DRAFT TANZANIA STANDARD

Textiles – Surgical face masks – Specification

TANZANIA BUREAU OF STANDARDS

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Foreword

This Draft Tanzania Standard is being prepared by the Hospital Textile Technical Committee, under the supervision of Textiles and Leather Divisional Standards Committee and it is in accordance with the procedures of the Bureau.

In the preparation of this Draft Tanzania Standard assistance was derived from:

IS 16289:2019 *Medical Textiles — Surgical Face Masks — Specification*

BS EN 14683:2014 *Medical face mask - Specifications*

In reporting the results of a test made in accordance with this Draft Tanzania Standard, if the final value, observed or calculated, is to be rounded off, it shall be done in accordance with TZS 4: 1979 *Rounding off numerical values*.

1. SCOPE

This Draft Tanzania Standard specifies the performance requirements, sampling and test methods of surgical face masks intended to limit the transmission of infective agents from staff to patients and (in certain situations) vice-versa during surgical procedures in operating theatres and other health care services such as patient care, with similar requirements.

This Draft Tanzania Standard is not applicable to masks intended exclusively for the personal protection of staff.

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:

TZS 4 *Rounding off numerical values*

TDC 9 (6787) P_1 *Textiles — Method for evaluation of the bacterial filtration efficiency surgical face masks*.

3. TERMS AND DEFINITIONS

For the purpose of this Draft Tanzania Standard, the following definitions shall apply:

3.1 surgical face mask

medical device covering the mouth, nose and chin providing a barrier to minimize the direct transmission of infective agents between staff and patient.

3.2 bacterial filtration efficiency (BFE)

effectiveness of a surgical face mask to filter (prevent passage of) aerosol droplets containing bacteria of specified particle size of 3.0 µm (micron) ± 0.3 µm. This is expressed as a percentage of a quantity that does not pass through the material.

3.3 differential pressure/delta P

pressure drop across a surgical mask under specific conditions of air flow, temperature and humidity. This is an indicator of the breathability of the mask.

3.4 sub-micron particle filtration efficiency (PFE)

effectiveness of a material to filter aerosol droplets containing bacteria of a specified particle size range 0.1 µm. This is expressed as a percentage of a quantity that does not pass through the material.

3.5 fluid/splash resistance

ability of a facemask's material construction to minimize fluids from traveling through the material and potentially coming into contact with the user of the facemask. Fluid resistance helps reduce potential exposure to blood and body fluids caused from splashes, spray or splatter. Resistance to penetration by synthetic blood is indicated as pass/fail at one of three distinct velocities of 80, 120 and 160 mm of Hg. Penetration (visual evidence) of synthetic blood on the side opposite impact results in fail at that pressure. Non-penetration results in a pass.

3.6 colony forming unit (CFU)

particle containing one or more bacterial cells which gives rise to a single bacterial colony on a culture plate.

3.7 infective agent

micro-organism that has shown to cause surgical wound infection or that might cause infection in the patient or in members of the surgical team.

3.8 surgical procedure

surgical intervention penetration skin or mucosa, performed by a surgical team under controlled environmental conditions.

3.9 aerosol

suspension of solid, liquid, or solid and liquid particles in gaseous medium, the particles having a negligible falling velocity, generally considered to be less than 0.25 m/s.

4. REQUIREMENTS

4.1 General

4.1.1 Materials

The surgical face mask (Non-woven fabric) shall be manufactured from polypropylene, polyethylene or cellulosic materials.

4.1.2 Design and construction

The surgical face mask shall have a minimum of three layers; the innermost layer, outermost layer and middle layer. The surgical 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.

4.1.3 Manufacturing

The production of surgical face mask shall be full automated to avoid human intervention and possible contamination.

4.1.4 Dyes and pigments

For dyed or printed fabrics, dyes and pigments used shall not be carcinogenic.

4.2 Performance requirements

The surgical face mask shall not disintegrate or split tear during intended use. The surgical face masks shall conform to the requirements specified in Table 1. The surgical masks have been categorized into three classes based on performance, Class 1, Class 2 and Class 3.

NOTE: Class 3 is splash/fluid resistant.

Table 1: Performance Requirements for Surgical Face Mask

S/N	Characteristics	Requirements			Test methods
		Class 1	Class 2	Class 3	
1.	Bacteria filtration efficiency, %, min.	95	98	98	TDC 9(6787) P_1
2.	Differential pressure, Pa, max.	29.4	29.4	49.0	Annex A
3.	Splash resistance, mm Hg, min.	-	-	120	Annex B
4.	Sub-micron particulate filtration efficiency at 0.1 μ, %, min.	-	-	98	Annex C

5. PACKING AND MARKING

5.1. Packing

The packing of surgical masks shall be done within an air-conditioned and dust free environment directly from the machine into dispenser boxes then outer cartons. The masks should not be packed in poly sacks which do not offer suitable protection against the environment at conditions.

5.2. Marking

Each package of the surgical face mask shall be legibly marked with the following information:

a) Name of the product (i.e. surgical face mask) and class.
b) Manufacturer's name, initials or trade-mark.
c) Month and year of manufacturing and expiry date or batch /lot number; and
d) Number of pieces in a single package.

6. Sampling and criteria for conformity

6.1. Lot

All the surgical face masks of the same grade and material, produced under similar conditions of manufacture shall constitute a lot.

6.1.1. Each lot shall be tested separately for ascertaining the conformity of the lot.
6.1.2. The number of masks to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 2, column3 and column 5 of Table 2.
6.1.3. These face masks shall be selected at random from the lot.

6.2. Number of tests and criteria for conformity

6.2.1. All the face masks selected as per col 3 of Table 2 shall be examined for workmanship and finish (**see 4.1**).

6.2.1.1 Any mask failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements, if the total number of defectives found in the sample is less than or equal to the acceptance number given in column 4 of Table 2. Otherwise, the lot shall be rejected.

6.2.2. Out of the sample already found satisfactory according to **6.2.1.1**, a sub-sample as per column 5 of Table 2 shall be taken. This sub-sample shall be further tested for the remaining requirements.

Table 2: Number of Face Masks to be Selected

S/N	Lot size	Non-destructive testing		Destructive testing	
		No. of masks to be selected	Acceptance number	No. of masks to be selected	Acceptance number
1.	Up to 280	13[1)]	1	8	0
2.	281-500	20	2	8	0
3.	501 to 1200	32	3	13	0
4.	1201 to 3200	50	5	13	0
5.	3201 to 10000	80	7	20	1

1) Or lot size when less than 13.

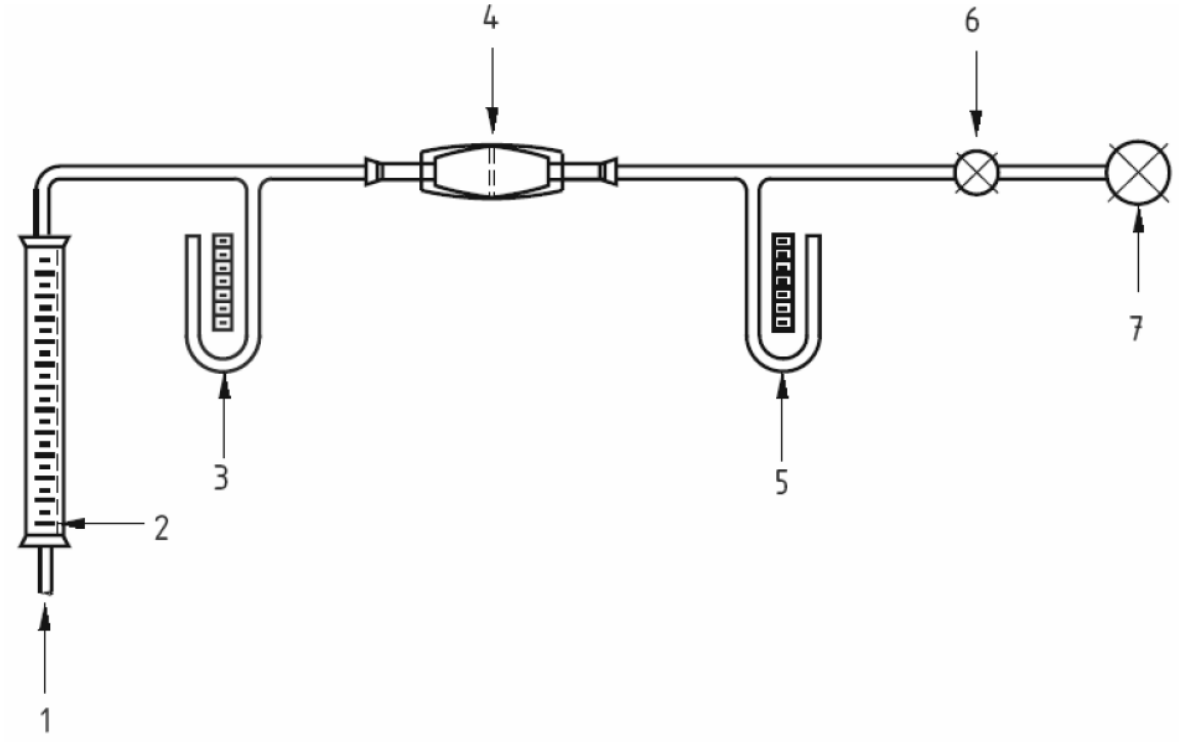
6.2.3. The lot shall be considered as conforming to the requirements of the specification, if the total number of defective masks found in the sample (as per 6.2.2) is less than or equal to the acceptance number as given in col 6 of Table 2.

ANNEX A
(normative)

METHOD FOR DETERMINATION OF BREATHABILITY (DIFFERENTIAL PRESSURE)

A-1 PRINCIPLE

A device which measures the pressure differential 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 surgical mask material, as shown in Fig.1. Water-filled manometers (M1 and M2) are used to measure the pressure differential. A flow meter is used for measurement of the air flow.



KEY

1 – Air inlet
2 – Flow meter
3 – Manometer M1
4 – Filter material
5 – Manometer M2
6 – Valve
7 – Vacuum pump

Figure 1 – Apparatus for measuring air resistance

An electric vacuum pump draws air through the apparatus and a needle valve is used to adjust the air flow rate.

A-2 APPARATUS

A-2.1 Flow Meter, capable of measuring an air flow of 8 litre/min.

A-2.2 Manometers, M1 and M2.

A-2.3 Electric Vacuum Pump

A-2.4 Valve

A-3 TEST SPECIMENS

Test specimens shall be complete masks or shall be cut from masks. Each specimen shall be able to provide five different circular test areas of 2.5 cm in diameter. The number of specimens that shall be tested shall be five.

A-4 PROCEDURE

A-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 that the tested area of the specimen will be in line and across the flow of air.

A-4.2 The pump is started and the flow of air adjusted to 8 litres/minute.

A-4.3 The manometers M1 and M2 are read and recorded.

A-4.4 The procedure described in steps **B-4.1** through **B-4.3** is carried out on five different areas of the mask and the readings averaged.

A-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} = water pressure, in mm, manometer 1, mean of five test areas, low pressure side of the material;

X_{m2} = water pressure, in mm, manometer 2, mean of five test areas, high pressure side of the material;

4.9 = area of the test material, in cm^2; and

ΔP = pressure differential per cm^2 of test material expressed as mm of water.

A-6 TEST REPORT

The test report shall include the following information:

a) Flow rate during testing; and

b) Differential pressure for each test specimen.

ANNEX B
(normative)

METHOD FOR DETERMINATION OF SPLASH RESISTANCE

B-1 PRINCIPLE

A volume of synthetic blood is disbursed at a specimen mask by a pneumatically controlled valve from a set distance at specified pressure to simulate the impact of blood or other body fluid onto the specimen. The velocity and volume of fluid are set to simulate a given health care scenario.

B-2 APPARATUS AND REAGENTS

B-2.1 A suitable test apparatus to dispense a specified volume of synthetic blood through a small diameter cannula (1.27 cm long with an internal diameter of 0.084 cm) over a controlled amount of time at a specimen mask a set distance away. The test apparatus consists of a specimen holding fixture, a targeting plate, a pressurized fluid reservoir, a pneumatically actuated valve with interchangeable cannula and a valve controller. The test apparatus includes a base for more convenient mounting of the components and a hood or other components to contain or control the splash.

B-2.2 Synthetic Blood

B-2.3 Isopropanol, laboratory grade, for cleaning the apparatus.

B-3 TEST SPECIMEN

B-3.1 Use complete surgical face masks as the test specimen. If in the design of a face mask, different materials or thickness of material are specified at different locations, test each area of the specimen separately. If in the design of a surgical face mask, seams are claimed to offer the same protection as the base material, test these areas of the face mask separately.

B-3.2 Prior to test, the specimens shall be conditioned to moisture equilibrium in the standard atmosphere of temperature 27 + 2 °C and relative humidity of 65 + 2 percent. When the test specimens have been exposed to standard atmosphere for at least 6 h in such a way to expose as far as possible, all portions of the specimens to the atmosphere, they shall be deemed to have reached moisture equilibrium.

B-4 PROCEDURE

B-4.1 Place a small droplet (approximately 0.1 ml) of the synthetic blood on the normal inside surface of an extra surgical face mask. The droplet must remain easily visible to ensure that a droplet penetrating the material shall be seen. If not, use talcum powder on the normal inside surface of the surgical face mask to enhance droplet visibility.

B-4.2 Mount a specimen on the specimen holding fixture and position the specimen so that the impact of the synthetic blood occurs in the desired area of the mask. If the mask contains pleats, spread the pleats out when mounting the face mask onto the test fixture to present a single layer of material as the target area. Use the centre of the specimen as the target area. The inside of the mask shall contact the entire perimeter of the viewing hole. The specimen mask shall be supported by the specimen holding form. Remount the specimen mask, if necessary.

B-4.3 Locate the exit of the cannula 30.5 cm from the target area of the specimen mask. Dispense the synthetic blood (approximately 2 ml) at a pressure of 120 mm of Hg onto the specimen surgical face mask. Ensure that the synthetic blood hits the target area of the surgical face mask.

B-4.4 Inspect the viewing side of the specimen for synthetic blood within 10 s of dispensing the synthetic blood against the target area. Using suitable lighting note whether any synthetic blood, or other evidence of wetness, or both appears on the viewing side of the specimen. Use a cotton absorbent

swab or similar item to lightly daub the target area, if doubt exists for visible penetration of the synthetic blood.

B-5 TEST REPORT

Any evidence of synthetic blood penetration on the inner facing of the surgical face mask constitutes a failure at the specified pressure.

ANNEX C
(normative)

METHOD FOR DETERMINATION OF SUB-MICRON PARTICULATE FILTERATION EFFICIENCY

C-1 PRINCIPLE

Filtered and dry air is passed through an atomizer to produce an aerosol containing suspended latex spheres. This aerosol is then passed through a charge neutralizer. The aerosol is then mixed and diluted with additional pre-conditioned air to produce a stable, neutralized and dried aerosol of latex spheres to be used in the efficiency test.

C-2 APPARATUS

Aerosol test system consisting of clean, dry compressed air supply, HEPA filters, aerosol generator, charge neutralizer, humidifier, test filter holder and duct assembly, pressure drop measuring device, air flow rate measuring device, temperature and humidity detectors and optical particle counters.

C-3 TEST SPECIMEN

C-3.1 Prior to test, the specimens shall be conditioned to moisture equilibrium in the standard atmosphere of temperature 27 + 2 °C and relative humidity of 65 + 2 percent. When the test specimens have been exposed to standard atmosphere for at least 6 h in such a way to expose as far as possible, all portions of the specimens to the atmosphere, they shall be deemed to have reached moisture equilibrium.

C-4 TEST PROCEDURE

C-4.1 Set main airflow, dilution airflow and aerosol generator airflow to test conditions. Establish airflow controls at required test face velocities as to have air dilution (drying) for aerosol generation of 2:1 or greater. Purge main airflow for 10 to 15 min. Warm up optical particle counter (OPC) for 15 to 30 minutes. After OPC warm up, check built in calibration signal or OPC output signal on an oscilloscope for stable gain on photomultiplier tube or other optical detectors. Switch the OPC into main airflow and balance OPC airflow against the main airflow. Observe OPC count data.

C-4.2 Set-up the aerosol generator with a nominal volume of the distilled water to be used in the latex dilutions. Without a material specimen in the test system, establish the main system airflow and the OPC sampling airflow for the upstream sampling probe. Sample the upstream and downstream airflow for 1 min each. Verify complete drying of the aerosol droplets by comparing these counts to count obtained in **D-4.1**. Run this drying test for 1 h, sampling every 15 min for upstream and downstream counting and record aerosol stability and system relative humidity. Measure the water consumption of the aerosol generator. Record any dilution airflow and the required air pressure for the aerosol generator.

C-4.3 Fill the aerosol generator with the desired dilution of latex suspension. Without a filter media sample in the test specimen, close the system and establish the required system airflows. Stabilize the system airflow with the aerosol suspension for approximately 5 min, then begin successive 1 min upstream and downstream counts for 15 min or until reproducible counts are established. Verify that counting is within a 10 percent coincidence of the OPC.

C-4.4 Install the material specimen in the test system and re-establish the required airflows. Monitor the OPC airflow and adjust for the added material specimen on the sample flow. Sample and record the upstream and downstream aerosol counts for a minimum of 5 counts at each position using a 1 min sampling time. If the downstream count is less than 100, extend the test until 100 counts are obtained. However, do not count longer than 5 min to avoid the loading the specimen.

C-4.5 Monitor the upstream counts; if these counts fall outside 100 + 1 percent penetration average with a coefficient of variation of 3 percent, stop the test and check the system for aerosol generation instability.

C-5 CALCULATION

Average the upstream counts and the downstream counts, then calculate the decimal efficiency by the following definition:

$$\text{Efficiency} = 1 - \frac{(\text{average downstream counts})}{(\text{average upstream counts})}$$

ANNEX D
(informative)

INFORMATION FOR USERS

D-1 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. Those droplets quickly evaporate and leave nuclei suspended in the air. The majority of the nuclei are between 0.5 µm and 12 µm in diameter and the larger ones can contain micro-organisms from the source site. Nuclei can subsequently spread through the air to a susceptible site such as an open operating wound or sterile equipment.

D-2 The surgical masks intended to be used in operating theatres and health care settings with similar requirements are designed to protect the working environment and not the wearer. When the primary intention is to protect the wearer from infection, the use of other devices should be considered.

D-3 A special case is that in which the wearer wishes to protect himself/herself against splashes of potentially contaminated fluids. For this application this standard specifies performance requirements and gives a test method for a special class of surgical masks offering protection against splashes.

D-4 The degree of protection offered by a mask depends on a number of factors such as the filtration capacity 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.

D-5 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 capacity may be reproducibly tested in vitro.

D-6 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.

D-7 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 throughout even very long operations whereas the less advanced ones are intended only for short procedures. There is no scientific evidence that demonstrates a limitation in wearing time for the advanced surgical masks that are available today.

D-8 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 mask or putting on a new one should always be followed by a full hand disinfection procedure.

D-9 In summary, to use an appropriate mask is an effective means to protect the working environment from droplet contamination from nose and throat during health care procedures. Masks with very different performance are, however, available. Therefore, such factors as infection risk and mask fi should be carefully considered when choosing a mask.