



**RWANDA FDA GUIDANCE ON MANUFACTURING AND USE OF BARRIER MASKS**

**RWANDA FDA**  
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Rwanda Food and Drugs Authority

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## FOREWORD

The “Barrier Masks” are devices intended to complement protective measures put in place for general public and in particular any healthy or asymptomatic person.

The barrier mask is in no way exonerating the user from routine application of the protective measures, which are essential, and of the social distancing requirements. The Barrier masks are not intended to be used by health care providers in contact with patients or other persons in zone at high risk of contamination.

Medical /Surgical face masks and Respiratory protective devices (FFP) are used by health care other persons in zone at high risk of contamination. This guidance is issued in reference to the WHO interim guidance dated 5<sup>th</sup> June 2020 on the use of masks in context of COVID-19

Barrier mask is not a medical device in reference to the provision of the article 4 of the law N° 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority and guidelines DIS/GDC/001 on requirements and specifications of masks. Barrier masks may offer limited protection against droplets and general public must take caution that barrier masks do not guarantee protection against COVID-19.

The Authority provides guidance on the manufacture of barrier masks in the current health emergency of COVID-19 pandemic.

  
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## **SCOPE OF THE GUIDANCE**

A barrier mask is intended for use by healthy people not presenting any clinical symptom of viral infection and not in contact with people presenting such symptoms.

Wearing of the mask is restricted to half a day and constitutes a protective barrier against possible penetration of the virus in the user's mouth and nose area or from a nearby person intended to protect this area against any contact with the hands.

Use of the barrier mask is envisaged for example for a person leaving their home to go to their place of work or to shop for essential items in authorized establishments. Barrier masks can contribute to the protection of a whole group wearing them limited protection against the only at limited protection against the claimed risk.

This document specifies the minimum requirements for the manufacture, design, performance, features of non medical masks including filtration efficiency (FE), or filtration, breathability, number and combination of material used, shape, coating and maintenance of barrier masks.



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## **INTRODUCTION**

Knowledge about transmission of the COVID-19 virus is accumulating every day. COVID-19 is primarily a respiratory disease and the spectrum of infection with this virus can range from people with very mild, non-respiratory symptoms to severe acute respiratory illness, sepsis with organ dysfunction and death. Some people infected have reported no symptoms at all.

According to the current evidence, COVID-19 virus is primarily transmitted between people via respiratory droplets and contact routes. Droplet transmission occurs when a person is in close contact (within 1 metre) with an infected person and exposure to potentially infective respiratory droplets occurs through coughing, sneezing or very close personal contact resulting in the inoculation of entry portals such as the mouth, nose or conjunctivae.

The use of masks is part of a comprehensive package of the prevention and control measures that can limit the spread of certain respiratory viral diseases, including COVID-19. Masks can be used either for protection of healthy persons (worn to protect oneself when in contact with an infected individual) or for source control (worn by an infected individual to prevent onward transmission)

WHO interim guidance recommended the use of non medical masks by general public in different circumstances such as areas with known or suspected widespread transmission and limited.

Non-medical (also referred to as “fabric” in this document) masks are made from a variety of woven and non-woven fabrics, such as polypropylene. They may be made of different combinations of fabrics, layering sequences and available in diverse shapes. The unlimited combination of fabrics and materials results in variable filtration and breathability.

This guidance is reviewed with inputs from the WHO interim guidance on the use of masks in context of COVID-19



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## 1. Terms and Definition

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

### **Exhaled air**

Air breathed out by the wearer

### **Inhaled air**

Air breathed in by the wearer

### **Head harness**

Means of holding a barrier mask in place on the head

### **Barrier mask or non medical mask**

Face piece covering the mouth, nose and chin fitted with a head harness

### **Breathing resistance**

Resistance of a barrier mask to the flow of air inhaled (inhalation resistance) or exhaled (exhalation resistance)

### **Breathability**

Breathability is the ability to breathe through the material of the mask. Breathability is the difference in pressure across the mask and is reported in millibars (mbar) or Pascals (Pa) or, for an area of mask, over a square centimeter (mbar/cm<sup>2</sup> or Pa/cm<sup>2</sup>).

### **Exhalation valve**

Non-return valve which allows the escape of exhaled air from the face piece

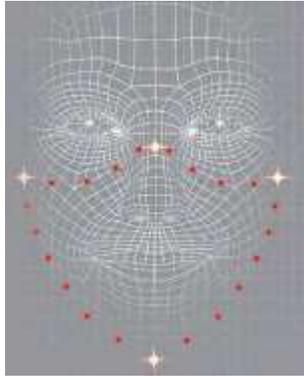
### **Inhalation valve**

Non-return valve which allows breathable gas to enter the face piece and prevents exhaled air from leaving via the inlet path

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## 2. Description

A barrier mask covers the nose, mouth and chin (protection area see Figure 1) and shall not incorporate any exhalation and/or inhalation valve(s).



**Figure 1 — The barrier mask's protection area**

The barrier mask is a multi-layer composite made of fabrics (nonwoven, woven, knit) with or without film. It has a device for adjustment on the user's head (head harness).

It shall be able to be adjusted to fit closely over the nose, cheeks and chin of the wearer to ensure sufficient sealing of the user's face against the ambient atmosphere, when the user's skin is dry or damp or when the user moves his/her head.

Inhaled air mostly penetrates the barrier mask through the multi-layer composite and arrives directly in the region of the nose and mouth. Exhaled air is discharged via the same route directly into the ambient atmosphere.

## 3. Requirements

### 3.1. Visual inspection

Visual inspection of the mask or of its components and verification of the corresponding technical documents shall be carried out.

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### 3.2. Dimensions

The barrier mask against COVID-19 shall be sized in such a way as to correspond to the average morphology of the target Rwandan population.

The proposed dimensions are based on certain anthropomorphic data in ISO/TS 16976-2:2015 “Respiratory protective devices - Human factors - Part 2: Anthropometrics”.

### 3.3. Packaging

The barrier masks shall be packaged in such a way as to protect them against any mechanical damage and any contamination before use. Individual or grouped packaging solutions are at the manufacturer's discretion.

### 3.4. Materials

The materials used shall be able to withstand handling and wear throughout the lifetime of the barrier mask, indicated by the manufacturer.

There is a list of recommended materials for making the barrier mask in Annex A. The source making claims about performances is given.

- a. Type of materials: filtration efficiency (FE), breathability of single layers of materials, filter quality factor*

The selection of material is an important first step as the filtration (barrier) and breathability varies depending on the fabric. Filtration efficiency is dependent on the tightness of the weave, fibre or thread diameter, and, in the case of non-woven materials, the manufacturing process (spunbond, meltblown, electrostatic charging). The filtration of cloth fabrics and masks has been shown to vary between 0.7% and 60%. The higher the filtration efficiency the more of a barrier provided by the fabric.

It is restricted to select elastic material for making masks; during wear, the mask material may be stretched over the face, resulting in increased pore size and lower filtration efficiency throughout

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use. Also, elastic materials may degrade over time and are sensitive to washing at high temperatures.

***b. Number of layers***

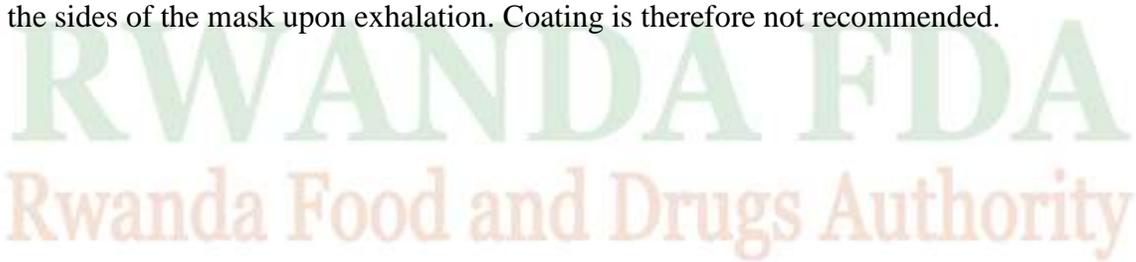
A minimum of three layers is required for non-medical masks, depending on the fabric used. The innermost layer of the mask is in contact with the wearer's face. The outermost layer is exposed to the environment. Fabric cloths (e.g., nylon blends and 100% polyester). It is important to note that with more tightly woven materials, as the number of layers increases, the breathability may be reduced. A quick check for breathability may be performed by attempting to breathe, through the mouth, and through the multiple layers.

***c. Combination of material used***

The ideal combination of material for non-medical masks should include three layers as follows: 1) an innermost layer of a hydrophilic material (e.g. cotton or cotton blends); 2), an outermost layer made of hydrophobic material (e.g., polypropylene, polyester, or their blends) which may limit external contamination from penetration through to the wearer's nose and mouth; 3) a middle hydrophobic layer of synthetic non-woven material such as polypropylene or a cotton layer which may enhance filtration or retain droplets.

***d. Coating of fabric***

Coating the fabric with compounds like wax may increase the barrier and render the mask fluid resistant; however, such coatings may inadvertently completely block the pores and make the mask difficult to breathe through. In addition to decreased breathability unfiltered air may more likely escape the sides of the mask upon exhalation. Coating is therefore not recommended.



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### 3.5. Cleaning and drying

The barrier mask is designed to be reusable; the materials used shall withstand the cleaning and drying products

### 3.6. Surface condition of the parts

The parts of the barrier mask likely to be in contact with the user shall be free of sharp edges and burrs.

### 3.7. Penetration of the multi-layer composite

Penetration of the barrier mask shall have either a filtering capacity of 70% for solid particles or for liquid particles (droplets). The retention efficiency applies to masks that have undergone the number of washes indicated by the manufacturer.

### 3.8. Harmlessness as regards the skin and inhaled air

Materials that may come into contact with the user's skin shall not present known risks of irritation or adverse effects on health.

Materials that may release irritating substances into the inhaled air shall not constitute a hazard or nuisance for the user.

### 3.9. Head harness

The head harness shall be designed such that the barrier mask can be easily put on and removed.

It shall be sufficiently robust to hold the barrier mask in place in such a way as to avoid excessive tightness and discomfort when worn.

The head harness can go around the user's head or ears.

It can be made using an elastic strip or a fabric tie of the bias tape-type or other type, attached to the multi-layer composite. It can be sewn or welded. Other attachment methods are permitted.

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**NOTE :**Use of staples can constitute a hazard or nuisance to the user.

### **3.10. Breathing resistance**

The material used for the barrier mask shall not present inhalation resistance.

## **4. Specific requirements for serial manufacture**

### **4.1. Cleaning and drying**

It is recommended that the barrier mask withstands at least 5 wash cycles. The full wash cycle (wetting, washing, rinsing) shall be at least 30 minutes (laundry or other) with a wash temperature of 60°C where applicable and using appropriate products.

## **5. Specific requirements for artisanal making**

### **5.1. Cleaning and drying**

The barrier mask is designed to be reusable; the materials used shall withstand the cleaning products and methods specified by the manufacturer of the multi-layer composite.

It is not recommended to use specific products other than those normally used for washing without being certain beforehand that they are non-toxic in terms of inhaled residues, and that their use does not damage the materials. The full wash cycle (wetting, washing, rinsing) shall be at least 30 minutes with a wash temperature of 60°C where applicable.

## **6. Inspection**

### **6.1. Visual inspection**

Visual inspection is carried out by the manufacturer or test laboratory on brand new samples.

### **6.2. Head harness strength test**

Verification of the tensile strength of the head harness is done by putting on and removing the barrier mask 5 times.

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## 7. Making of barrier masks

### 7.1. General

The dimensions and shape of the pieces of the multi-layer composite shall be designed such that on completion of assembly with the head harness (and if applicable the nose bridge), the barrier mask can be adjusted to the user's morphology.

At the time of making, the hygiene conditions shall be controlled such as to reduce risks of contamination. The hygiene conditions are at the manufacturer's discretion.

Making shall be followed by cleaning of the barrier masks before packaging and before use.

## 8. Labelling instructions

The barrier masks shall be clearly and durably marked on the smallest marketable package available or shall be legible through the packaging if the packaging is transparent.

- a) The name, trademark or any other means of identification of the manufacturer or supplier.
- b) The number of this document and the visible wording "Barrier mask".
- c) The recommended period of use for the barrier mask.
- d) The cleaning instructions (number of washes, washing and drying method).
- e) The following instruction : "This device is not a medical device"
- f) A pictogram of how to put the barrier mask in place may be substituted for the instructions.

## 9. Use of a barrier mask

### 9.1. General

The barrier mask does not exempt the user from application of other protective measures put in place for general public.

### 9.2. Putting on a barrier mask

To be effective, the barrier mask must be used correctly. For this, it is recommended to wear the mask on bare skin (in other words without the presence of hair in contact with the user's skin and, for certain people, a shaven skin) and to comply with the following steps:

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- a) Wash your hands with soap and water or rub with a alcoholic based hand sanitizer before any handling of the mask;



- b) For reuse of the mask, ensure that it has been properly washed as recommended



- c) Locate the top of the mask;
- d) Place the barrier mask on the face, with the nose bridge (if it exists) on the nose;
- e) Hold the barrier mask on the outside and pass the elastics strips or fabric ties of the head harness behind the head, at either side of the ears, without crossing them;
- f) Pull down the bottom of the barrier mask under the chin;
- g) Check that the mask covers the chin properly;
- h) Pinch the nose bridge (if it exists) with both hands to adjust it over the nose;
- i) Check that the barrier mask is correctly positioned. This should be done by checking the sealing and that there is no breathing discomfort. To verify sealing, cover the mask with a plastic film and when inhaling, the mask should flatten against the face;

**WARNING** Use of a plastic bag for verification purpose is definitely excluded.

- j) Once adjusted, no longer touch the face mask with the hands. Each time the barrier mask is touched, the user must wash the hands with soap and water or rub with a hydroalcoholic solution;

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## 10. Removing a barrier mask

In order not be contaminated when removing a barrier mask, it must be correctly removed and isolated, either to be thrown away, or to be washed. For this, the recommendations are:

- a) If wearing protective gloves, it is necessary to first remove them;
- b) Wash your hands with soap and water or rub with a alcoholic hand sanitizer;
- c) Remove the barrier mask by holding the back of the elastic strips of the head harness without touching the front part of the barrier mask;
- d) Place a barrier mask to be thrown away in a designated container;
- e) Place a barrier mask to be washed in a designated container (clean plastic bag);
- f) Wash your hands with soap and water or rub with a alcoholic hand sanitizer;
- g) Clean the outside of the specific container with a cleaning product;

## 11. Period of use of the barrier mask

The barrier mask must be washed each time it is dirty, wet or poorly positioned on the face. It should not be put in a waiting position on the forehead or under the chin during and after use

The wearing period shall be compliant with the instructions for use if they exist. In all cases, it shall be less than 6 hours over a single day (equivalent to half a day)

### Mask maintenance

Masks should only be used by one person and should not be shared. All masks should be changed if wet or visibly soiled; a wet mask should not be worn for an extended period of time. Remove the mask without touching the front of the mask, do not touch the eyes or mouth after mask removal. Either discard the mask or place it in a sealable bag where it is kept until it can be washed and cleaned. Perform hand hygiene immediately afterwards. Non-medical masks should be washed frequently and handled carefully, so as not to contaminate other items.

If the layers of fabrics look noticeably worn out, discard the mask.

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Table Summary guidance and practical considerations for non-medical mask production and management

<b>Guidance and practical considerations</b>
<b>Fabric selection:</b>
Choose materials that capture particles and droplets but remain easy to breathe through.
Avoid stretchy material for making masks as they provide lower filtration efficiency during use and are sensitive to washing at high temperatures.
Fabrics that can support high temperatures (60° or more) are preferable.
<b>Construction:</b>
A minimum of three layers is required, depending on the fabric used: an inner layer touching the mouth and an outer layer that is exposed to the environment.
Choose water-absorbing (hydrophilic) materials or fabrics for the internal layers, to readily absorb droplets, combined with an external synthetic material that does not easily absorb liquid (hydrophobic).
<b>Mask management:</b>
Masks should only be used by one person.
All masks should be changed if soiled or wet; a soiled or wet mask should not be worn for an extended period of time.
Non-medical masks should be washed frequently and handled carefully, so as not to contaminate other items.
Clothing fabrics used to make masks should be checked for the highest permitted washing temperature, which is indicated on the clothing label.
Non-woven polypropylene (PP) spunbond may be washed at high temperature, up to 140°C.
The combination of non-woven PP spunbond and cotton can tolerate high temperatures;

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masks made of these combinations may be steamed or boiled.

Where hot water is not available, wash mask with soap/detergent at room temperature water, followed by either i) boiling mask for one minute OR ii) soak mask in 0.1% chlorine for one minute then thoroughly rinse mask with room temperature water, to avoid any toxic residual of chlorine.

**Annex A: Recommended List of materials to be used**

	Single layer or multi-layer composite				Comment
	Structure	Name	Composition	Basis weight	
1	Interlock knit			150	
	Membrane	Nano membrane		30	
	Interlock knit			150	
2	Woven, plain weave		Cotton	150	
	Nonwoven		Viscose	130	
	Woven, plain weave		Cotton	150	
3		Microfibre		100	

		Polycotton	Cotton, polyester		
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Rwanda FDA Guidance on Manufacturing and Use of Barrier Masks

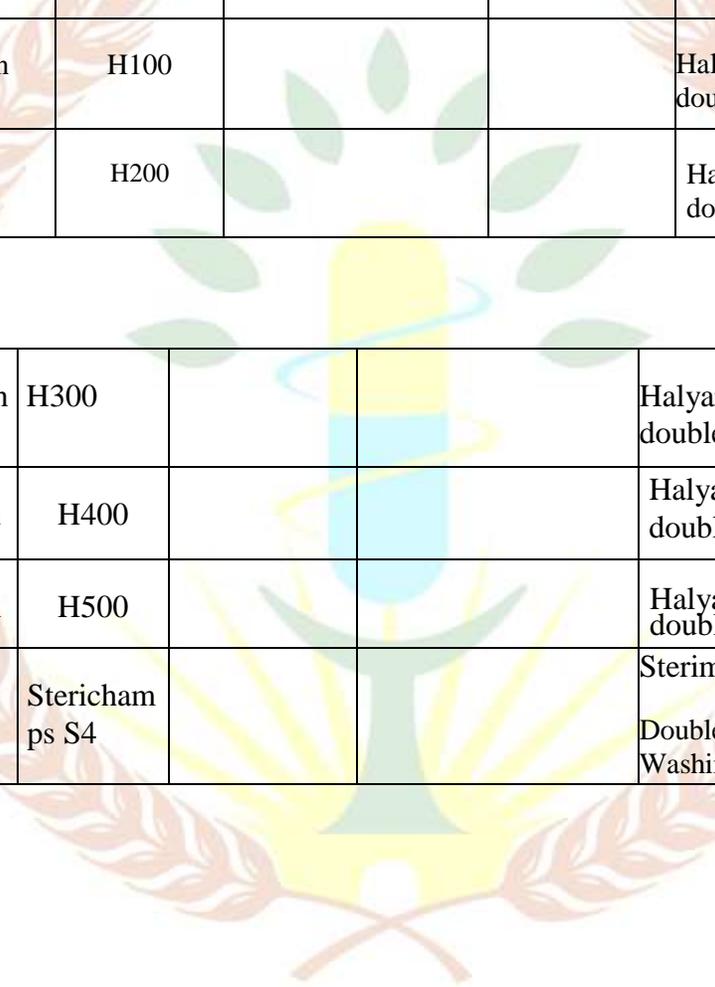
4	Nonwoven, wadding type		Polyester (textured)		Overall basis weight: 260 g/m <sup>2</sup>
		Polycotton	Cotton, polyester		
5	Woven	Poplin “120 thread”	Cotton		“Duckbill” type barrier mask
	Woven	Poplin “120 thread”	Cotton		
6					“Flat-fold” barrier mask
	Woven	Poplin “120 thread”	Cotton		
7	Knit (flat knit, weft insertion)		100% polyamide	25	2-layer laminate by chemical bonding
	Nonwoven		100% polyester		
8	Knit (flat-knit, weft insertion)		100% polyamide	25	2-layer laminate by thermal bonding
	Nonwoven		100%		
9	Woven			270	
		Microfleece	100%	125	
	Woven			200	
10					
	Nonwoven		Polypropylene	60	

11	Nonwoven, SMS	Reliance SMS 200		43	Amcor® Single and double layer
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12	Nonwoven, SMS	Reliance SMS 300		50	Amcor® Single and double
13	Nonwoven, SMS	Reliance SMS 400		60	Amcor® Single and double layer
14	Nonwoven	H100			Halyard® Single and double layers
15	Nonwoven	H200			Halyard® Single and double

16	Wonwoven	H300			Halyard® Single and double
17	Nonwoven	H400			Halyard® Single and double layer
18	Nonwoven	H500			Halyard® Single and double layer
19	Nonwoven , SMS	Sterichamps S4			Sterimed® Double layer Single use Washing impossible


  
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**Recommendations for artisanal making**

<b>DO</b>	<b>DON'T</b>
<ul style="list-style-type: none"> <li>- Use tightly constructed fabrics;</li> <li>- Assemble in two or three layers (same fabrics or different fabrics);</li> <li>- Use fabrics allowing air to pass through when breathing;</li> <li>- Use fabrics that are sufficiently soft and supple to apply around the face to ensure sealing;</li> <li>- Use fabrics that are not too warm;</li> <li>- Use smooth, non-irritating fabrics</li> </ul>	<ul style="list-style-type: none"> <li>- Do not use light and loosely constructed fabrics;</li> <li>- Do not make a mask with a single thickness of fabric;</li> <li>- Do not use staples when designing or assembling the barrier mask;</li> <li>- Do not use fabrics blocking the passage of air when breathing;</li> <li>- Do not use fabrics that are too stiff that would not be appropriate for sealing;</li> <li>- Do not use warm fabrics that would make masks difficult to wear;</li> <li>- Do not use irritating fabrics that would make masks difficult to wear;</li> <li>- Do not make vertical seams, along the nose, mouth and chin;</li> </ul>



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## REFERENCES

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2. WHO interim guidance on advice on use of masks in context of COVID-19 accessible on <https://apps.who.int/iris/handle/10665/332293>

## DOCUMENT REVISION HISTORY

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28/8/2020	1	DIC/GDC/001	- Gisagara Alex - Kabatende Joseph - Lazare Nirenganya - Mukunzi Antoine - Ndayambaje Theogene	To relate the first version published on 17 <sup>th</sup> April 2020 with WHO interim guidance on advice on use of masks in context of COVID-19

End of Document

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