

CEN

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WORKSHOP

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AGREEMENT

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English version

Community face coverings - Guide to minimum requirements, methods of testing and use

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Voorbereiding
Preview

European foreword

CWA 17553:2020 was developed in accordance with the decision BT 034/2020:

"Subject: Covid-19 – Establishment of a CEN Workshop for community face coverings

BT

- having noted the EC letter addressed to CEN on 2020-05-12 requesting to develop a European standardization deliverable for community face coverings with the following remarks:
 - Target date of mid-June 2020
 - Based on existing specifications at national level
 - Easy to implement
 - With clear information to users
 - Freely available to the widest possible audience
 - Explicitly distinct from standards applicable to PPEs or MDs;
- considering the current several national standardization initiatives on this matter and the discussion during the CEN BT meeting;
- acknowledging the need to have an initial deliverable to be developed fast that will be used as a basis for a wider consensus-based document;
- decides, for this specific case only, to
 - establish CEN Workshop "Response to Covid-19 – Community face coverings (masks)",
 - request the CEN Workshop to develop a CEN Workshop Agreement in compliance with the remarks expressed by the EC letter by 15 June 2020 at the latest,
 - request CCMC to provide editorial support to the CEN WS with the effect that the CWA is published immediately upon adoption,
 - set the date of the kick-off meeting to 26 May 2020,
 - allocate the secretariat of the CEN Workshop to AFNOR,
 - grant the Workshop the following exceptions to the applicable rules for a maximum duration of one month:
 - participation is based on national membership of CEN and limited to those national members having already developed or are developing a national specification, with one representative from Annex III organisations
 - each relevant national member may appoint up to three representatives,
 - work will be conducted exclusively online,
 - asks CEN/CA to decide on the participation and lifetime requirements and apply retroactively the CA decision to be taken at the meeting in June."

It was agreed on 2020-06-10 in a Workshop by representatives of interested parties, approved and supported by CEN. It does not necessarily reflect the views of all stakeholders that might have an interest in its subject matter.

This document has been prepared with the support of CCMC (Ms. Christina THORNGREEN) and the secretariat provided by AFNOR (Secretariat: Mr. Matthis ROUSSEL, support secretariat: Ms. Rim CHAOUY and Mr. Rémi REUSS, with the participation of the Director General of AFNOR: Mr. Olivier PEYRAT).

The final text of CWA 17553:2020 was submitted to CEN for publication on 2020-06-12. It was developed and approved by:

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Introduction

Community face coverings are intended for use by people not displaying any clinical symptoms of viral or bacterial infection and who do not come into contact with people displaying such symptoms.

Community face coverings are not suitable for children under 3 years of age. It is recommended that children between 3 and 12 years are supervised while wearing the community face covering.

NOTE The minimum age criteria can be higher in function of the national recommendations.

This community face covering minimizes the projection of user's respiratory droplets saliva, sputum or respiratory secretions when talking, coughing or sneezing. This community face covering may also limit penetration in the user's area of nose and mouth of the respiratory droplets from external origin without claiming the user protection. It also prevents this user's area from any contact with the hands.

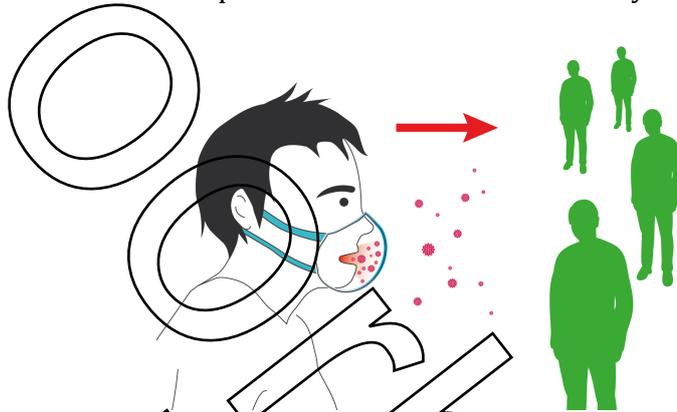


Figure 1 — Limitation of the respiratory droplets projection to the environment

This document specifies the minimum performance requirements for community face coverings. The appropriate test methods are also defined and some recommendations for use are given as examples.

This document defines filtration levels for the community face coverings corresponding to the use defined by national authorities. Examples of where the general public should be encouraged to use them are given in World Health Organization recommendation [1].

This document provides a support for the potential producers of these community face coverings.

IMPORTANT Community face coverings are not subject to a mandatory conformity assessment by notified bodies or laboratories. Their design in accordance with accepted best practices and production quality control remain the producer's responsibility. The producer may need to call upon a laboratory to verify the required performance.

IMPORTANT It must be noted that community face coverings will have maximum effectiveness if it is worn in direct contact with bare skin. Beards can reduce the filtration efficiency to below the limits set out in this document.

IMPORTANT The community face covering specified in this document do not fall under as a medical device (MD) within the meaning of Directive 93/42/CEE or Regulation EU/2017/745, nor as a personal protective equipment (PPE) with the meaning of Regulation EU/2016/425.

1 Scope

This document specifies the minimum requirements for reusable or disposable community face coverings intended for the general public. These minimum requirements include:

- design,
- performance,
- test methods,
- packaging,
- marking and,
- information for use.

This document is not intended for community face coverings for children under the age of 3.

2 Terms and definitions

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

2.1

air permeability

volume of air per unit surface area (square meter or m²) and time unit (second or s) passing perpendicularly through a fabric in the specified test conditions (surface area, pressure loss and duration)

2.2

breathing resistance

resistance of community face coverings to the flow of inhaled air (inhalation resistance) or exhaled air (exhalation resistance)

2.3

community face covering

facepiece covering the mouth, nose and chin fitted with the head harness which can be head or ears attachment

2.4

determined by experts

according to expert opinion based on knowledge and experience

2.5

exhaled air

air exhaled by the user

2.6

exhalation valve

non-return valve which allows the escape of exhaled air from the facepiece

2.7

inhaled air

air inhaled by the user

**2.8
inhalation valve**

non-return valve which allows breathable gas to enter the facepiece and prevents exhaled air from leaving via the inhalation path

**2.9
material**
element of community face coverings forming the barrier

**2.10
nose bridge**
device that clamps the community face covering on the nose and thus makes fit better

**2.11
producer [2]**
producer means:

- the manufacturer of the product, when he is established in the European Union, and any other person presenting himself as the manufacturer by affixing to the product his name, trade mark or other distinctive mark, or the person who reconditions the product;
- the manufacturer's representative, when the manufacturer is not established in the European Union or, if there is no representative established in the European Union, the importer of the product;
- other professionals in the supply chain, insofar as their activities may affect the safety properties of a product.

**2.12
product(s)**
item intended for use or likely, under reasonably foreseeable conditions, to be used by users even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned

**2.13
cleaning cycle**
full processing cycle (washing and drying) consisting of the steps recommended by national authorities or the community face covering producer

3 Description

Community face coverings cover the nose, mouth and chin (coverage area, see Figure 2) and shall not incorporate any inhalation and/or exhalation valve(s).

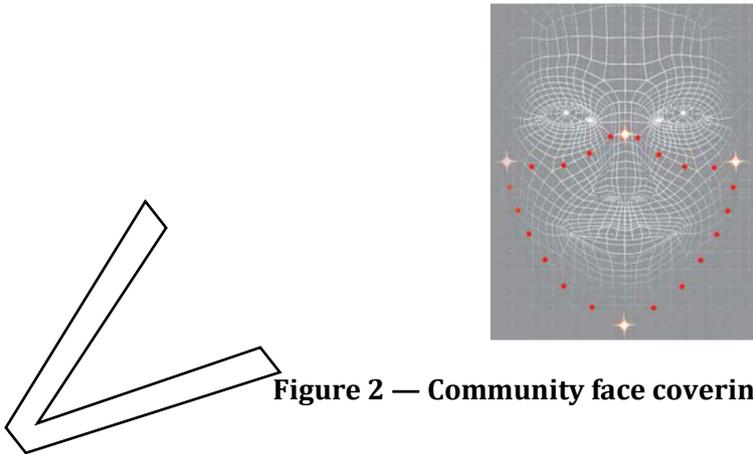


Figure 2 — Community face coverings coverage area

Community face coverings are made of one or multiples fabric layers (woven, knitted, nonwoven, etc.) with or without film. They shall have a means of attachment for either the head or ears.

It shall be able to be fixed and maintained over the nose, cheeks and chin of the user, when the user's skin is dry or damp or when the user moves his/her head.

Inhaled air mostly penetrates community face coverings through the material 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 Designation

Community face coverings to be placed on the market that meet the requirements of this document shall be designated as follows.

Community face coverings CWA 17553:2020 or National specification designation followed by CWA 17553:2020.

5 Requirements

5.1 General

All test samples shall meet the requirements.

The community face coverings are intended to be reusable or disposable.

NOTE For the disposable community face coverings it's recommended to use the material known as recyclable or compostable to reduce the environmental impact.

The producer shall keep at the disposal all necessary documentation in relation to the materials that are used in the manufacturing of community face coverings.

Recommendations for making Do It Yourself (DIY) community face coverings are given in the informative Annex A.

5.2 Visual inspection

The producer shall carry out a visual inspection of the community face coverings or its components to meet the requirements of this clause. There shall be no defects visible (tears, detachment of the head harness, less accurate fit, deformation, wear, etc.). If any damage to the community face coverings are detected, they are deemed non-compliant.

The corresponding technical documents shall be available.

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