TURKISH STANDARDS INSTITUTION

# Certification Criterion

# TSEK 599

**May 2020**

ICS13.100; 13.340.20; 13.340.30

## Reusable protective face masks made of textile – Non medical

Tekstilden mamul tekrar kullanılabilir koruyucu yüz maskeleri - Tıbbi olmayan

Masques protecteurs réutilisables en textile - Non médical

Wiederverwendbare schützende Gesichtsmasken aus Textil - Nicht medizinisch



**TSE Standard Hazırlama Merkezi Başkanlığı**
Necatibey Caddesi No: 112
TR-06100 Bakanlıklar * ANKARA

**Phone:** + 90 312 416 68 30
**Fax :** + 90 312 416 64 39
**E-mail:** dokumansatis@tse.org.tr
**Web:** www.tse.org.tr

## Foreword

This certification criterion was prepared by TSE and it was decided to publish it with the approval of the General Secretariat dated 11 May 2020.

Some words or expressions used in this certification criterion may be subject to patent rights. If such a patent right is determined, TSE cannot be held responsible.

# Contents



# Introduction

Due to the high demand for virus protection systems and products during the pandemic due to COVID-19, it became necessary to draft a criterion document that covers the minimum requirements that hygienic masks shall satisfy.

The use of face masks by the community can be used as a source control tool to reduce the spread of infection in the community by minimizing the excretion of respiratory droplets from infected people who have not yet developed symptoms or remain asymptomatic. It is not yet known how much use of masks in the community can contribute to the reduction in contamination, in addition to other measures.

The use of face masks in the community can be considered especially when visiting crowded, indoor areas such as markets, shopping malls, or using public transportation.

Especially in an environment where medical face masks are prioritized by healthcare professionals as personal protective equipment -due to supply problems-, the use of **non-medical** face masks made of various textile materials may be considered. This is based on a limited number of indirect studies that support the use of non-medical face masks as a means of resource control.

The use of face masks under this criterion does not replace preventive measures such as paying attention to the safe (social) distance, hand hygiene, avoiding face, nose, eyes, and mouth contact.

Proper use of face masks is essential for the effectiveness of the measure, and these masks shall be used by individuals in accordance with the instructions for use. This criterion does not define specific sealing requirements for the interface between the mask and the wearer's face.

Recommendations regarding the use of face masks in the community shall be taken into consideration by monitoring their supply status and potential negative side effects.

**IMPORTANT - Hygienic masks under this criterion shall not be considered a medical device (MD) within the scope of the 93/42 EC Directive or EU / 2017/745 Regulation, or personal protective equipment (PPE) within the scope of the EU Regulation.**

**WARNING - The use of a mask under this criterion does not strictly exempt the user from the physical distance measure and other measures applied.**

## 1 Scope

This document specifies production, design, performance requirements, and test methods for masks that aim to limit the possibility of transmission of infective agents during daily use and in other environments (other than medical environments) with similar requirements.

This criterion does not apply to masks intended exclusively for personal protection of personnel or surgical masks for medical purposes.

NOTE 1 Standards for masks to be used as medical and personal protective equipment are also available.

NOTE 2 In this criterion, hereinafter the term “Face Mask/Mask” will be used instead of “Reusable Protective Face Masks Made of Textile”.

## 2 Normative References

**2.1** The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies.

**2.2** For undated references, the latest edition of the referenced document (including any amendments) applies.

TS EN 149:2001+A1:2010, *Respiratory protective devices - Filtered half masks for protection against particles - Properties, tests and marking*

TS EN 14683:2019+AC:2019, *Medical face masks - Requirements and test methods*

TS EN ISO 3758, *Textile - Care guide code with symbols*

TS EN ISO 6330:2012, *Textile- For textile tests- Washing and drying operations with household washing machine*

TS EN ISO 11137-1:2015/A2:2020, *Sterilization of healthcare materials - Radiation - Part 1: Conditions for the development, validation and routine control of the sterilization process for medical devices*

TS ISO 2859-1:2012, *Sampling methods for inspection and testing - According to qualitative characteristics - Part 1: Sampling programs indexed according to acceptance quality limit (aql) for batch inspection*

TS EN 1149-2:2000, *Protective clothing - Electrostatic properties - Part 2: Test method for measuring electrical resistance to the depth of the material (vertical resistance)*

## 3 Terms and definitions

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

**4.1**
**Bacterial Filtration Efficiency**
**BFE**

efficiency of the face mask material(s) as a barrier to bacterial penetration

Note 1 to entry: The BFE test method is used to measure the bacterial filtration efficiency (BFE) of the mask material.

**4.2**
**cleanliness**

freedom from unwanted foreign matter

Note 1 to the entry: Such matter can be micro-organisms, organic residues or particulate matter.

**4.3**
**microbial cleanliness**

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

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

**4.4**
**Colony Forming Unit**
**CFU**

unit by which the culturable number of microorganisms is expressed

Note 1 to entry: The culturable number is the number of microorganisms, single cells or aggregates, able to form colonies on a solid nutrient medium.

**4.5**
**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

Note 1 to entry: The differential pressure is an indicator of the “breathability” of the mask.

**4.6**
**Face Mask**

equipment covering the mouth, nose, and chin that can surround the head and face, or hooked over ears

# 4 Classifications and requirements

## 4.1 Classifications

Face masks under this criterion are a class. This class is denoted by code M-90.

### 4.1.1 Sizes

Masks are divided into following 3 sizes:

- Small (S),
- Medium (M),
- Large (L).

A maximum deviation of ±5 mm from the values indicated in Figure 2 is permitted for each size.

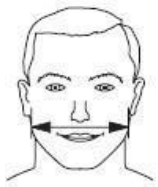
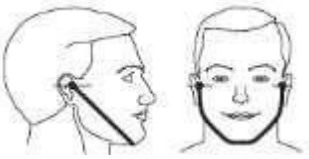
| | | | |
|---|---|---|---|
|  |  |  |  |
| Bigonial distance<br>132.5 - 144.5mm | Chin length<br>123 - 135 mm | Pupils distance<br>65 - 71 mm | Bitragus-gnathion Arc<br>295 - 315 mm |

**Figure 1 —General Size Diagram**

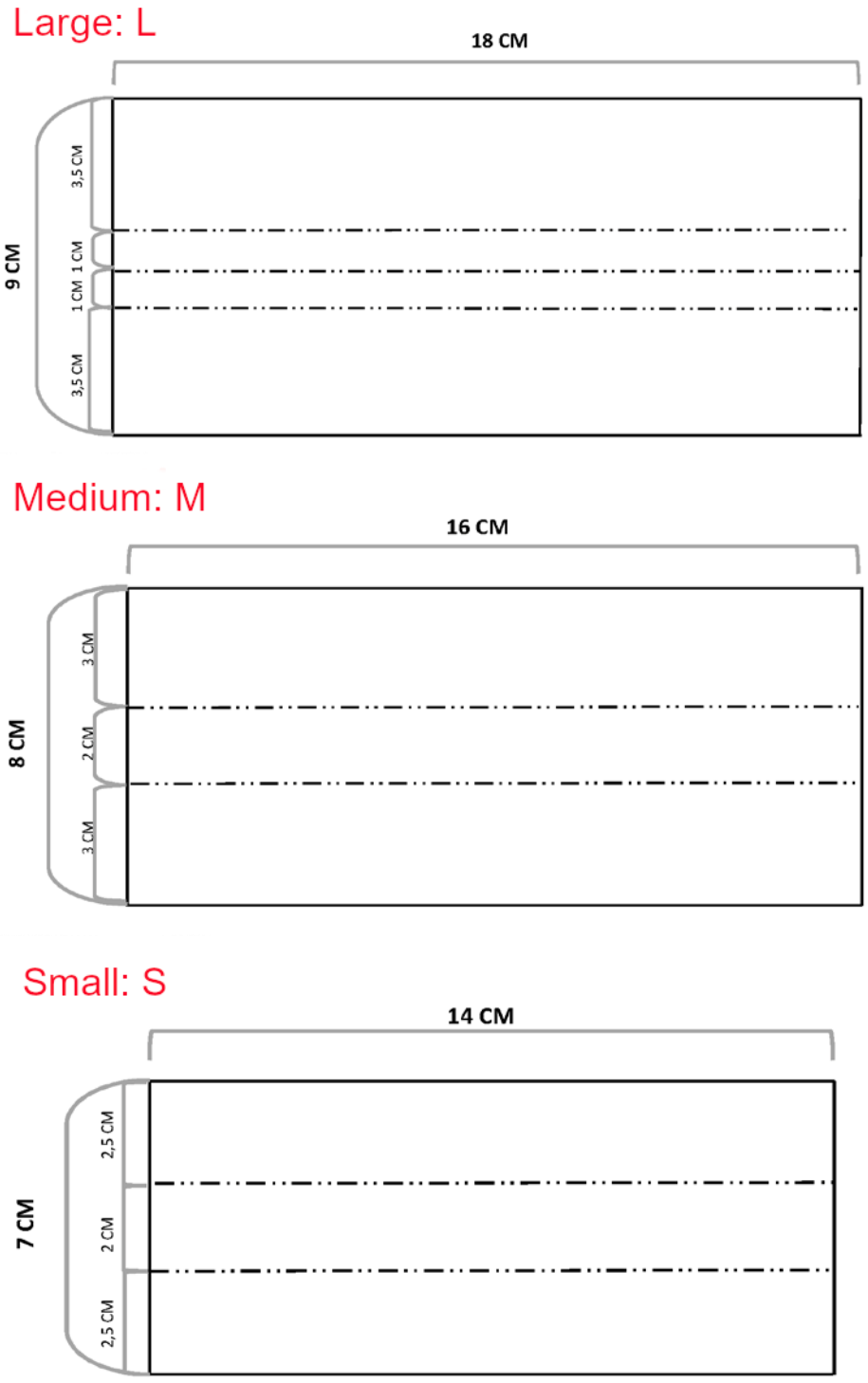



**Figure 2 — L/M/S Mask Sizes**
(Maximum ± 5 mm deviation from the values given in the figure is allowed)

## 4.2 Requirements

### 4.2.1 General

The performance of fabric/fabric face masks varies greatly depending on the shape and fit of the mask, as well as the structural properties of the fabric and the number of layers.

- - Mask fabrics can preferably be developed from Synthetic and/or natural fibers.
- - Mask fabrics can be produced by weaving, knitting, knitwear, or non-woven textile method.

The purpose of the fabric face mask is to create a barrier for droplets larger than 3 microns secreted during a speech, sneezing or coughing, reducing their spread to the outside environment. The higher the performance of the mask in terms of barrier efficiency, the better the droplet retention.

The face mask shall have the following features:

- There shall be no defects (tearing, disintegration of joints, etc.) in the mask or its components,
- It shall be breathable,
- It shall be designed to be worn properly and easily,
- Any component of the mask shall be easy to clean and disinfect at home,
- It shall be produced from the materials that do not pose a risk in case of a skin contact,
- It shall be made of fabrics which are known to cause no irritation or negative health effect,
- The fabric used shall be durable and maintain its integrity throughout the life of the product,
- The parts of the mask that may be in contact with the user shall not have sharp edges that could injure the user, (e.g. clips).
- Masks shall be accompanied by instructions explaining how to use them. The instructions shall highlight what the mask's limitations are and when to change it.

### 4.2.2 Materials and production

The face mask is a piece of equipment composed of a single layer or a filter layer that is placed, glued, or molded between the fabric layers. The mask shall not disintegrate, split, or tear during intended use. While choosing filter and layer materials, attention shall be paid to cleanliness.

### 4.2.3 Design

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.

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 e.g. with a wire slot, etc.).

The mask shall be designed so that it can be worn and removed easily. It shall sufficiently intact to hold the mask in place to prevent over-tightening and discomfort when wearing the mask on the face. The strap set can surround the wearer's head or ears. It can be self-adjusting or made of laces and can be made by means of an elastic band or bias or different type of fabric attachment that is fixed to the material. It can be stitched or patched. Other crafting tools are also allowed.

**CAUTION - Use of staples may create danger or discomfort to the user.**

## 4.3 Performance requirements

### 4.3.1 General

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

#### 4.3.2 Bacterial Filtration Efficiency (BFE)

When tested according to Annex B of the TS EN 14683+AC:2019 standard, the bacterial filtration efficiency (BFE) of the face mask shall conform to the minimum value given for the relevant type in Table 1.

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.

#### 4.3.3 Breathability

When tested in accordance with Annex C of the TS EN 14683 + AC: 2019 standard, the differential pressure of the face mask shall conform to the value given in Table 1.

#### 4.3.4 Microbial cleanliness (Bioburden)

When tested according to TS EN ISO 11737-1:2018, the bioburden of the mask shall be ≤ 30 CFU/g (see Table 1). The number of masks that shall be tested is minimum 5 of the same batch/lot .

#### 4.3.5 Cleaning, washing and drying procedures

The mask shall be able to withstand at least 5 wash and dry cycles without losing performance.

By choosing one of the cycles and methods are given in the TS EN ISO 6330 standard, the manufacturer shall choose a washing procedure that eliminates the virus. (e.g. 5 cycles of washing at 60 ° C (TS EN ISO 6330 program 6N) and air drying (such as TS EN ISO 6330, type A).

After these procedures, the manufacturer shall be able to guarantee that the reusable mask meets the criteria specified in Table 1.

#### 4.3.6 Summary of performance requirements

**Table 1 — Performance requirements for face masks**

| Test | Value |
|---|---|
| Bacteria filtration efficiency (BFE), (%) | ≥ 90 |
| Differential pressure (Pa/cm$^2$) | < 60 |
| Microbial cleanliness (kob/g) | ≤ 30 |
| **CAUTION - The face mask should be used to reduce the risk of transmission of infections, especially in epidemic or pandemic situations. Masks meeting these performance requirements are not designed for use by professional healthcare professionals in operating theaters or other medical environment with similar conditions.** | |

Reusable masks that are produced with the materials specified in Clause 5 and are in accordance with the design and performance parameters specified in this criterion, provide a presumption of conformity to this criterion. Changes in design, material, or production methods are within the responsibility of the manufacturer and in order to re-conform to this criterion and the rest of the requirements, conformity with the test methods and criteria specified in Table 1 shall be sought again.

# 5 Sampling, inspection and tests

## 5.1 Sampling

Masks that are submitted at a time to the inspections or tests are considered a batch. Depending on the size of the batch, "sampling" is performed from the mask lot in accordance with the TS ISO 2859-1 standard. The samples taken are recorded. Samples for inspections shall be selected randomly according to Table 2.

**Table 2 — Sampling plan for visual and dimensional inspection and material control**

| Batch Size | Sample Amount | Acceptable number of critical errors (max.) | Acceptable number of big errors (max.) | Acceptable number of large + small errors (max.) |
|---|---|---|---|---|
| 2-8 | 2 | 0 | 0 | 0 |
| 9-15 | 3 | 0 | 1 | 1 |
| 16-25 | 5 | 0 | 1 | 2 |
| 26-50 | 8 | 0 | 1 | 3 |
| 51-90 | 13 | 0 | 2 | 5 |
| 91-150 | 20 | 0 | 3 | 7 |
| 151-280 | 32 | 0 | 4 | 9 |
| 281-500 | 50 | 0 | 5 | 11 |
| 501-1200 | 80 | 0 | 6 | 13 |
| 1201-3200 | 125 | 0 | 7 | 15 |
| 3201-10000 | 200 | 0 | 8 | 17 |
| 10001-32000 | 315 | 0 | 9 | 19 |

Samples for tests shall be selected randomly according to Table 3, from the samples taken for visual and dimensional inspection and material control.

**Table 3 — Sampling plan for tests**

| Number of samples to be taken for visual and dimensional inspection and material control | Number of samples to be taken for the test |
|---|---|
| 2-50 | 2 |
| 51-500 | 5 |
| 501-3200 | 8 |
| 3201-10000 | 13 |
| 10001 - 35000 | 20 |

## 5.2 Inspections

### 5.2.1 Dimensional inspection

Samples shall be taken from the packages reserved for inspection and those samples taken shall be measured using proper tools. The conformity of the measurement results of the obtained values to the dimensions given in Figure 2 for each length is evaluated.

### 5.2.2 Visual inspection

Masks separated as samples shall be visually inspected for defects. It is checked whether the components specified in the masks are present and if there are visible surface defects.

Sample packages, bags, and markings are visually checked for suitability.

Presence of any kind of defect (Any holes, cuts, tears, color fluctuation and distortion in textile materials, etc.) is checked visually and manually.

### 5.2.3 Material control

Fabric of the mask is checked for conformity by reviewing the manufacturer's declaration (i.e. whether the fabric used contains a component harmful to human health and / or the environment, and that there are no allergen components that may irritate the skin. (Test reports on fabric and related directive / methodical declarations of conformity etc.))

### 5.2.4 Detection of the ability to wear the mask continuously

The mask is put on a healthy person for at least 4 hours at 25 ° C ± 5 ° C. At the end of this period, it is checked whether there is an allergic, irritating effect on the skin that the mask touches.

### 5.2.5 Electrostatic feature (only for Polyester Fabric)

For masks made of polyester, the vertical resistance of the material declared by the manufacturer is tested according to TS EN 1149-2 standard and the result is checked. A maximum of 5% deviation from the declared value is allowed.

## 5.3 Inspection and test report

At least the following information shall be included in the inspection and test report:

- Names, duties, and professions of the place and laboratory where the inspection and experiment are carried out, the inspector and the tester and/or the signatories of the report,
- Inspection and test date,
- Description of the sample,
- Numbers of standards applied in inspection and test,
- Demonstration of the results,
- Measures taken to eliminate the factors which could change the results of the inspection and the test,
- Actions that are not specified in the inspection and test methods applied or that are not mandatory, but have taken place in the inspection and test,
- Whether it conforms with this document,
- Report date and number,

# 6 Marking, labeling and packaging

Masks shall be packaged to protect them from mechanical damage and contamination before use. Individual or grouped packaging is at the discretion of the manufacturer. Masks shall be placed on the market in packaging.

Masks shall be clearly and durably marked on the smallest packaging available on the market, or if this mark is transparent, it shall be visible and readable from the inside of the packaging. Similarly, if the sale is made over the Internet, this information shall be displayed on the website.

The sign shall include:

a) name, trademark or any other identification method of the manufacturer or supplier,

b) mask class code (M-90) and related length code as S / M / L,

c) the number and name of this document,

**d)** The following warning:

**"WARNING: This device is not a medical device under Directive 93/42 or Regulation EU / 2017/745 and not personal protective equipment under Regulation EU / 2016/425.",**

e) mask placement pictogram,

f) personal use warning,

g) warning about adult supervision of masking, removing (for children's masks),

h) Protection symbols and maximum number of washes (number of washes guaranteed by the manufacturer) in accordance with TS EN ISO 3758 (see Note)

i) a statement that the mask is reusable.

Masks shall be supplied with the required instructions for use.

NOT The minimum number of washes that shall be guaranteed under this criterion is determined as 5 and shall be marked on the package with a graphic as follows. The manufacturer shall give the mask with the number of washes declared as a result of verification of the mask by fulfilling the performance requirements defined in this criterion in more than 5 washes. Below is an example of the minimum marking of the criteria and the different marking of markings:

Minimum wash cycle for the criterion: 


Wash cycle given on manufacturer's declaration(e.g.): 


## 7 Miscellaneous

The manufacturer or seller is obliged to submit or declare a declaration of conformity to the mask when requested for the mask that it declares manufactured in accordance with this standard. In this declaration, it shall be stated that the inspection and performance tests for the mask and fabric that are subject of the sale have been performed and that conformity has been achieved.

# Annex A
(informative)

## Instructions of mask

For the mask to be effective, the steps should be followed in the correct order as indicated in the figures below. Therefore, the placement, use, and removal of children's masks should be supervised by an adult.

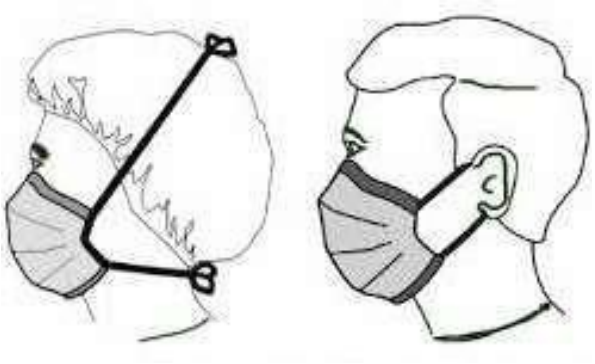


**Figure A.1 — Mask Connection points**

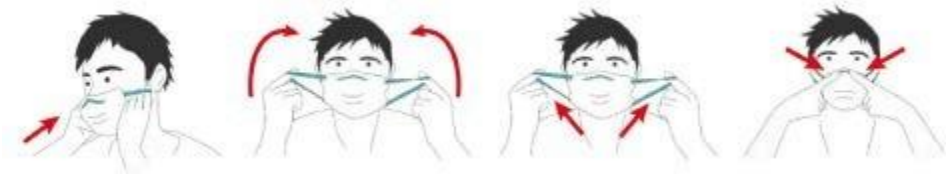


**Figure A.2 — Wearing the Adult mask**

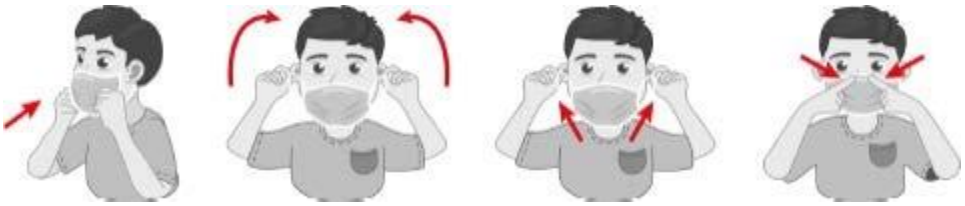


**Figure A.3 — Wearing the children's mask**

Verify that the mask is placed correctly. For this, it is necessary to verify the tightness and absence of respiratory distress. Do not touch the mask with your hands after it is adjusted. If the user needs to touch the mask, he must first wash his hands with soap and water or rub with a hydroalcoholic solution.

When removing a mask, the following steps must be followed to prevent contamination:

1) remove the protective gloves,
2) wash your hands with soap and water or rub them with a hydroalcoholic solution,
3) remove the mask without touching the front of the mask.

Washing and drying of the mask should be in accordance with the manufacturer's recommendations. The manufacturer should state the washing method to be applied in the instructions for the consumer. For example: "A complete wash

cycle (moistening, washing, rinsing) should be done at 60 ° C washing temperature with the usual detergent". Avoid contact between the dirty mask (to be washed) and clean clothes. The person responsible for washing should protect himself to handle dirty masks. Products that may damage or damage materials and reduce their protective capacity should not be used. It is recommended that the mask dry completely within 2 hours after washing. It should not be dried or disinfected with a microwave oven.

Environments, where the mask may become dirty, should be avoided, both during drying and during subsequent storage of the mask. A visual inspection (with protective gloves or washed hands) should be carried out after each wash cycle. If any damage to the mask is detected (minor fit, deformation, wear, etc.), the mask should be discarded.

To reduce the risk of using these masks, it should be remembered that they should be discarded after exceeding the maximum number of washes. Procedure for disposal of the mask:

Masks should be discarded in a container equipped with a plastic bag. If the outer bag is torn, it is recommended to use a pair of bags to preserve the contents of the first bag. The masks used can also be disposed of in biological waste containers.

Due to the comfort and hygiene, it is recommended not to wear the mask for more than 4 hours. If it gets wet or deteriorates, it is recommended to replace it with another one. During the period of use, the mask can be removed only according to the instructions. The mask should be washed every time it gets dirty, moistened, or not placed correctly on the face. The mask should not be used if it is dirty or wet. In the case of temporary storage, contact with any surface should be avoided. Also, it should not be placed in a standing position on the forehead or under the chin during and after use.

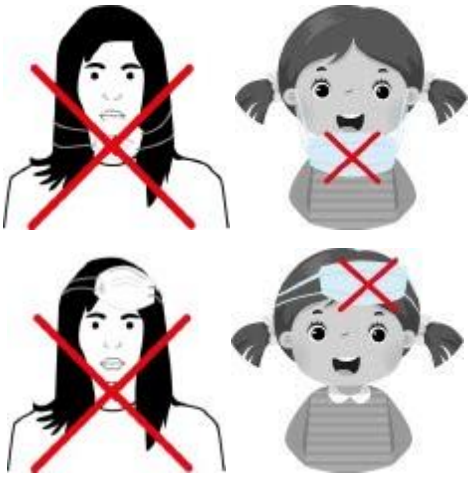


**Figure A.4 — Misuse**

# Bibliography


[1] Specification UNE 0065:2020, *Reusable hygienic masks for adults and children Requirements for materials, design, construction, marking and use*

[2] AFNOR Spec S76-001:2020 *Masques barriers - Guide d'exigences minimales, de méthodes d'essais, de confection*

[3] TS EN 149:2001+A1:2010, *Respiratory protective devices - Filtered half masks for protection against particles - Properties, tests and marking*

[4] TS EN 14683:2019+AC:2019, *Medical face masks - Requirements and test methods*

[5] TS EN ISO 3758, *Textile - Care guide code with symbols*

[6] TS EN ISO 6330:2012, *Textile - For textile tests - Washing and drying operations with household washing machine*

[7] TS EN ISO 11137-1:2015/A2:2020, *Sterilization of healthcare materials - Radiation - Part 1: Conditions for the development, validation and routine control of the sterilization process for medical devices*

[8] TS ISO 2859-1:2012, *Sampling methods for inspection and testing - According to qualitative characteristics - Part 1: Sampling programs indexed according to acceptance quality limit (aql) for batch inspection*

[9] TS 251, *Woven fabrics - Determination of unit length and unit area mass*

[10] TS EN ISO 2286-2, *Rubber or plastic coated fabrics - Determination of top properties - Part 2: Total unit area mass, unit area mass of the coating and methods for determining the unit area mass of the main fabric*

[11] TS EN ISO 811, *Textile - Determination of resistance against water penetration - Hydrostatic pressure test*

[12] TS EN ISO 4674-1, *Rubber or plastic coated fabrics - Determination of tear strength - Part 1: Methods of tearing at constant speed*

[13] TS EN 1149-2:2000, *Protective clothing - Electrostatic properties - Part 2: Test method for measuring electrical resistance to the depth of the material (vertical resistance)*

[14] http://www.treasury.gov.za/comm_media/press/2020/Annexure%20B%20-%20Recommended%20Guidelines%20Fabric%20Face%20Masks%20RSA%20DTIC.pdf