enterprise europe network

28 Αυγούστου, 2020

Καλύμματα προσώπου (community masks) - Ποιες είναι οι ελάχιστες προδιαγραφές που πρέπει να πληρούν

Λόγω της έλλειψης τεχνικών προδιαγραφών για καλύμματα προσώπου όπως οι υφασμάτινες μάσκες, χειροποίητες μάσκες κλπ, η Ευρωπαϊκή Επιτροπή ζήτησε από τον Ευρωπαϊκό Οργανισμό Τυποποίησης CEN την ετοιμασία ευρωπαϊκού προτύπου.

Έτσι, ο CEN πραγματοποίησε εργαστήριο για την ανάπτυξη ενός εγγράφου αναφοράς τυποποίησης (CWA) έχοντας βάση τις υφιστάμενες εθνικές προδιαγραφές. Έπειτα από εκτεταμένες ανταλλαγές απόψεων κατά τη διάρκεια του εργαστηρίου, στις 17 Ιουνίου 2020 ο CEN προχώρησε στην έκδοση του εγγράφου CWA 17553 με τίτλο "Community face coverings - Guide to minimum requirements, methods of testing and use ".

Το έγγραφο καθορίζει τις ελάχιστες απαιτήσεις για επαναχρησιμοποιήσιμα ή μίας χρήσης καλύμματα προσώπου για το ευρύ κοινό. Αυτές οι ελάχιστες απαιτήσεις περιλαμβάνουν:

- Σχεδιασμό,
- Απόδοση (Αποτελεσματικότητα υλικού στο φιλτράρισμα, αντίσταση αναπνοής και διαπερατότητα από τον αέρα),
- Μέθοδοι δοκιμής,
- Συσκευασία,
- Σήμανση (στοιχεία που πρέπει να περιλαμβάνει η ετικέτα) και
- Πληροφορίες χρήσης (συμπεριλαμβανομένου και του τρόπου καθαρισμού της μάσκας)

Αναλυτικότερα, στο έγγραφο που επισυνάπτεται.

Καλούνται λοιπόν, όσες επιχειρήσεις σκοπεύουν να κατασκευάσουν ή να εισάγουν καλύμματα προσώπου (υφασμάτινες μάσκες) ή μάσκες «κοινότητας» (community masks) όπως τις αποκαλούν, να λάβουν υπόψη τις τεχνικές απαιτήσεις που αναφέρονται στο σχετικό έγγραφο.

Αυτές οι απαιτήσεις δεν αφορούν τις πιο κάτω μάσκες καθότι αυτές ρυθμίζονται από συγκεκριμένες νομοθεσίες.

1. Μάσκες που ικανοποιούν τις βασικές απαιτήσεις ασφάλειας του Ευρωπαϊκού Κανονισμού (ΕΕ) 2016/425 για τα Μέσα Ατομικής Προστασίας

een.ec.europa.eu







enterprise europe network

2. Χειρουργικές / ιατρικές μάσκες προσώπου, που ικανοποιούν τις βασικές απαιτήσεις ασφάλειας της Ευρωπαϊκής Οδηγίας 93/42/ΕΟΚ για τα Ιατροτεχνολογικά Προϊόντα

Παραμένοντας στη διάθεσή σας για τυχόν απορίες.

Με εκτίμηση Στάλω Δημοσθένους Ανώτερη Λειτουργός, ΚΕΒΕ Τμήμα Εκπαίδευσης & Ευρωπαϊκών Προγραμμάτων Τηλ. 22889752, E-mail: <u>stalo@ccci.org.cy</u>







CEN

CWA 17553

WORKSHOP

June 2020

AGREEMENT

ICS 13.340.20

English version

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

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties, the constitution of which is indicated in the foreword of this Workshop Agreement.

The formal process followed by the Workshop in the development of this Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN-CENELEC Management Centre can be held accountable for the technical content of this CEN Workshop Agreement or possible conflicts with standards or legislation.

This CEN Workshop Agreement can in no way be held as being an official standard developed by CEN and its Members.

This CEN Workshop Agreement is publicly available as a reference document from the CEN Members National Standard Bodies.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION COMITÉ EUROPÉEN DE NORMALISATION EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

© 2020 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.



Con	tents	Page
Europ	oean foreword	4
Intro	duction	6
1	Scope	7
2	Terms and definitions	
3	Description	
4	Designation	9
5	Requirements	
5.1	General	
5.2 5.3	Visual inspection Dimensions / Sizing	
5.3.1	Adult sizing	
5.3.2	Child sizing	
5.4	Packaging	
5.5	Materials	
5.6	Cleaning	
5.7 5.8	Surface condition of the partsFiltration efficiency of the material	
5.0 5.9	Head harness	
5.10	Breathing resistance and air permeability	
6	Test methods	13
6.1	General	
6.2	Visual inspection	
6.3	Head harness strength test	
6.4	Material filtration efficiency test	
6.5	Breathing resistance and air permeability test	
7	Marking and instructions for use	
7.1 7.2	MarkingInstructions for use	
8	Use of community face coverings	
8.1 8.2	GeneralReminder on essential protective measures even when wearing the community face	
0.2	coverings	
8.3	Use of community face coverings: what to avoid!	16
Anne	x A (informative) Specific recommendations for Do It Yourself (DIY) making	17
Anne	x B (informative) European standards for filtration efficiency	18
Anne	x C (informative) National specifications developed by CEN members	19
Anne	x D (informative) Main test conditions for filtration efficiency test methods	20
Anne	x E (informative) Example of use of community face coverings	21
E.1	Putting on community face coverings	21
E.2	Removing community face coverings	24
E.3	Cleaning community face coverings	25
E.4	Disposing of community face coverings	26

E.5	Period of use of the community face covering	.27
Biblio	graphy	. 20

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

ВТ

- 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:

- Chairperson: Ms. Ewa MESSAOUDI
- AFNOR experts: Mr. François GAIE-LEVREL, Mr. Laurent HOUILLON, Mr. Olivier VILA COBARSI
- ANEC expert: Ms. Herdis STORGRAARD
- IPQ experts: Ms. Antonia ANDRADE LOPES, Ms. Micaela Carla PEREIRA
- MSZT experts: Mr. Domokos KRANTZ
- NBN experts: Ms. Lies ALBOORT, Ms. Karin EUFINGER, Mr. Edwin MAES
- NEN experts: Ms. Paula BOHLANDER, Mr. Geert DRIESSEN, Ms. Miriam GEELHOED
- NSAI experts: Mr. Steven DARBY, Ms. Elizabeth O'FERRALL, Mr. John SHEERAN
- UNE experts: Ms. Pilar CACERES, Ms. Cristina HERNAN, Ms. Judith SISTERNES
- UNI experts: Mr. Marco DE NARDI, Mr. Claudio GALBIATI, Mr. Paolo TRONVILLE

It is possible that some elements of CWA 17553:2020 may be subject to patent rights. The CEN-CENELEC policy on patent rights is set out in CEN-CENELEC Guide 8 "Guidelines for Implementation of the Common IPR Policy on Patents (and other statutory intellectual property rights based on inventions)". CEN shall not be held responsible for identifying any or all such patent rights.

The Workshop participants have made every effort to ensure the reliability and accuracy of the technical and non-technical content of CWA 17553:2020, but this does not guarantee, either explicitly or implicitly, its correctness. Users of CWA 17553:2020 should be aware that neither the Workshop participants, nor CEN can be held liable for damages or losses of any kind whatsoever which may arise from its application. Users of CWA 17553:2020 do so on their own responsibility and at their own risk.

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.

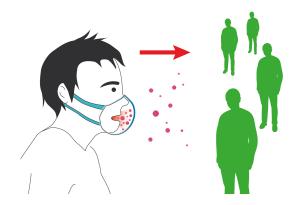


Figure 1 — Limitation of the respiratory droplets projection to the environment

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 foreseaeable 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).

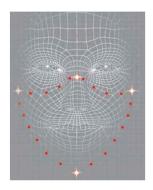


Figure 2 — Community face coverings coverage area

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.

If the material has been pre-tested by the material supplier, verification of the results (suitable certificate/certificate of conformance) shall be carried out.

5.3 Dimensions / Sizing

5.3.1 Adult sizing

Community face coverings shall be sized in such a way as to correspond to the average morphology of the target European population. The choice of the community face coverings dimension shall be adapted to the morphology of the user.

A community face covering which hinders the user's ability to breathe when first put on is deemed unsuitable. The user should be aware that it can take time to become comfortable with the community face covering.

The community face covering shall be designed and manufactured to meet the requirements when intended for use by adults. Face and head size dimension ranges in Figure 3 are provided as guidance.

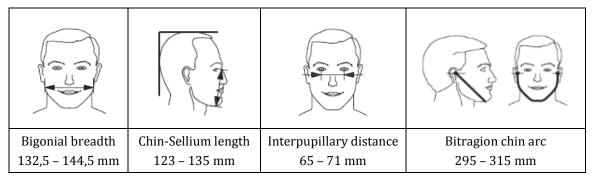
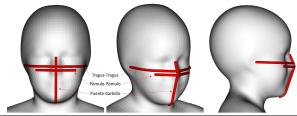


Figure 3 — Adult facial and head dimensions [8]

5.3.2 Child sizing

Community face coverings are also intended for use by children. Due to the wide range of morphologies, the dimensions of the community face covering shall be determined by experts and shall be adapted to the morphology of the user. The breathability shall be defined on the basis of supervision of the young user. A community face covering which hinders the user's ability to breathe when first put on is deemed unsuitable. The user and the superviser should be aware that it can take time to become comfortable with the community face covering.

The community face covering shall be designed and manufactured to meet the requirements when intended for use by children. Face and head size dimension ranges in Figure 4 are provided as guidance.



Age Range	Cheekbone - Cheekbone	Sellium - Chin	Tragion - Tragion	Head Circumference
3 – 5 yrs.	88 - 109 mm	93 – 127 mm	202 – 253 mm	477 – 549 mm
6 – 9 yrs.	94 – 116 mm	105 – 136 mm	220 – 279 mm	500 – 560 mm
10 – 12 yrs.	98 – 121 mm	114 – 146 mm	233 – 290 mm	515 – 580 mm

Figure 4 — Child face and head dimensions [3]

5.4 Packaging

Community face coverings shall be packaged in such a way as to protect them against any mechanical damage and any contamination before use. Individual or grouped packages are at the producer's discretion.

Testing shall be carried out in accordance with 6.2.

5.5 Materials

The materials used for manufacturing the community face coverings shall be able to withstand handling and wear throughout the lifetime of community face coverings, indicated by the producer.

The producer shall take into account the following when selecting material:

- Its breathability.
- The ability to absorb moisture to prevent condensation falling on to the user.
- The adequacy of biocompatibility features of the materials which come into direct contact with the skin of the user. These materials shall not be known to cause irritation, allergenic effects or other toxic effect. The evaluation should be done through an analysis of Safety Material Data Sheet (SMDS) for materials used, colorants and finishes if applicable. This evaluation is under the responsibility of the producer.
- For reusable community face coverings, the materials used shall withstand the cleaning cycles, detergents and methods specified by the producer.

NOTE When selecting materials, the producer shall take into account the ability to be recycled or composted to ensure sustainability.

5.6 Cleaning

The community face coverings specified as reusable shall withstand the number of cleaning cycles claimed by the producer (at least 5 cleaning cycles) with a minimum washing temperature of 60° C.

The cleaning cycles shall follow either:

— the producer's detailed cleaning instructions;

or,

— the procedure describe in EN ISO 6330.

For cleaning, only products shall be used which do not present any health risk, e.g. by leaving behind hazardous substances at the end of the process. For this reason it is recommended to use standard detergent and to not use fabric softener.

If any damage to the community face coverings is detected (tears, detachment of the head harness, less accurate fit, deformation, wear, etc.) after each cleaning cycle, the community face coverings are deemed non-compliant.

The community face coverings shall not be dry cleaned as this process leaves substances in the fabric which are hazardous to health.

Testing shall be carried out in accordance with 6.2.

5.7 Surface condition of the parts

The parts of the community face covering shall be free of sharp edges or burrs. The use of staples for connecting parts is forbidden as it poses a safety hazard to the user.

Testing shall be carried out in accordance with 6.2.

5.8 Filtration efficiency of the material

Two levels of community face coverings are considered according to their filtration efficiency to particles around 3 (\pm 0,5) µm:

- level 90%: greater than or equal to 90%,
- level 70%: greater than or equal to 70%.

In some countries, national regulations could apply to define the different level of filtration efficiency when tested with particles different than 3 (\pm 0,5) μ m.

The filtration efficiency requirements apply to both new materials and to materials that have been through the number of cleaning cycles for which the producer states that the community face covering remains compliant.

Testing shall be carried out in accordance with 6.4.

The national regulations apply to indicate what level of filtration efficiency is suitable for the given use of the community face covering.

5.9 Head harness

The head harness shall be designed such that the community face coverings can be easily put on and removed. It shall withstand 5 cycles of being put on and removing (donning and doffing) and shall be checked on at least three test subjects with different morphologies.

It shall be sufficiently robust to hold the community face coverings 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 self-adjusting or made up of laces, and can be made using an elastic strip or a fabric tie such as bias tape or other fabric, attached to the material. It can be sewn or welded. Other attachment methods are permitted.

Head harnesses to be used for children shall only be fixed by using earloops without an adjusting device nor straps to be tied.

NOTE A self-adjusting head harness that does not hold the community face covering correctly in place is deemed non-compliant.

Testing shall be carried out in accordance with 6.2 and 6.3.



5.10 Breathing resistance and air permeability

The material used for the community face coverings shall not exceed the following limits:

Differential pressure of the material less than or equal to 70 Pa/cm² correlates to about 80 l/s/m² for a vacuum pressure of 100 Pa.

NOTE Differential pressure of the material of 60 Pa/cm² correlates to about 93 l/s/m² for a vacuum pressure of 100 Pa.

or,

- Breathing resistance:
 - Inhalation resistance of 2.4 mbar.
 - Exhalation resistance of 3 mbar.

or,

— The air permeability greater than or equal to 96 l/s/m² for a vacuum pressure of 100 Pa.

The test shall be carried out in accordance with 6.5.

6 Test methods

6.1 General

The producer shall perform verification and validation tests within its facility or in collaboration with a test laboratory that has the appropriate means of testing before placing any community face covering on the market.

The producer shall establish and document routine checks (production control) to ensure the performance of the community face coverings.

6.2 Visual inspection

Visual inspection shall be carried out by the producer or test laboratory on production samples of the completed community face coverings.

All visible defects (e.g. less well-fitting, tears, detachment of the harness, sharp edges, etc.) shall be considered as non-compliant.

For reusable community face coverings, the visual inspection shall be carried out on samples that have been cleaned to the producer's instructions to ensure the performance declared by the producer.

6.3 Head harness strength test

The verification of the testing of the main attachment is done by putting on and removing (donning and doffing) the community face covering 5 times.

6.4 Material filtration efficiency test

The filtration efficiency is measured on the material of the community face coverings. Producers can determinate filtration efficiency using:

existing European standards listed in the informative Annex B of this document;

or,

— available methodologies based on the experience developed at the national level in the different countries listed in the informative Annex C of this document.

To ensure the results comparability for filtration efficiency tests, it is suitable to take into account the values associated with filtration velocity, upstream concentration and particle size and to adopt informations associated with the nature of aerosols and measurement. These main test conditions are described in the informative Annex D of this document.

6.5 Breathing resistance and air permeability test

To determine the breathing resistance, one of the following tests shall apply:

— Differential pressure: test set out in EN 14683:2019+AC:2019, Annex C on the material;

or,

Breathing resistance: test set out in in EN 13274-3 for constant flow (95 l/min);

or,

Air permeability: test set out in EN ISO 9237 on the material.

7 Marking and instructions for use

7.1 Marking

The community face coverings to be placed on the market shall be clearly and durably marked with the information below on the smallest marketable package available or shall be legible through the packaging if the packaging is transparent and contain the minimum information below. National regulations may require additional information. The text shall be printed in the official language(s) of the country or region of the user.

- The producer name, trademark, or other means of identification.
- The postal or web address at which the producer can be contacted.
- A means of product identification e.g. batch number.
- The designation "Community face coverings CWA" followed by the version of the document or national specification designation followed by CWA.
- The filtration efficiency level:
 - "level 90%" or "level 70%" for filtration efficiency to particles around to 3 (± 0,5) μm;

or,

- "obtained value%" for filtration efficiency to particles different than 3 (± 0,5) μm.
- The filtration efficiency test method used i.e. standard or national test method identification reference.
- The type of community face coverings i.e. "reusable" or "disposable".
- The type of users i.e. "child" or "adult".
- The age appropriate restriction warning i.e. "Not suitable for children under 3 years of age."
- The storage conditions.

7.2 Instructions for use

In addition, the information provided by the producer in the instructions for use shall include at least the following elements:

The cleaning instructions (washing and drying).

- For reusable community face coverings, the maximum number of cleaning cycles for which the community face covering is guaranteed to be compliant.
- The warnings below, with the words "WARNING" in front of them:
 - In order to use this community face covering correctly, it is important that you follow these instructions.
 - If you are ill, this community face covering is unsuitable. Seek advice from your doctor.
 - This community face covering is not a medical device within the meaning of Directive 93/42/CEE or Regulation EU/2017/745 (surgical masks) nor is it personal protective equipment in the sense of Regulation EU/2016/425 (respiratory protective devices).
 - Always check that the community face covering is correctly fitted and covers your nose, mouth and chin. It is recommended that this community face covering be worn on bare skin; beards can reduce the filtration efficiency to below the limits set out.
 - If applicable: 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. A community face covering which hinders the user's ability to breathe when first put on is deemed unsuitable. It can take time to become comfortable with the community face covering.
 - This community face covering does not replace protective measures (regular hand-washing, physical separation, reduced contact with other people). It minimizes the projection of user's respiratory droplets saliva into the environment.
 - Do not use when participating in vigorous physical activity.
 - Stop using this product at the first signs of damage.
 - The community face covering specified as reusable should be washed before the first use unless recommended by producer.
 - Do not use dry cleaning and fabric softener.
 - Clean the reusable community face covering after each use.
 - The way how to fit, use, put on and removing (donning and doffing) the community face covering which may be informed by a pictogram.

8 Use of community face coverings

8.1 General

The community face coverings do not exempt the user from application of the collective measures which are supplemented, where possible, by physical distancing measures, which are essential (regular handwashing, physical separation, reduced contact with other people).

The community face coverings shall be used taking account of the compatibility of its use with the wearing of other equipment (goggles, headgear, headphones, etc.).

Some examples of the following topics are presented in the informative Annex E:

Putting on community face coverings.

- Removing community face coverings.
- Cleaning community face coverings.
- Disposing of community face coverings.
- Period of use of the community face covering.

8.2 Reminder on essential protective measures even when wearing the community face coverings

The health instructions are given on the national government's web site.

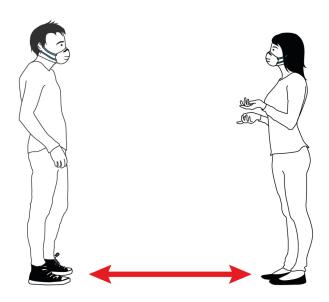


Figure 5: Compliance with physical distancing rules, even with a community face covering

8.3 Use of community face coverings: what to avoid!

The following list contains examples of uses of community face coverings that shall be avoided and is based on the feedback collected:

- The community face coverings cannot be used for protection against chemicals.
- It is not possible to decontaminate community face coverings by freezing. The viral or bacterial agent is retained and at 4°C it does not lose its infectious character.
- Physical distancing rules shall be complied with as far as possible even if wearing a community face covering.
- Boiling the community face coverings is not recommended unless recommended by producer. There
 is no guarantee that the fabric can withstand the 100°C temperature of boiling water without
 degrading.
- If the cleaning cycle is followed, it is usually not necessary recommended to disinfect the community face coverings before wearing it.

Annex A

(informative)

Specific recommendations for Do It Yourself (DIY) making

Recommendations

- Use tightly constructed fabrics;
- Assemble in two or three layers (same fabrics or different fabrics);
- Use fabrics allowing air to pass through when breathing;
- Use fabrics that are sufficiently soft and supple to apply around the face to ensure sealing;
- Use fabrics that are not too warm;
- Use smooth, non-irritating fabrics;
- Wash fabric before cutting, minimum at 60°C.

- Do not use light and loosely constructed fabrics;
- Do not make a community face covering with a single thickness of fabric;
- Do not use staples when designing or assembling the community face covering;
- Do not use fabrics blocking the passage of air when breathing;
- Do not use fabrics that are too stiff that would not be appropriate for sealing;
- Do not use warm fabrics that would make community face covering difficult to wear;
- Do not use irritating fabrics that would make community face covering difficult to wear;
- Do not make vertical seams, along the nose, mouth and chin;
- Do not use as fabrics vacuum cleaner bags, insolation material used in building construction, diapers etc.;
- Do not use textile that is possibly treated with harmful chemicals.

Annex B

(informative)

European standards for filtration efficiency

- EN 13274-7, "Respiratory protective devices Methods of test Part 7: Determination of particle filter penetration"
- EN 14683:2019+AC:2019, "Medical face masks Requirements and test methods"
- EN ISO 16890-2, "Air filters for general ventilation Part 2: Measurement of fractional efficiency and air flow resistance"
- EN ISO 21083-1:2018, "Test method to measure the efficiency of air filtration media against spherical nanomaterials Part 1: Size range from 20 nm to 500 nm"

Annex C (informative)

National specifications developed by CEN members

- AFNOR Spec S76-001 Barrier masks Guide to minimum requirements, methods of testing, making and use: https://masques-barrieres.afnor.org/home/telechargement?culture=en-GB\u00e8 ga=2.57986978.982535567.1591807091-250053314.1544543671
- DNP TS C004202007 Reusable community mask Level 2 and level 3: http://www1.ipq.pt/PT/Normalizacao/Documents/DNP%20TS%20C0042020007 M%C3%A1sca ra%20comunit%C3%A1ria%20reutiliz%C3%A1vel%20(Ingl%C3%AAs).pdf
- MSZ 4209:2011 Egészségügyi maszk: https://ugyintezes.mszt.hu/Publications/Details/152181
- NEN Spec 1 Non-medical mouth nose mask Recommendations for design, manufacturing process, use and maintenance under COVID-19: https://www.nen.nl/web/file?uuid=56b23312-ae27-4b39-aea3-f2af587943f0&owner=f661b260-2145-4ed7-ae93-6641a555e6b2
- NBN/DTD S65-001:2020 Community masks and artisanal masks Guide minimum requirements, manufacture, maintenance and use: https://www.nbn.be/nl/nieuwsberichten/zelf-mondmasker-maken-officiele-regels-experten; https://www.nbn.be/fr/actualites/faire-soi-meme-masque-buccal-regles-officielles-experts
- Specification UNE 0065 Reusable hygienic masks for adult and children. Materials, design, manufacturing, marking and use requirements: https://www.une.org/encuentra-tu-norma/busca-tu-norma/norma/?c=N0063661
- SWIFT 19:2020 Barrier masks for consumers Requirements: https://shop.standards.ie/enie/Standards/SWiFT-19-2020-1187181 SAIG NSAI NSAI 2836947/
- Swiss National COVID-19 Science Task Force Recommendations for minimal specifications for the community masks for swiss manufacturers: https://www.empa.ch/documents/12524755/0/22.04.2020+Community+mask+spec+and+recommendations+for+minimal+values+V4-final.pdf/8aa76f3c-428c-46e2-b9c3-4d4af29716f2?version=1.0
- UNI/PdR 90-1 Community face mask Part 1: requirements, classification and marking <a href="http://store.uni.com/catalogo/index.php/catalogsearch/advanced/result/?tpqual var=201&tpqual%5B%5D=1a&tpqual var pdr=201&ttbloc=0&q=&name=&short description=&description=&dtnasc%5Bfrom%5D=&dtnasc%5Bto%5D=&dtfiva%5Bfrom%5D=&dtfiva%5Bto%5D=&category ics=&category ct=
- UNI/PdR 90 -2 Community face mask Part 2: test method <a href="http://store.uni.com/catalogo/index.php/catalogsearch/advanced/result/?tpqual var=201&tpqual%5B%5D=1a&tpqual var pdr=201&ttbloc=0&q=&name=&short description=&description=&dtnasc%5Bfrom%5D=&dtnasc%5Bto%5D=&dtfiva%5Bfrom%5D=&dtfiva%5Bto%5D=&category ics=&category ct=</p>

Annex D

(informative)

Main test conditions for filtration efficiency test methods

To determinate the filtration efficiency, it is recommended to apply the following parameters:

- a) Nature of the aerosol:
 - Solid particles (Sodium Chloride NaCl, Talcum powder, Holi powder, dolomite, PSL) are recommended,
 - Liquide particles (DEHS Di-Ethyl-Hexyl-Sebacat, parafin oil) are recommended.
- b) The filtration velocity shall be of $6 (\pm 1)$ cm/s.
- c) The upstream concentration should be at least 40 particles per cm³.
- d) The particle size shall be a monodisperse or polydisperse aerosol characterized by a sufficient 3 (\pm 0,5) µm particle concentration upstream of the test media.

For measurement equipment a particle sizer is recommended to determine the number concentration of particles with a diameter around 3 μ m. The technology of the instrument used and the type of equivalent diameter measured shall be specified in the test report.

The results could be presented as average values.

The determination of the filtration efficiency could be calculated as follows:

$$E(\%) = \frac{C_{upstream} - C_{downstream}}{C_{upstream}} \times 100$$

With:

 $C_{upstream}$: the particle number concentration associated to particles denoting a diameter around 3 μm and measured upstream of the media composing the tested community face covering.

 $C_{downstream}$: the particle number concentration associated to particles denoting a diameter around 3 μ m and measured downstream of the media composing the tested community face covering.

The test report shall include the set-up used (reference to standard if applicable) and parameters used for testing:

- nature of aerosol;
- airflow and sample size.

Annex E (informative)

Example of use of community face coverings

E.1 Putting on community face coverings

To be effective, the community face coverings shall be used correctly and the producer's instructions should be followed. For this, it is recommended that the community face covering be worn on bare skin (in other words without the presence of hair in contact with the user's skin and, for certain people, shaved skin) and that the following steps be taken:

a) Wash your hands with soap and water or rub with a hand sanitiser before any handling of the community face covering.



Figure E.1: Hand washing

b) For reusable community face covering, ensure that it has been properly washed beforehand in accordance with the recommendations supplied by the producer.



Figure E.2: Cleaned community face covering

- c) Locate the top, the outer and the inner side of the community face covering.
- d) Place the community face covering on the face (mouth and nose covered), with the nose bridge (if it exists) on the nose.



Figure E.3: Placement of the community face covering

e) Hold the community face covering on the outside and pass the elastic strips or fabric ties of the head harness behind the head or around the ears.



Figure E.4: Placement of the head harness

f) Pull down the bottom of the community face covering under the chin without uncovering the nose.



Figure E.5: Placement of the community face covering regarding the chin

- g) Check that the community face covering covers the chin properly.
- h) Pinch the nose bridge (if it exists) with both hands to adjust it over the nose.



Figure E.6: Pinching of the nose bridge

- i) Check that the community face covering is correctly positioned. This should be done by checking the sealing and that there is no breathing discomfort.
- j) Once adjusted, no longer touch the exterior of the community face covering with the hands. Each time the community face covering is touched, the user must wash the hands with soap and water or rub with a hand sanitiser.



Figure E.7: Do not touch an adjusted community face covering



Figure E.8: How to readjust a community face covering

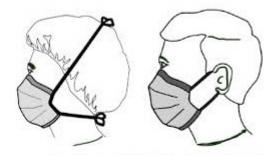


Figure E.9: Positioning of the head harness depending on the model

E.2 Removing community face coverings

It is possible to contaminate your face or surroundings when removing the community face cover. To avoid this, the recommendations are:

- a) If applicable, remove your protective gloves.
- b) Wash your hands with soap and water or rub with a hand sanitiser.



Figure E.10: Hand washing

c) Remove the community face covering by holding the back of the elastic strips or fabric ties of the head harness without touching the front part of the community face covering.



Figure E.11: Removal of the community face covering

d) Place a community face covering to be thrown away in a specific container as described in E.4.

e) Place a community face covering to be washed in a specific container (clean plastic bag).



Figure E.12: Put the community face covering in a specific container

f) Wash your hands with soap and water or rub with a hand sanitiser.



Figure E.13: Hand washing

g) Clean the outside of the specific container with a cleaning product.



Figure E.14: Container washing

E.3 Cleaning community face coverings

The complete cleaning cycle (machine washing with a standard detergent followed by drying) consists of the steps recommended by the national authorities or the community face covering producer (instructions for use, cleaning instructions). The washing temperature shall be a minimum of 60° C.

Any contact between worn community face coverings and clean items of clothing should be avoided. Those responsible for washing should protect themselves when handling worn community face coverings if they are not in a specific container (clean plastic bag).

NOTE 1 A possible additional measure is, before washing community face coverings, to clean your washing machine by doing a cold rinse with bleach or operating it empty at 60°C or 95°C without spinning.

NOTE 2 The use of fabric softener is not recommended.

Community face coverings shall be washed with ballast (e.g. towels or sheets) in the washing machine, to retain the mechanical aspect of the washing.



Figure E.15: Community face covering washing

Complete drying of the community face covering is recommended within under two hours after washing is finished.

NOTE 3 Drying using a microwave oven or a hair dryer is not recommended due to the lack of control of the temperature of each point of the community face coverings, and possible damage to the filtering material if it is heat-sensitive.

A visual inspection (with protective gloves or washed hands) shall be carried out after each cleaning cycle. If any damage to the community face coverings is detected (tears, detachment of the head harness, less accurate fit, deformation, wear, etc.) the community face coverings shall be thrown away.

E.4 Disposing of community face coverings

If a community face covering is damaged or has reached its recommended service life, it can be disposed of with normal waste after cleaning in accordance with the recommendations in E.3. Community face coverings shall be disposed of in a bin fitted with a plastic bag (preferably with a lid and non-hand operation). Double bagging is recommended to retain the contents of the first bag in the case of tearing of the outer bag during collection.



Figure E.16: Example of bin with lid and non-hand operation



Worn community face coverings can be disposed of in bins for biological waste.



Figure E.17: Example of bin for biological waste

There are eco-friendly waste management organizations responsible for collecting used textiles for recycling. As with all household waste, it is advisable to contact your local council for information about the appropriate collection point, stating that it is for community face coverings.

E.5 Period of use of the community face covering

The community face coverings shall be washed each time it is worn, 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.





Figure E.18: Dirty and wet community face coverings





Figure E.19: Waiting positions of the community face covering

Do not reuse worn or wet community face coverings. Clean the community face coverings after each use. The wearing period should be compliant with the information provided by the producer.

Bibliography

- [1] WORLD HEALTH ORGANIZATION (WHO). Advice on the use of masks in the context of COVID-19 Interim Guidance, https://apps.who.int/iris/rest/bitstreams/1279750/retrieve
- [2] General Product Safety Directive 2001/95/EC
- [3] Instituto de Biomecanica de Valencia (IBV): 3D Anthropometry Database of the Child population (2014)
- [4] EN 149, Respiratory protective devices Filtering half masks to protect against particles Requirements, testing, marking
- [5] EN 13274-3, Respiratory protective devices Methods of test Part 3: Determination of breathing resistance
- [6] EN ISO 9237, Textiles. Determination of permeability of fabrics to air (ISO 9237)
- [7] EN ISO 6330, Textiles Domestic washing and drying procedures for textile testing (ISO 6330)
- [8] ISO/TS 16976-2, Respiratory protective devices Human factors Part 2: Anthropometrics