Republic of Rwanda

RWANDA FDA
Rwanda Food and Drugs Authority

RWANDA FDA GUIDELINES ON REQUIREMENTS AND SPECIFICATIONS OF MASKS

April, 2020

Doc. No.: DIS/GDL/027	Revision Date: 13/04/2020	Review Due Date: 13/04/2023
Revision No.: 0	Effective Date: 13/04/2020	

FOREWORD

Rwanda Food and Drugs Authority is a regulatory body established by the Law N° 003/2018 of 09/02/2018 to regulate matters related to quality, safety and efficacy of regulated products including medical devices; specifically in its article 9, where the Authority is given powers to formulate regulations and guidelines for regulating the manufacture, import and export, distribution, sale and use of regulated products.

Based on the available evidence, including the recent publications, WHO continues to recommend droplet and contact precautions for those people caring for COVID-19 patients. WHO continues to recommend airborne precautions for circumstances and settings in which aerosol generating procedures and support treatment are performed, according to risk assessment. Personal protective equipments (PPE) including masks is one of the effective measures within a package of administrative and environmental and engineering controls, as described in WHO's Infection prevention and control of epidemic and pandemic-prone acute respiratory infections in health care.

These guidelines provide guidance on the manufacture of masks in the current health emergency whereby, there is an urgent need of these products to contain the spread of the pandemic. Adherence to these guidelines will ensure the quality standards of masks and Respiratory protective devices on the market during this emergency situation.

Dr. Charles KARANGWA
Ag. Director General

TABLE OF CONTENTS

ABBREVIATIONS AND ACRONYMS

BFE	Bacterial filtration efficiency
cfu	Colony Forming Unit
COVID	Coronavirus virus disease
EN	European Norms
FFP	Filtering Face piece
ISO	International Organization for Standardization)
KS	Kenya Standards
PPE	Personal protective Equipment
PVC	Polyvinyl Chloride
WHO	World Health Organization
SARS	Severe Acute Respiratory Syndrome
US NIOSH	United States *National Institute for Occupational Safety and Health*

1. INTRODUCTION

Rwanda Food and Drugs Authority plays a critical role in protecting public health in Rwanda by ensuring the compliance of quality standard of regulated products including face masks and respiratory protective devices as in the category of medical devices. COVID-19 is currently known to spread through four means: contact (direct or via a fomite); droplet infection (droplets from the respiratory tract of an infected individual during coughing or sneezing are transmitted onto a mucosal surface or conjunctiva of a susceptible individual or environmental surfaces); airborne (transmission of infectious agents in small airborne particles, particularly during procedures such as intubation); and faeco-oral.

Coughing and sneezing can generate aerosol particles and droplets which can be prevented by using appropriate PPE.

WHO recommends among other preventives measures of COVID-19, wearing a medical mask if someone has respiratory symptoms and performing hand hygiene after disposing of the mask. Healthcare providers should specifically wear a medical mask when entering a room where patients with suspected or confirmed COVID-19 are admitted; however, masks and respirators should not be considered as isolated interventions. Other protection measures include hand hygiene, aprons or gowns, goggles or face shields, and gloves;but globally stockpile of PPE is insufficient, particularly for medical masks and respirators. It is in this regard thatRwanda FDA is issuing this guidance to help manufacturers expand the availability of face masks and respiratory protective devices for the general public and medical personel.

1.1. Background

Currently, the outbreak of respiratory disease caused by a novel coronavirus that was first detected in Wuhan City, Hubei Province, China, has also been detected in Rwanda and WHO declared the Coronavirus outbreak (COVID-19) as pandemic.

The virus has been named “SARSCoV-2” and the disease it causes has been named “Coronavirus Disease 2019” (COVID-19). SARS-CoV-2 has demonstrated the capability to rapidly spread, leading to significant impact on healthcare systems and causing societal

disruption and deaths. The potential public health threat posed by COVID-19 is high, both globally and in Rwanda. Different higher institutions have communicated the preventive measures including performing hand hygiene frequently with an alcohol-based handrub or with soap and water; avoiding touching your eyes, nose, and mouth; practicing respiratory hygiene by coughing or sneezing into a bent elbow or tissue and then immediately disposing of the tissue; wearing a medical mask if you have respiratory symptoms and performing hand hygiene after disposing of the mask. Rwanda FDA believes that the current guidelines will help address these urgent public health concerns by clarifying the regulatory landscape of face masks and respirators and facilitating those who want to manufacture these products. This will increase their availability to the general public and healthcare professionals in healthcare settings.

Rwanda FDA issues these guidelines for guiding local manufacturers in manufacturing appropriate masks for prevention of COVID-19.

1.2. Scope of these Guidelines

The scope of these guidelines apply to all applicants intending to manufacture face masks to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements; and as an effective protective measure to reduce the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with or without clinical symptoms during times like now where COVID-19 is widely affecting everyone.

2. NORMATIVE REFERENCES

The following referenced documents are indispensable for the application of this guidelines some 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 and latest edition of the referenced document (including any amendments) applies. All the European

Standardization Organizations (EN) standards are available for free download on its website to help in the Prevention of Covid-19 Contagion**:**

- KS 2636: 2016 : Surgical masks — Specifications
- EN 14683:2019 Medical face masks. Requirements and test methods.
- EN 149:2001+A1:2009 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking

SECTION I: MEDICAL FACE MASKS REQUIREMENTS AND SPECIFICATIONS

MEDICAL FACE MASKS GENERAL REQUIREMENTS

3.1. Definitions

For the purposes of these guidelines, the following definitions shall apply:

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

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

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

3.2 Types of masks

3.2.1 Type 1 mask

Fluid shield mask with or without eye shield

3.2.2 Type 2 mask

Particulate filtration respirator for use by patients with diseases such as tuberculosis

3.2.3 Type 3 mask

Fog free mask for use with spectacles

3.2.4 Type 4 mask

Mask for use by persons with sensitive skin

3.2.5 Type 5 mask

Standard mask

3.3 Material requirements

3.3.1 General

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

3.3.2 Mask layers

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

3.3.3 Tape

The tape shall be spun bonded polypropylene tape ultrasonically sewn to the mask. The tensile strength of the attaching of the tape to the mask shall be at least 20 N

3.3.4 Elastic

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

3.3.5 Nose piece

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

3.3.6 Reinforcing strip

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

3.3.7 Foam strip

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

3.3.8 Eye shield

The eye shield shall be a clear PVC sheet of thickness 0.1 mm with a light transmittance of at least 89 %.

3.3.9 Workmanship

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

3.3.10 Design and size

The mask types 1, 2, 3, 4, and 5 shall be rectangular in shape and shall be of finished width 180 mm and finished depth 95 mm. The masks shall be pleated horizontally and the edges ultrasonically sealed with tape.

3.4 Composition

3.4.1 Type 1 mask

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

3.4.2 Type 2 mask

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

3.4.3 Type 3 mask

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

3.4.4 Type 4 mask

The mask shall be made from the three layers of fabric in accordance with the requirements in Table 1. These layers comprise an outer layer, a filter layer and an absorption layer, in that order. All three layers shall be pleated horizontally with three pleats of finished depth 15 mm and at the front of the mask (the outer layer side) the pleats shall face downwards. The top of the mask shall be bound with tape to a depth of 15 mm, enclosing on the front side, a nose piece. A foam strip shall be attached to the back, across the full width, to the top edge of the mask. The bottom of the mask shall also be bound with tape to a depth of 10 mm. Each side of

the mask shall be bound with tape to a depth of 10 mm and this tape shall then be folded and shall continue in each direction beyond the mask to give a tie of nominal length 380 mm. The binding of the tape to the mask, and the folding of the tape on the free sections shall be ultrasonically sealed.

3.4.5 Type 5 mask

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

Table 1: Material requirements for Medical masks

SL No	1	2	3	4	5	6
	Property	**Requirement**				
		Type of mask				
		Type 1	**Type 2**	**Type 3**	**Type 4**	**Type 5**
i)	**Fibre composition. min.**					
	1st layer (outermost)	Cotton and polyester	Polypropylene	Polypropylene	Cotton and Polyester	Cotton and Polyester
	2nd layer	Polypropylene	Polypropylene	Polypropylene	Polypropylene	Polypropylene
	3rd layer	Polypropylene	Polypropylene	Cotton and polyester	Cotton and polyester	Cotton and polyester
	4th layer	Cotton and polyester	Polyester and Polypropylene			

ii)	**Mass per unit area, g/m2, min.**					
	1st layer (outermost)	19	35	24	20	20
	2nd layer	18	87	22	15	15
	3rd layer	29	32	19	19	19
	4th layer	19	20			
iii)	**Tensile Strength, N min.**					
	1st layer (outermost)	1.7	5.7			
	2nd layer	1.0	3.4	5.4	1.7	1.7
	3rd layer	1.8	1.5	1.0	1.0	1.0
	4th layer	1.9	2.9	1.4	1.4	1.4
iv)	**Absorption rate**, s, min, 1st layer	>60[a]	>60[a]	>60[a]	>60[a]	>60[a]
v)	**Water vapour transfer**, g/m2/24h, min.	3767[b]	4040[b]	3872[b]	3767[b]	3767[b]
vi)	**Penetration**, %, min.	30	4	24	26	26
vii)	**Differential pressure**, Pa, min.	56	357	40	30	35
viii)	**Aerosolized bacterial filtration efficiency**, %, min.	98	98	98	98	98

A:Sample does not absorb water.
B:Tested as a composite.

4. MEDICAL MASKS SPECIFICATIONS

4.1 .Introduction

The transmission of infective agents during surgical procedures in operating theatres and other medical settings can occur in several ways. Sources are, for example, the noses and mouths of members of the surgical team. The main intended use of medical face masks is to protect the patient from infective agents and, additionally, in certain circumstances to protect the wearer against splashes of potentially contaminated liquids. Medical face masks may also be intended to be worn by patients and other persons to reduce the risk of spread of infections, particularly in epidemic or pandemic situations A medical face mask with an appropriate microbial barrier can also be effective in reducing the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms.

4.2. Classification

Medical face masks specified in these guidelines 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.

4.3 Materials and 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.

4.4 Design

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. Medical face masks may have different shapes and constructions as well as additional features such as 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).

4. 5 Performance requirements

4.5.1 General

All tests shall be carried out on finished products or samples cut from finished products.

4.5.2 Bacterial filtration efficiency (BFE)

When tested in accordance with Annex B of EN 14683, the BFE of the medical face mask shall conform to the minimum value given for the relevant type in Table 1. 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. 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.

4. 5.3 Breathability

When tested in accordance with Annex C of EN 14683, the differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1. If the use of a respiratory protective device as face mask is required in an operating theatre and/or other medical settings, it might not fulfil the performance requirements with regard to differential pressure as defined in this guideline . In such case, the device should fulfil the requirement as specified in EN 149:2001 Respiratory protective devices — Filtering half masks to protect against particles-Requirements, testing, marking

4. 5.4 Splash resistance

When tested in accordance with ISO 22609:2004 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given in Table 2

4.5. 5 Microbial cleanliness (Bioburden)

When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ≤ 30 CFU/g tested (see Table 2).

Table 2: Summary of performance requirements

Test	Type I a	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure(Pa/cm2)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 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.			

4.6 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 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. The medical face masks intended to be used in operating rooms and health care settings with similar requirements are designed to protect the entire working environment. These Guidelines describes two types of medical face masks with associated protection levels. As a minimum, Type I medical face masks are used for patients in order to reduce the risk of the spread of infections, particularly in epidemic or pandemic situations. Type II masks are principally intended for use by healthcare professionals in an operating room or other medical settings with similar requirements. A special case, also covered is that in which the wearer wishes to protect him/herself against splashes of potentially contaminated fluids.

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 is applicable in accordance with the Personal Protective Equipment (PPE), 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.

It is 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.

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.

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

- The body of the mask is not touched by the fingers/hands of the wearer;
- Hands are disinfected (full hand disinfection) after mask removal;
- 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;
- 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.

SECTION II: REQUIREMENTS FOR RESPIRATORY PROTECTIVE DEVICES FILTERING HALF MASKS TO PROTECT AGAINST PARTICLES

5.1 Introduction

These guidelines specify minimum requirements for filtering half masks as respiratory protective devices to protect against particles except for escape purposes

5.2. Description

A particle filtering half mask covers the nose and mouth and the chin and may have inhalation and/or exhalation valve(s). The half mask consists entirely or substantially of filter material or comprises a facepiece in which the main filter(s) form an inseparable part of the device. It is intended to provide adequate sealing on the face of the wearer against the ambient atmosphere, when the skin is dry or moist and when the head is moved. Air enters the particle filtering half mask and passes directly to the nose and mouth area of the facepiece or, via an inhalation valve(s) if fitted. The exhaled air flows through the filter material and/or an exhalation valve (if fitted) directly to the ambient atmosphere. These devices are designed to protect against both solid and liquid aerosols.

5.3. Classification

Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage. There are three classes of devices: FFP1, FFP2 or "N95" respirator according to US NIOSH, or "FFP2" according to EN 149 and FFP3.

The protection provided by an FFP2 or FFP3 device includes that provided by the device of lower class or classes. In addition, particle filtering half masks are classified as single shift use only or as re-usable (more than one shift)

5.4. Requirements

5.4.1 Nominal values and tolerances

Unless otherwise specified, the values stated in these guidelines are expressed as nominal values. Except for temperature limits, values which are not stated as maxima or minima shall be subject to a tolerance of ± 5 %. Unless otherwise specified, the ambient temperature for testing shall be (16 - 32) °C, and the temperature limits shall be subject to an accuracy of ± 1 °C.

5.4.2 Visual inspection

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

5.4.3 Material

Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used. After undergoing the conditioning described in EN 149 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer

5.4.4 Cleaning and disinfecting

If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. With reference to EN 149:2001, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.

5.4.5 Practical performance and Specifications

The particle filtering half mask shall undergo practical performance tests under realistic conditions.These general tests serve the purpose of checking the equipment for imperfections

that cannot be determined by the tests described elsewhere in these guidelines. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections.

5.4.6 Finish of parts

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.

5.5. Leakage

5.5.1 Total inward leakage

The laboratory tests in accordance with EN 149 shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected. The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration. For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than: 25 % for FFP1, 11 % for FFP2/N95 and 5 % for FFP3 and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 22 % for FFP1, 8 % for FFP2/N95 and 2 % for FFP3.

5.5.2 Penetration of filter material

The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 3.

Table 3: Penetration of filter material

Classification	**Maximum penetration of test aerosol**	
	Sodium chloride test 95 l/min Paraffin oil test 95 l/min % max.	Paraffin oil test 95 l/min % max.
FFP1	20	20

FFP2/N95	6	6
FFP3	1	1

A total of 9 samples of particle filtering half masks shall be tested for each aerosol. Three samples as received and 3 samples after the simulated wearing treatment described in EN 149. Testing in accordance using the exposure test with a specified mass of test aerosol of 120 mg, and for particle filtering devices claimed to be re-usable additionally the storage test, according to EN 13274-7, shall be performed:

- for non-re-usable devices on: 3 samples after the test for mechanical strength followed by temperature conditioning in accordance with EN 149,
- for re-usable devices on: 3 samples after the test for mechanical strength followed by temperature conditioning and followed by one cleaning and disinfecting cycle according to the manufacturer's instruction

5.6. Compatibility with skin

Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.

5.7. Flammability

The material used shall not present a danger for the wearer and shall not be of highly flammable nature. When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 seconds after removal from the flame. The particle filtering half mask does not have to be usable after the test.

5.8. Carbon dioxide content of the inhalation air

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume) when tested in accordance with EN 149

5.9. Head harness

The head harness shall be designed so that the particle filtering half mask can be donned and removed easily. The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.

5.10. Exhalation valve(s)

A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations. If an exhalation valve is provided, it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask. Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s. When the exhalation valve housing is attached to the face blank, it shall withstand axially a tensile force of 10 N applied for 10 s.

5.11.Breathing resistance

The breathing resistances apply to valved and valveless particle filtering half masks and shall meet the requirements of Table 4. Testing shall be done in accordance with EN 149

Table 4: Breathing resistance

Classification	**Maximum permitted resistance (mbar)**		
	inhalation		**exhalation**
	30 l/min	95 l/min	160 l/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

5.12. Clogging

For single shift use devices, the clogging test is an optional test. For re-usable devices the test is mandatory. Devices designed to be resistant to clogging, shown by a slow increase of breathing resistance when loaded with dust, shall be subjected to the treatment described in EN 149. The specified breathing resistances shall not be exceeded before the required dust load of 833 mg•h/m3 is reached.

5.13.Breathing resistance

5.13.1. Valved particle filtering half masks

After clogging the inhalation resistances shall not exceed at 95 l/min continuous flow; FFP1: 4 mbar FFP2/N95: 5 mbar and FFP3: 7 mbar. The exhalation resistance shall not exceed 3 mbar at 160 l/min continuous flow.

5.13.2. Valveless particle filtering half masks

After clogging the inhalation and exhalation resistances shall not exceed, at 95 l/min continuous flow:

- FFP1: 3 mbar,
- FFP2/N95: 4 mbar and
- FFP3: 5 mbar

5.13.3. Penetration of filter material

All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements given in EN 149 for the Penetration test according to EN 13274-7, after the clogging treatment.

5.13.4. Demountable parts

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand. Summary of requirements and test is available in EN 149:2001 +A1:2009 Respiratory

protective Devices Filtering half masks to protect against Particles-Requirements, testing, marking available *for* free download *on EN website*

6. PACKAGING

The following packaging requirements shall apply for masks:

a) Masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use
b) The pack shall be free of contaminants.

7. LABELLING

The following labelling requirements shall apply for the surgical masks:

a. Labeling shall be legible.
b. Labeling shall be in officially recognized languages as Rwandan constitution, imprinted in indelible ink with bold block letters.
c. Labeling shall have the manufacturers name and address.
d. Labeling shall have the date of manufacturing and expiry date.
e. Labeling shall have the country of origin stated clearly.
f. Each box and carton shall be clearly labelled with the name and characteristics (type) of the article and production batch number.
g. Each box & carton shall indicate number of units per carton and weight.
h. The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then:
    1. "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or
    2. "R" if the particle filtering half mask is re-usable or types (Type I and Type II) according to bacterial filtration efficiency for medical masks
i. The manufacturer's recommended conditions of storage (at least the temperature and humidity

8. REFERENCES

1. Rational use of PPE for COVID-19. https://apps.who.int/iris/bitstream/handle/10665/331498/WHO-2019-nCoV-IPCPPE_use-2020.2eng.pdf.
2. WHO, Requirements and technical specifications of personal protective equipment (PPE) for the novel coronavirus (2019-ncov) in healthcare settings, 2020 , accessible on https://iris.paho.org/bitstream/handle/10665.2/51906/requirements-%20PPE-coronavirus-eng.pdf?sequence=1&isAllowed=y
3. Oxford COVID-19 Evidence Service, What is the efficacy of standard face masks compared to respirator masks in preventing COVID type respiratory illnesses in primary care staff?, 2020 accessible on https://www.cebm.net/wp-content/uploads/2020/03/COVID-CAT-PPE-MASKS-7.pdf
4. US FDA Policy for Face Masks and Respirators in COVID-19 (2020) accessible on https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health
5. Kenya standard Board ,*KS 2636: 2016 : Surgical masks — Specifications*
6. BS EN 14683:2019 Medical face masks. Requirements and test methods.
7. BS EN 149:2001+A1:2009 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking