RWANDA STANDARD

RS 433-1

First edition

2020-04-24

Face masks — Specification —

Part 1: Medical masks

ICS 11.140

Reference number

RS 433-1: 2020

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Rwanda Standards Board

P.O Box 7099 Kigali-Rwanda

KK 15 Rd, 49

Tel. +250 788303492

Toll Free: 3250

E-mail: info@rsb.gov.rw

Website: www.rsb.gov.rw

ePortal: www.portal.rsb.gov.rw

Contents

Page

Foreword

Rwanda Standards are prepared by Technical Committees and approved by Rwanda Standards Board (RSB) Board of Directors in accordance with the procedures of RSB, in compliance with Annex 3 of the WTO/TBT agreement on the preparation, adoption and application of standards.

The main task of technical committees is to prepare national standards. Final Draft Rwanda Standards adopted by Technical committees are ratified by members of RSB Board of Directors for publication and gazettment as Rwanda Standards.

RS 433-1 was prepared jointly by Technical Committee RSB/TC 034, *Medical equipment and accessories devices and* RSB/TC 029, *Textile and leather technology*

In the preparation of this standard, reference was made to the following standards

1) ASTM F2100 – 19, *Standard Specification for Performance of Materials Used in Medical Face Masks*

2) KS 2636: 2016, *Surgical masks — Specification*

3) EN 14683:2014, *Medical face masks — Requirements and test methods*

The assistance derived from the above sources is hereby acknowledged with thanks.

RS 433 consists of the following parts, under the general title *Face masks — Specification*:

— *Part 1: Medical masks*

— *Part 2: Barrier masks*

Committee membership

The following organizations were represented on the Technical Committee on *Textile and leather technology* (RSB/TC 029) and *Medical equipment and accessories* (RSB/TC 034) in the preparation of this standard.

Centre Hospitalier Universitaire de Butare (CHUB)

Centre Hospitalier Universitaire de Kigali (CHUK)

Rwanda Military Hospital (RMH)

UTEXRWA Ltd

Dokmai Rwanda Ltd

GLO CREATIONS

LIXIL/SATO

ABAHIZI RWANDA Ltd

Rene Pharmacy

Rwanda Standards Board (RSB) – Secretariat

Face masks — Specification — Part 1: Medical masks

1 Scope

This Rwanda Standard specifies requirements, methods sampling and test for medical face masks intended to limit the transmission of infective agents from staff to patients and vice-versa during surgical procedures and other medical settings with similar requirements.

It covers materials and construction for Type 1, Type 2 and Type 3 medical face masks.

2 Normative references

The following 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.

ASTM 1862, *Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)*

ASTM F 2299, *Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres1*

ASTM F2101, *Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus*

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

ISO 12952-1, *Textiles — Assessment of the ignitability of bedding items — Part 1: Ignition source: smouldering cigarette*

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

ISO 9073-3, *Textiles — Test methods for nonwovens — Part 3: Determination of tensile strength and elongation*

3 Terms and definitions

For the purposes of this standard, the following terms and definitions apply:

3.1

medical face mask

single use medical device covering the mouth and nose providing a layer material barrier to minimise the direct transmission of infective agents between staff and patient or vice versa

NOTE 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 stress and bacterial putrefaction

NOTE The BFE test method is used to measure the bacterial filtration efficiency (BFE) of medical face mask materials

3.3

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

3.5

cleanliness

freedom from unwanted foreign matter

NOTE Such matter can be micro-organisms, organic residues or particulate matter.

3.5.1

microbial cleanliness

freedom from population of viable micro-organisms on a product and/or a package

Note 1 In practical use, microbial cleanliness is often referred to as "bioburden".

3.5.2

particulate matter

particles that are contaminating a material and can be released but are not generated by mechanical impact

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

surgical procedure

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

3.8

aerosol

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

NOTE 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

splash resistance

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

3.11

non-woven

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.

3.12

body fluid stimulant

liquid which is used to act as a model for human body fluids

3.13

flammability

characteristics of a material that pertain to its relative ease of ignition and relative ability to sustain combustion

3.14

penetration

protective clothing material or item, the flow of a chemical on a non-molecular level through closures, porous materials, seams and pinholes or other imperfections in protective clothing

3.15

protective clothing

item of clothing that is specifically designed and constructed for the intended purpose of isolating all or part of the body from a potential hazard; or, isolating the external environment from contamination by the wearer of the clothing

3.16

sub-micron particulate filtration efficiency

efficiency of the filter material in capturing aerosolized particles smaller than one micron, expressed as the percentage of a known number of particles that does not pass the medical face mask material at a given flow rate

3.17

synthetic blood

mixture of a red dye/surfactant, thickening agent, and distilled water having a surface tension and viscosity representative of blood and some other body fluids, and the colour of blood

4 Classification and application

4.1 Medical face masks covered under this standard shall be designated as one of the following types based on the barrier performance properties of the materials in their manufacturing: Type 1 barrier, Type 2 barrier, and Type 3 barrier. They are evaluated for their ability to capture sub-micron particles, resistance to penetration by synthetic blood at the minimum, middle and maximum velocities, respectively specified in ASTM F1862, bacterial filtration efficiency, and differential pressure.

4.2 Medical face masks have different intended applications depending on the level of risk of exposure to contaminated body fluids:

a) **Type 1** – Low risk of exposure; medical face masks used for personal protection in order to reduce the risk of the spread of infections, particularly in epidemic or pandemic situations;

b) **Type 2** – moderate risk of exposure; medical face masks principally intended for use by healthcare professionals in an operating room or other medical settings with similar requirements; and

c) **Type 3** – high risk of exposure; medical face masks used for protection against splashes of potentially contaminated fluids.

5 Requirements

5.1 General requirements

5.1.1 Materials

5.1.1.1 All materials used in the construction of a medical face mask shall be free from latex and glass.

5.1.1.2 The medical face mask shall not disintegrate, split or tear during intended use.

5.1.1.3 In the selection of the filter and layer materials, attention shall be paid to cleanliness (i.e. absence of particulate matter).

5.1.1.4 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.

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

5.1.1.6 There enforcing strip shall be a strip of a synthetic spun bonded material.

5.1.1.7 When provided, the eye shield shall be a clear PVC sheet of thickness 0.1 mm with a light transmittance of at least 89 %.

5.1.2 Construction

5.1.2.1 The medical face mask shall be generally composed of a filter layer that is placed, bonded or moulded between layers of non-woven fabric made of:

a) cotton and polyester;

b) polypropylene and;

c) polyester and polypropylene.

5.1.2.2 The medical face mask shall have 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.

5.1.2.3 Medical face masks may have different shapes and constructions as well as additional features such as an eye shield (to protect the wearer against splashes and droplets).

5.1.2.6 The tape shall be spun bonded polypropylene tape ultrasonically sewn to the mask.

5.1.2.7 The masks shall be made with high quality workmanship throughout and shall be free from defects that affect their appearance, may affect their serviceability (or both), and free from marks spots or stains.

5.2 Specific requirements

5.2.1 Medical face mask material shall comply with the specific requirements given in Table 1 when tested in accordance with test methods specified therein.

5.2.2 When the BFE of a mask consisting 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.

Table 1 — Specific requirements for medical face masks by type

S/N	Parameter		Type 1	Type 2	Type 3	Test Method
i.	Bacterial filtration efficiency (BFE), (%), min.		95	98	98	ASTM F2101
ii.	Differential pressure (Pa/cm^2), max.		40	40	60	Annex A
iii.	Sub-micron particulate filtration efficiency at 0.1 micron, %, min.		95	98	98	ASTM F2299
iv.	Splash resistance*, min.	kPa	8	12	16	ISO 22609
		mm Hg	80	120	160	ASTM 1862
v.	Microbial cleanliness (Bioburden), cfu/g, max.		30	30	30	ISO 11737-1
vi.	Flammability		Class I	Class I	Class I	ISO 12952-1
vii.	The tensile strength of the attaching of the tape to the mask , N, min.		20	20	20	ISO 9073-3

NOTE 1 The level of protection provided by each type of medical face masks depends on several factors not considered in this standard. Examples include facial fit and material degradation from wearer challenges such as perspiration, talking, sneezing, and the length of time the medical face mask is worn etc.

NOTE 2 In general, increasing synthetic blood penetration resistance (and bacterial filtration efficiency and sub-micron particulate filtration efficiency) results in increasing pressure drop or reduction of breathability for medical face masks of the same design

* One of both test method can be used

6 Packaging and labelling

6.1 Packing

6.1.1 Medical face masks shall be packaged in suitable and environmental friendly packaging material, and then packed in suitable containers as to protect them from damage and contamination during shipping, distribution and storage.

6.1.2 Medical face masks shall be packed 50 pieces or 100 pieces per box

6.2 Labelling

6.2.1 Medical face masks

Each medical face mask shall be neatly, legibly, and indelibly marked with the following information:

a) trade mark;

b) description of the material used; and

c) the Type (protection level)

6.2.2 Containers

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

a) manufacturer's name and address;

b) trade mark;

c) type of mask;

d) description of the material used;

e) batch number;

f) manufacture and expiry date;

g) country of origin;

h) number of pieces of medical masks; and

i) illustration of the face mask and how to use and dispose it.

7 Sampling and compliance

7.1 Compliance to the requirements of this Standard shall be done through inspection for freedom from physical damage, packaging and labelling as per the requirements of Clause 6, availability of data on Biocompatibility as per relevant part of ISO 10993-1 and or testing for performance requirements in clause 5.2.

7.2 Random sampling shall be done by drawing the number of face masks relative to the appropriate lot size as specified in Table 2.

Table 2 — Sample sizes

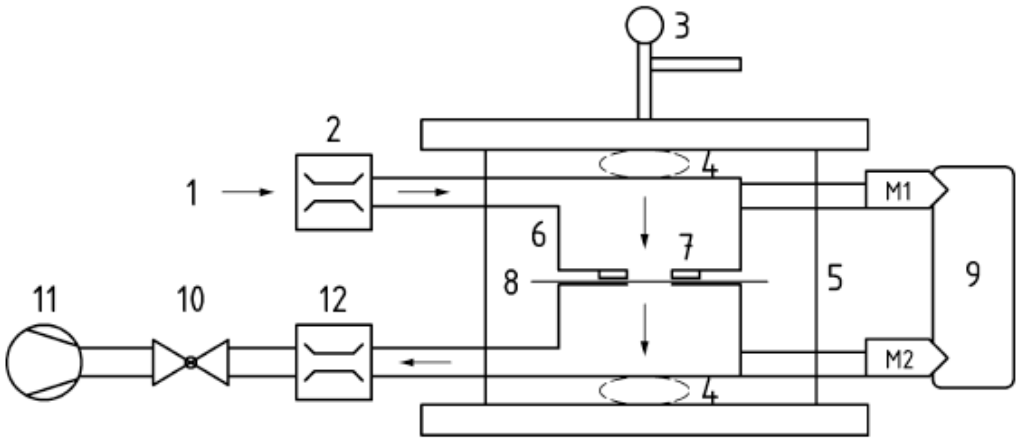
S/N	Lot size	Sample for inspection		Sample for testing	
		Sample size	Maximum number of failure	Sample size	Permissible number of failure
i.	10 - 100	10	None	2	None shall fail
ii.	101 - 500	20	1	5	
iii.	501 - 1000	30	2	8	
iv.	1001 - 1500	40	3	10	
v.	1501 - 2500	55	4	12	
vi.	2501 and above	80	5	14	

Annex A
(normative)

Method for determination of differential pressure (breathability)

A.1 Principle

A.1.1 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 A.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	7	metallic ring (3 mm thick)
2	mass flow meter	8	filter material
3	lever for mechanical clamping	9	differential manometer or M1 and M2 manometers
4	system for final adjustment of the pressure (either at the top or the bottom)	10	valve
5	system ensuring optimal alignment of the 2 parts of the sample holder	11	vacuum pump including a pressure buffer tank
6	sample holder with a metal sealing mechanism	12	mass flow meter for checking leaks (optional)

Figure A.1 — Test apparatus for measuring differential pressure

A.2 Apparatus

A.2.1 Mass flow meter, capable of measuring airflow of 8 l/min

A.2.2 Manometers, 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

A.2.3 Electric vacuum pump including a pressure buffer tank

A.2.4 Valve permitting the adjustment of the flow rate

A.2.5 Sample holder

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

A.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.

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

A.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.

A.2.5.5 Validation of the test apparatus shall consist of a leak test. A second flow meter (12) placed 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 l/min. 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.

A.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.

A.4 Procedure

A.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.

A.4.2 The holder is opened and the test specimen is placed across the 25 mm diameter orifice (total area 4.9 cm2) 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 A.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.

A.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.

A.4.4 The procedure described in steps A.4.1 to A.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.

A.5 Calculation of differential pressure

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

$$\Delta\rho = (\times m1 - \times m2)/4.9$$

where

$\times m1$ is pressure in Pa, manometer M1, mean of 5 test areas, low pressure side of the material;

$\times m2$ is pressure in Pa, manometer M2, mean of 5 test areas, high pressure side of the material;

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

$\Delta\rho$ is the differential pressure per cm^2 of test material expressed in Pa.

A.6 Test report

The following information shall be given in the test report:

a) number and date of this Rwanda Standard;

b) lot number or batch code of the masks tested;

c) flow rate during testing; and

d) differential pressure for each test specimen.

Annex B
(informative)

Note to the users

B.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. The majority of the nuclei are between 0.5 µm and 12 µm in diameter and especially the larger droplets can contain microorganisms from the source site. Nuclei can subsequently spread through the air to a susceptible site such as an open operating wound or sterile equipment.

B.2 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.

B.3 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.

B.4 It is important to consider 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.

B.5 Due to the fact that used masks are considered highly contaminated, it is essential that:

a) The body of the mask is not touched by the fingers/hands of the wearer;

b) Hands are disinfected (full hand disinfection) after mask removal;

c) A mask is worn covering the nose and mouth of the wearer, at no time a mask is hanging around the neck of the wearer;

d) A used mask should be disposed of when no longer needed or between two procedures; when there is a further need for protection a new mask should be put on.

B.6 Information on Barrier cloth masks to be used by general public during pandemic or epidemic period is available in RS 433-2.

Bibliography

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

[2] Council Directive 93/42/EEC of 14 June 1993 *concerning medical devices*

[3] RS 433-2, Face masks — Specification — Part 2: Barrier masks

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