

# Republic of Rwanda



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

# RWANDA FDA

April, 2020

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. This device is 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 device 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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**Ag. Director General**



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## **1. 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.

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. This device can contribute to the protection of a whole group wearing this barrier mask only at limited at only limited protection against the said risk is claimed.

This document specifies the minimum requirements for the manufacture, design and performance of the barrier masks.



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## 2. 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**

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)

**Exhalation valve**

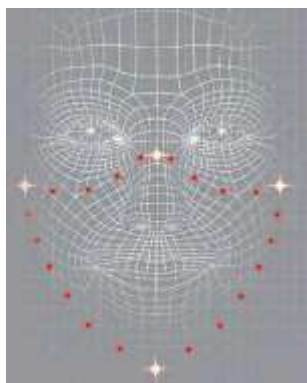
Non-return valve which allows the escape of exhaled air from the face piece

**Inhalation valve**

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

## 3. 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**

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The barrier mask is a single layer or 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 single layer or 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.

#### **4. Requirements**

##### **4.1 Visual inspection**

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

##### **4.2 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".

##### **4.3 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.

##### **4.4 Materials**

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

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

#### **4.5 Cleaning and drying**

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

#### **4.6 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.

#### **4.7 Penetration of the single layer or 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.

#### **4.8 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.

#### **4.9 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 single layer or multi-layer composite. It can be sewn or welded. Other attachment methods are permitted.

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

#### **4.10 Breathing resistance**

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

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

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

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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.

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

### **6.1 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 single layer or 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.

### **6.2 Penetration of the single layer and multi-layer composite**

So as to ensure that the penetration requirement for the single layer or multi-layer composite is met, the barrier mask shall be composed of one of the single layers or multi-layer composites listed in Annex A.

### **6.3 Breathing resistance**

So as to ensure that the breathing resistance requirement for the single layer or multi-layer composite is met, the barrier mask shall be composed of one of the single layers or multi-layer composites listed in Annex A.

## **7. Inspection**

### **7.1 Visual inspection**

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

### **7.2 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.

## **8. Making of barrier masks**

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### 8.1 General

The dimensions and shape of the pieces of the single layer or 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.

### 9. 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.

### 10. Use of a barrier mask

#### 10.1 General

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

#### 10.2 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:

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

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- 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;

### 11. 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:

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- 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;

## 12. 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)

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

|   | Single layer or multi-layer composite |               |             |                                  | Comment |
|---|---------------------------------------|---------------|-------------|----------------------------------|---------|
|   | Structure                             | Name          | Composition | Basis weight (g/m <sup>2</sup> ) |         |
| 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                              |         |

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|   |  |            |  |     |  |
|---|--|------------|--|-----|--|
| 3 |  | Microfibre |  | 100 |  |
|---|--|------------|--|-----|--|

|    |                                  |                     |                              |     |                                      |
|----|----------------------------------|---------------------|------------------------------|-----|--------------------------------------|
| 4  | Nonwoven, wadding type           | Polycotton          | Cotton, Polyester (textured) |     | Overall basis weight:                |
|    |                                  | Polycotton          | Cotton, polyester            |     |                                      |
| 5  | Woven                            | Poplin “120         | Cotton                       |     | “Duckbill” type barrier mask         |
|    | Woven                            | Poplin “120 thread” | Cotton                       |     |                                      |
| 6  | Woven                            | Poplin              | Cotton                       |     | “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%                         |     |                                      |
| 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  |                                      |

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

|    |               |                |  |  |  |
|----|---------------|----------------|--|--|--|
| 16 | Nonwoven      | H300           |  |  | Halyard® Single and double layer                           |
| 17 | Nonwoven      | H400           |  |  | Halyard® Single and double layer                           |
| 18 | Nonwoven      | H500           |  |  | Halyard® Single and double layer                           |
| 19 | Nonwoven, SMS | Sterichamps S4 |  |  | Sterimed®<br>Double layer Single use<br>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> </ul> <p>Use smooth, non-irritating fabrics</p> | <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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