 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.

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

EN ISO 10993-5, Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity (ISO 10993-5)

EN ISO 10993-10, Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization (ISO 10993-10)

EN ISO 11737-1, Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products (ISO 11737-1)

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
face mask
device covering the mouth and nose providing a barrier to minimize the direct transmission of infective agents between one person and another

Note 1 to entry: Transmission of blood-borne agents from patients to staff may occur via splashes.

3.2
bacterial filtration efficiency (BFE)
efficiency of the medical face mask material(s) as a barrier to bacterial penetration expressed as percentage.

Note 1 to entry: The BFE test method is used to measure the bacterial filtration efficiency (BFE) of medical face mask materials.

3.3
Filter efficiency
The ability of the mask body to filter out particulate matter under specified conditions, expressed as percentage.

3.4differential 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 1 to entry: The differential pressure is an indicator of the "breathability" of the mask.

3.4
colony forming unit (cfu)
unit by which the culturable number of micro-organisms is expressed

Note 1 to entry: The culturable number is the number of micro-organisms, single cells or aggregates, able to form colonies on a solid nutrient medium.

3.5
cleanliness
freedom from unwanted foreign matter

Note 1 to entry: Such matter can be micro-organisms, organic residues or particulate matter.

3.6
infective agent
micro-organism that has been shown to cause surgical wound infections or that might cause infection in the patient, members of staff or other

3.7
Particulate matter
refers to the particulate matters with air dynamics equivalent diameter less than or equal to 2.5 microns in the ambient air.

3.8
aerosol
gaseous suspension of solid and/or liquid particles, the particles having a negligible falling velocity

Note 1 to entry: This velocity is generally considered to be less than 0,25 m/s.

3.9
filter
material used for mechanical and physical separation or deposition of aerosol particles (liquid or solid) from the inhaled and exhaled air

3.10
particle protective performance
The ability of the mask to block particulate matter under specified conditions, expressed as a percentage.

4. Requirements

4.1.1 General
The face mask for general public use shall not disintegrate, split or tear during intended use. In the selection of the filter and layer materials, attention shall be paid to cleanliness (absence of particulate matter).

4.1.2 Visual inspection
The visual inspection shall also include the marking and the information supplied by the manufacturer.

4.1.3 Cleaning and disinfecting

If the particle filtering cloth mask is designed for more than a single shift (i.e. not designed for single use only), the materials used shall withstand the cleaning and disinfecting agents recommended by the manufacturer when tested in accordance with the method decsribed in Annex B.

4.1.4 Design

The face mask for general public use 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.

Face masks shall have different shapes and constructions as shown in figure 1 (a) and (b). They may as well have, as additional features, a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).

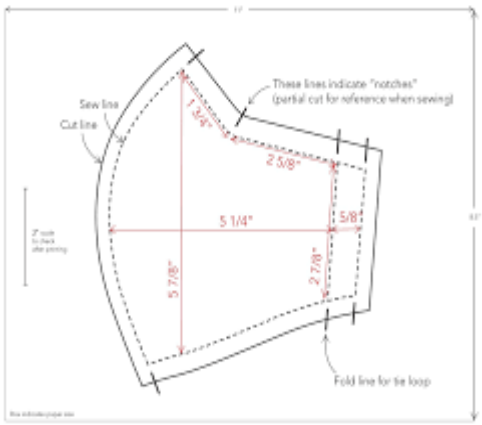


Figure 1 (a)

Figure 1 (b)

4.2 Basic requirements

4.2.1 The mask shall be able to cover mouth and nose safely and firmly.

4.2.2 The mask shall not be made from recycled materials and materials with high toxicity, carcinogenicity, or potentially carcinogenic. They shall also not be made of materials known to cause skin irritation or other adverse reactions. The residues of other restrictions on the material shall comply with the relevant requirements, no odor.

4.2.3 Masks shall not have accessible sharp angle and edges, and shall not cause injury to the wearer.

4.2.4 Masks shall be easy to wear and to remove, have no obvious pressure or complications in the process of wearing, and shall not affect head movements.

4.3 Performance requirements

4.3.1 General

All tests shall be carried out on finished products or samples cut from finished products, if applicable in their sterile or unused state.

4.3.2 Elastic

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

4.3.3 Nose piece (optional)

This, if used, shall be flexible strips of materials of 3 mm and shall enable the mask to take the shape around the nose of wearer.

4.3.5 Breathability – Inhalation resistance and exhalation resistance

When tested in accordance with C, the differential pressure of the medical face mask shall conform to the value given in Table 1.

4.3.4 Filter efficiency

Masks shall have filter efficiency levels of 90 and 80 for salt and oil mediums respectively, when tested in accordance to Annex D

TABLE 1. PERFORMANCE REQUIREMENTS FOR FACE MASK FOR GENERAL PUBLIC USE

Test	Requirement(s)
Decomposable carcinogenic aromatic amine dyes	Shall not be present
Filter Efficiency levels: (%)	
Salt medium	90
Oil medium	80
Breathability - Differential pressure (Pa/cm^2)	≤ 29.4
Breaking strength of mask band at the joint	≤20
Microbial cleanliness (bioburden)(cfu/g)	
Coliforms	Nil
Pathogenic purulent bacteria	Nil
Total fungal colonies /(CFU/g)	≤ 100
Total bacterial colonies /(CFU/g)	≤ 200
Ethylene oxide residues (µg/g)	≤10

4.5 Microbial cleanliness (Bioburden)

When tested according to EN ISO 11737-1 the bioburden of the medical mask shall be as shown in Table 1.

4.7 Dimensions

Dimensions and design for face masks for general public use shall be 17.7 X 9.6 length by width (cm) for adults, and 15 X 8.9 (cm) length by width for children

Note. Any other size shall be as agreed between purchaser and manufacturer.

5 Labelling and information to be supplied

The following information shall be supplied in addition:

a) number of this Kenya Standard;
b) Trade Mark of the mask.
c) Name and physical address of manufacturer
d) Width in centimetres and length in metres.
e) The word ‘Sterilized’, if sterile.

f) Mass of package in kilograms and grams.

6. PACKING

6.1 Face masks shall be individually packed in paper cartons or any other suitable packages such as cellophane or plastic. The packet shall be well closed on both sides and stuck so as to avoid infiltration of any foreign matter into the masks.

ANNEX A
(informative)
Information for users

When breathing, speaking, coughing, sneezing etc., one releases smaller or larger amounts of droplets of secretions from the mucous membranes in the mouth and nose. The majority of the nuclei are between 0,5 µm and 12 µm in diameter and especially the larger droplets can contain micro-organisms from the source site. Nuclei can subsequently spread through the air to a susceptible site such as mouth, eyes and nose or sterile equipment.

The face masks intended to be used in operating rooms and health care settings with similar requirements are designed to protect the entire working environment. This standard, however, describes face masks with associated protection levels. As a minimum, face masks for general public use should protect the general public in order to reduce the risk of the spread of infections, particularly in epidemic or pandemic situations, like the Covid-19.

If the intended use of the mask is to protect the wearer against infective agents (bacteria, viruses or fungi), the use of a respirator device should be considered. Performance requirements for respirators are the scope of EN 149.
The level of efficiency offered by a mask depends on a number of factors such as the filtration efficiency, quality of the material and the fit of the mask on the wearer's face. Different designs are suited for different applications and the careful choice of mask is therefore important in order to achieve the desired result.

The filtration capacity of mask materials can vary depending on the filter media. The fit of masks varies considerably from those which are held in place by ear loops fastened behind the wearer's ears to those with tie bands around the head and a nose clamp that can be shaped to the wearer's nose. The effect of a very good or less good fit can be tested in vivo whereas the filtration efficiency may be reproducibly tested in vitro. The considerable variations in results when masks are tested in vivo results in the need for large groups of test subjects and observations. It is thus usual to characterize mask performance using in vitro tests of the material from which the mask is made. It is, however, important to consider the fit of the mask carefully when a mask for a certain application is chosen. Users should request such information from their suppliers.

A further factor to be considered is the capacity of the mask to absorb moisture from the exhaled air and thereby to maintain its performance over a longer period of time. The more advanced designs easily maintain their performance through longer periods.

The contamination risk resulting from hand contact with a used mask means that it is essential that the mask is taken off and disposed of when no longer worn over nose and mouth. When there is a further need for protection then a new mask should be put on. Touching a used face mask or putting on a new one should always be followed by a full hand disinfection procedure and a used mask should always be disposed of when no longer needed or between two procedures.

In summary, to use an appropriate mask is an effective means to protect the working environment from droplet contamination from nose and throat during public discourse. Masks with very different performance are, however, available. Therefore, such factors as infection risk and mask fit should be carefully considered when choosing a mask.

Annex B
Cleaning and disinfecting
(Normative)

B.1 General

B.1.1 A total of 2 particle filtering half masks shall be tested: both as received.

B.1.2 All tests shall be carried out by two test subjects at ambient temperature and humidity shall be recorded.

B.1.3 Prior to the test there shall be an examination to assure that the particle filtering half mask is in good working condition and that it can be used without hazard.

B.1.4 Examination shall be done in accordance with clause B.1.3.

B.1.5 For the test, persons shall be selected who are familiar with using such or similar equipment.

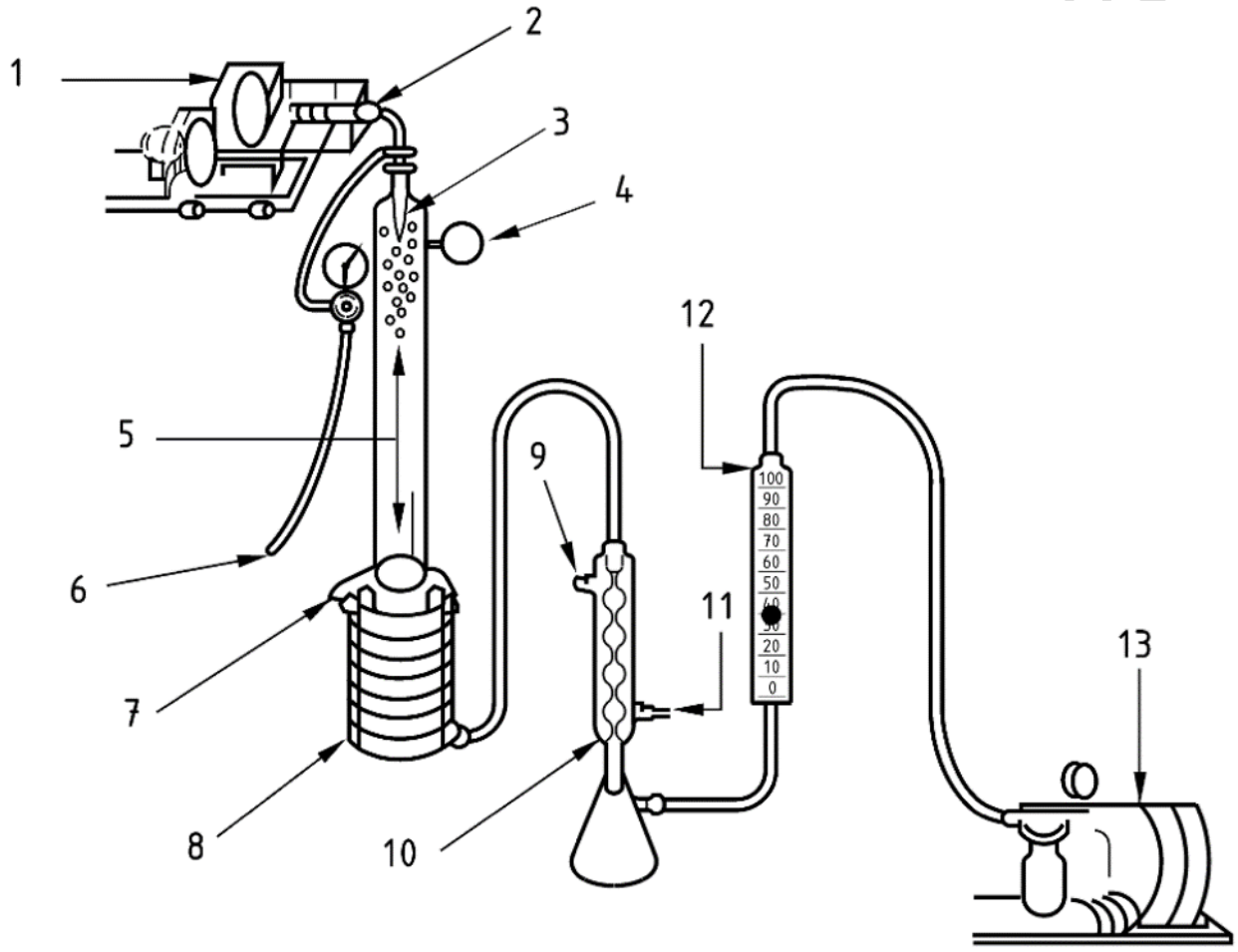
B.1.6 During the tests the face mask shall be subjectively assessed by the wearer and after the test, comments on the following shall be recorded:

a) security of fastenings
c) field vision
d) any other comments reported by the wearer on request.

Annex C
(normative)
Method for determination of breathability (differential pressure)

C.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 C.1. Water-filled manometers (M1 and M2) are used to measure the differential pressure. A flow meter is used for measurement of the airflow. An electric vacuum pump draws air through the apparatus and a needle valve is used to adjust the airflow rate.



Key

1 drive mechanism
2 bacterial suspension
3 nebulizer
4 filter
5 aerosol chamber
6 high pressure air source
7 test material
8 microbial sampler
9 outlet to sink
10 condenser
11 cold water inlet
12 calibrated flow meter
13 compressor (vacuum pump)

Figure C.1 — BFE test apparatus

C.2 Apparatus

C.2.1 Flow meter, capable of measuring an airflow of 8 l/min
C.2.2 Manometers, M1 and M2 or differential manometer
C.2.3 Electric vacuum pump
C.2.4 Valve

C.3 Test specimens

Test specimens are complete masks or shall be cut from masks. Each specimen shall be able to provide 5 different circular test areas of 2,5 cm in diameter. If one specimen cannot provide 5 test areas of 2,5 cm in diameter, the number of test areas retrieved should be representative for the entire 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 of 4 %. All specimens tested shall be taken from areas representative from the mask to incorporate all/any variation in construction.

Each test specimen shall be conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for the time required to bring them into equilibrium with atmosphere prior to testing.

C.4 Procedure

C.4.1 The test specimen is placed across the 2,5 cm diameter orifice (total area 4,9 cm_2) and clamped into place so as to minimize air leaks and that the tested area of the specimen will be in line and across the flow of air.

C.4.2 The pump is started and the flow of air adjusted to 8 l/min.

C.4.3 The manometers M1 and M2 are read and recorded.

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

C.5 Calculation of differential pressure

For each test specimen calculate the differential pressure ΔP as follows:

$$\Delta P = (X_{m1} - X_{m2})/4{,}9$$

where
X_{m1} is pressure in Pa, manometer M1, mean of 5 test areas, low pressure side of the material;
X_{m2} is pressure in Pa, manometer M2, mean of 5 test areas, high pressure side of the material;
4,9 is the cm^2 area of the test material;
ΔP is the differential pressure per cm^2 of test material expressed in Pa.

C.6 Test report

The following information shall be given in the test report:
a) number and date of this Publicly Available Standard;
b) lot number or batch code of the masks tested;
c) flow rate during testing;
d) differential pressure for each test specimen.

Annex D
(normative)
Test for filter efficiency

D.1 Principle
Aerosol particles of a certain concentration and particle size distribution are generated by the aerosol generator, passed through the mask cover at a predetermined gas flow rate. An appropriate particle detector shall be used to detect the particle size through the mask body. The percentage of particle matter reduction before and after the aerosol passed through the body of mask is used to evaluate the filtering efficiency of the mask body.

D.2 Samples and pre-treatment
D.2.1 Sixteen samples are divided into two groups of eight each; One group to be tested in the oil medium while the other is to be tested in salt medium.

D.2.2 Five samples are untreated, while the other three samples are pre-treated as described in D.3.

D.3 Pre-treatment by temperature and humidity
D.3.1.1 Pre-treatment equipment
a) Test Chamber for humidity tests
b) Test Chamber for high/low temperatures

D.4 Method
Take the samples from original package and pre-treat as follows;
a) Keep requisite test samples at 38±2.5 ^{0} C and 85±5 relative humidity for 24±1 hrs
b) Keep designated samples at 70±3 ^{0} C dry environment for 24±1 hrs
Keep designated samples in 30±3 ^{0} C for 24±1 hrs.
Before undertaking any step, ensure that the temperatures of all samples are conditioned at room temperatures. Pre-treated samples shall be placed in closed containers/chambers and tested within 10 hours.

D.5 Equipment
D5.1 Filter efficiency test system for NaCl particles meeting the following requirements;
a) The concentration of NaCl particles are less than 30 mg/m3. The count median diameter (CMD) is (0.075±0.020) μm, and the geometric standard deviation of particle size distribution size is less than 1.86.
b) b) The detected dynamic range of particles is 0.001~100 mg/m3, and the accuracy is 1%.
c) The detected flow range is 30 ~ 100L/min, and the accuracy is 2%.
d) The testing range of Filter efficiency is 0~99.999%.
e) There shall be a neutralized device for neutralizing the charge of particles.

D. 5.2 Filter efficiency testing system for oil particles
The requirements of Filter efficiency test system for oily particles are as following:
a) Test medium is dioctyl sebacate (DEHS) or other applicable oily particles, such as paraffin oil. The particle concentration is less than 30 mg/m3, and the count median diameter (CMD) is (0.185±0.020) μm. The geometric standard deviation of particle size distribution is less than 1.60.
b) The detected dynamic range of particles is 0.001~100 mg/m3, and the accuracy is 1%.
c) The detected flow range is 30 ~ 100L/min, and the accuracy is 2%.
d) The test range of Filter efficiency is 0~99.999%.

D. 6 Test conditions
The test ambient temperature is (25±5) ℃ and the relative humidity is (30±10) %.

A. 7 Test process

a) Test air flowing is (85±4) L/min (the air flowing should be divided equally if adopt multiple filtering element, such as dual filter element. The test flow of each filter element should be (42.5±2) L/min; if the multiple filter element may be used alone, the test shall be applied as single filter element).
b) Adjust Filter efficiency test system and the relevant parameters into test condition.
c) Fix the main body of the mask or filter element to the detection device airtight.
d) Record sample Filter efficiency after test start and the sampling frequency is no less than 1 time/ min. The test shall be continued until particles on mask loaded to 30 mg.

A. 8 Data processing

Take the minimum value in the course of the entire test as the Filter efficiency for the batch of test samples. The value keeps a decimal.