

SLOVENSKI STANDARD SIST-TS CEN/TS 17553:2023

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Tekstilije in tekstilni izdelki - Obrazne maske za splošno uporabo - Minimalne zahteve, metode preskušanja in uporaba

Textiles and textile products - Community face coverings - Minimum requirements, methods of testing and use

Textilien und textile Produkte - Alltagsmasken - Mindestanforderungen, Prüfverfahren und Verwendung

Textiles et produits textiles - Masques communautaires - Exigences, méthodes d'essai et instructions d'utilisation

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Textiles and textile products - Community face coverings - Minimum requirements, methods of testing and use

Textiles et produits textiles - Masques grand public - Exigences minimales, méthodes d'essai et utilisation

Textilien und textile Produkte - Alltagsmasken -Mindestanforderungen, Prüfverfahren und Verwendung

This Technical Specification (CEN/TS) was approved by CEN on 19 September 2022 for provisional application.

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

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European foreword

This document (CEN/TS 17553:2022) has been prepared by Technical Committee CEN/TC 248 "Textiles and textile products", the secretariat of which is held by BSI.

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This document supersedes CWA 17553:2020.

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

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Introduction

The use of community face coverings was acknowledged during the SARS-CoV-2 pandemic as part of a comprehensive strategy of measures. They are intended for use by people in areas of known or suspected community or cluster transmission of respiratory infection. Typically, the general public wear community face coverings in indoor (for example, shops, shared workplaces, schools, transport, etc.) and outdoor settings where physical distancing can be impractical. Further guidance on where the general public may be encouraged to use community face coverings, is given by national or local health authorities and through World Health Organization recommendation^[1].

Community face coverings are not suitable for children up to 4 years of age. It is recommended that children between 4 and 12 years of age are supervised while wearing the community face covering.

NOTE 1 The minimum age criteria can be higher if required by national legal provisions or as advised by national health professionals.

The wearing of a community face covering, schematically shown in Figure 1, reduces the projection of the wearer's respiratory droplets of saliva, sputum or respiratory secretions when talking, coughing or sneezing. A community face covering might also reduce penetration of the respiratory droplets from an external source to a wearer's nose and mouth, without claiming protection for the wearer. It might also reduce how often a wearer touches his/her face with the hands.

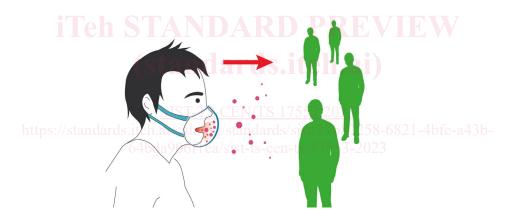


Figure 1 — Limitation of the respiratory droplets projection to the environment

This document specifies the functional and performance levels for community face coverings together with information for use, marking, labelling and packaging. The appropriate test methods are also defined.

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 — The community face coverings specified in this document are not medical devices (MD) within the meaning of Regulation EU/2017/745, nor are they personal protective equipment (PPE) within the meaning of Regulation EU/2016/425.

The informative Annex G lists topics of further investigation which might lead to necessary improvement of the safety requirements of the community face coverings.

1 Scope

This document specifies the minimum requirements for reusable or single use community face coverings intended for the general public, covering the nose, mouth and chin (for minimum coverage area, see Figure 2) in order to reduce the risk of droplet/aerosol projection towards nearby people. These requirements include:

- innocuousness,
- design (including fit),
- performance,
- test methods,
- marking,
- packaging,
- information for use.



Figure 2 — Community face coverings minimum coverage area (dark area)

These requirements are applicable to:

- community face coverings made of one or multiple fabric layers (including woven, knitted, nonwoven), and including community face coverings with a removable filter in between the layers;
- community face coverings including a transparent window which allows for the wearer's mouth and facial expressions to be seen, in order to facilitate full facial recognition, lip reading and/or sign language alongside other methods of communication (see A.6);
- structured community face coverings including moulded plastic shells and rigid face coverings' components.

This document is not intended for community face coverings for children up to 4 years of age (it means until 3 years and 11 months) (see A.1).

This document is not intended for medical face masks (medical devices specified in EN 14683), nor for filtering masks to protect against particles (personal protective equipment specified in EN 149).

This document excludes impermeable nose and mouth shields (including visors) and face coverings incorporating inhalation and/or exhalation valve(s) (see A.2).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 13274-3:2001, Respiratory protective devices - Methods of test - Part 3: Determination of breathing resistance

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

EN ISO 6330, Textiles - Domestic washing and drying procedures for textile testing (ISO 6330)

EN ISO 7500-1, Metallic materials - Calibration and verification of static uniaxial testing machines - Part 1: Tension/compression testing machines - Calibration and verification of the force-measuring system (ISO 7500-1)

EN ISO 9237:1995, Textiles - Determination of permeability of fabrics to air (ISO 9237:1995)

EN ISO 16890-2:2016, Air filters for general ventilation - Part 2: Measurement of fractional efficiency and air flow resistance (ISO 16890-2:2016)

ISO 21501-1, Determination of particle size distribution — Single particle light interaction methods — Part 1: Light scattering aerosol spectrometer

ISO 21501-4, Determination of particle size distribution — Single particle light interaction methods — Part 4: Light scattering airborne particle counter for clean spaces

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at https://www.iso.org/obp
- IEC Electropedia: available at https://www.electropedia.org/

3.1

aerosol

suspension of solid, liquid, or solid and liquid particles in a gaseous medium, having a negligible falling velocity

[SOURCE: EN 16972:2020, 3.6 without "(3.170)" and "(generally considered to be less than 0,25 m/s)"]

3.2

air permeability

volume of air per unit surface area (square metre or m^2) and unit time (second or s) passing perpendicularly through a fabric under the specified test conditions (surface area, pressure loss and duration)

3.3

breathing resistance

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

3.4

cleaning cycle

full processing cycle (washing and drying) of the product

3.5

community face covering

facepiece covering at least the mouth, nose and chin, with or without a head harness which can fastened behind the head, looped behind the ears or other means of being retained in position

Note 1 to entry: The expression "community face covering" is used to differentiate from the term "mask", commonly used for personal protective equipment (PPE) or medical devices (MD).

3.6

droplet

very small drop of liquid

Note 1 to entry: A small drop, such as a particle of moisture discharged from the mouth during coughing, sneezing, or speaking.

Note 2 to entry: These can transmit pathogens, resulting in infection, by dispersion into the air.

[SOURCE: ISO 15190:2020, 3.10]

3.7

exhaled air

air exhaled by the wearer

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3.8

exhalation valve

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

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3.9

inhaled air

air inhaled by the wearer

3.10

inhalation valve

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

3.11

material

component of community face coverings forming the barrier

3.12

material assembly

combination of all materials making up the community face covering presented exactly as the finished community face covering construction

3.13

nose bridge

device of the community face covering to enhance fit by conforming to the contours of the nose

3.14

particle

solid or liquid substance in the finely divided state

[SOURCE: EN 16972:2020, 3.170]

3.15

particle size

diameter of a sphere that produces a response, by a given particle-sizing instrument, that is equivalent to the response produced by the particle being measured

Note 1 to entry: For discrete-particle light-scattering instruments, the equivalent optical diameter is used.

[SOURCE: ISO 14644-1:2015, 3.2.2]

3.16

producer

- 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 their 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

[SOURCE: General Product Safety Directive 2001/95/EC [2]]

3.17

reusable

designed by the producer as suitable for re-use after maintenance

3.18

single use

product intended to be used once and then discarded

3.19

head harness

means of holding a face covering in place on the head

3.20

innocuousness

quality of a product causing no chemical, physical, mechanical harm to the wearer

3.21

essential articles worn on the head

medical devices and implants to improve hearing, sight, or for reduction head/skull damage

EXAMPLE Hearing aids, cochlear implants, spectacles/glasses, protective cap.

4 Requirements

4.1 General

The community face coverings are intended to be reusable or single use.

For the single use community face coverings, it is recommended to use material known to be recyclable or compostable to reduce the environmental impact (see A.9).

Community face coverings shall meet the following requirements as received and, when reusable, after durability assessment (Clause 5).

There shall be no visible defects when tested according to 6.2. Examples of defects include tears or deformation of components. If any damage to the community face coverings is detected, they are deemed non-compliant.

The community face coverings, specified as reusable, shall withstand at least five cleaning cycles (or cleaning procedures) or the higher number of cleaning cycles (or cleaning procedures) claimed by the producer (see Clause 5) at the claimed cleaning conditions.

For machine washable community face coverings, the claimed cleaning conditions of reusable community face coverings shall include (see A.11):

- The minimum washing temperature of 40 °C with the use of consumer laundry detergent;
- The minimum washing temperature of 60 °C if the use of consumer laundry detergent is not instructed;

NOTE Health agencies in some countries recommend a minimum washing temperature of 60 °C.

- The duration of washing machine cycle of a minimum of 30 min (normal settings not the economic settings)
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- The prohibition of the dry cleaning (see A.11). engls 17553.2023

For non-machine washable community face covering, the claimed cleaning conditions of reusable community face coverings shall include a disinfection process based on hand washing with soap/detergent at room temperature water, followed by soaking in a bleach solution, containing 0.1% active chlorine, for one minute then thoroughly by rinsing with room temperature water (in order to avoid any toxic residue of chlorine).

If provisions of certain countries differ from the requirements of this document, they are listed in Annex C.

Design consideration can be found in Annex E.

4.2 Innocuousness

The community face coverings shall not adversely affect the health or hygiene of the wearer. The materials shall not, in the foreseeable conditions of normal use, release substances known to be toxic, carcinogenic, genotoxic (mutagenic), sensitizing (allergenic), toxic to reproduction or irritating to skin, eyes, or respiratory tract or identified as endocrine disrupting.

Particular attention shall be paid to the presence of plasticisers, unreacted components, heavy metals, impurities and the chemical identity of pigments, dyes, perfluorinated compounds (PFAS) and biocides. In case of use of biocides, particular attention should be given to ensuring that the active substances have been assessed for their oral toxicity and inhalation toxicity as these community face coverings are used in close proximity to the mouth and nose (see A.10).

NOTE The safety or health of the user (wearer) is mentioned in the EU General Product Safety Directive ^[2], the REACH Regulation ^[3], the POP Regulation ^[4] and the Biocide Regulation ^[5].

If the determination of harmful substances has not been reported on the components of a community face covering, the determination can be carried out on community face coverings as received (it means without applying the durability assessment as described in 5.2).

Cleaning products shall not present any health risk, for example, by leaving behind hazardous substances at the end of the process. For this reason, it is recommended to use consumer laundry detergent (see A.11). Use of laundry fabric softener is not recommended (see A.11).

The community face coverings shall be designed to ensure that the non-textile components and welds shall not have sharp edges, roughness or projections which are likely to cause injury to the wearer. The use of staples for connecting parts is not permitted. Verification of the fulfilment of this requirement shall be made by manual and visual inspection (6.2).

4.3 Design

4.3.1 General

The community face coverings shall have a means of attachment for around either the head or ears that ensures the community face covering remains in the correct position during use - when breathing, talking, nodding, etc. (see also F.3.5).

It shall be able to be fixed and maintained over the nose (for example with a nose bridge or other design feature), cheeks and chin of the wearer in order to ensure that the inhaled and exhaled air passes through the materials of the community face covering, when the wearer's skin is dry or damp or when the wearer moves their head.

The construction of the community face covering shall not be pierced or perforated (for example to ease the breathing) or valves through which the air can move in and out of the community face covering freely (see A.2).

When designing community face coverings, care should be taken to consider compatibility with essential articles worn on the head of the wearer (see A.7) – for example, with head harness (see also E.2).

Verification of the fulfilment of this requirement shall be made by manual and visual inspection (6.2).

4.3.2 Dimensions / Sizing

Community face coverings should be made available in appropriate sizes taking into account the variation of the morphology of the intended wearers.

Community face coverings shall have minimum dimensions in order to always cover the critical nose / mouth / chin zone.

Critical facial measurements, as defined in Table 1, are considered for sizing for both adults and children.

Other facial measurements and head size dimension ranges in Annex D are provided as guidance. The dimensions provided are anthropometric data. Actual face coverings might need to be larger to ensure that the community face covering when worn covers the nose, mouth and chin while breathing, talking nodding, etc.

Description	Definition	Diagram
Face width (Bizygomatic breadth)	Maximum horizontal breadth of the face as measured with a spreading calliper ^a between the zygomatic arches. The subject sits looking straight ahead and with teeth together (lightly occluded). Only enough pressure is exerted to ensure that the calliper tips are on the zygomatic arches.	
Face length (menton-sellion length)	The distance in the midsagittal plane between the menton landmark at the bottom of the chin and the sellion landmark at the deepest point of the nasal root depression is measured with a sliding calliper ^a . The subject sits looking straight ahead and with teeth together (lightly occluded). The fixed blade of the calliper is placed on the sellion. Only enough pressure is exerted to obtain contact between the calliper and the skin is exerted.	

Table 1 — Description, definition, and diagrams of selected landmarks (Extract from ISO/TS 16976-2:2015)

4.3.3 Head harness

device.

Where provided, the head harness shall be designed such that the community face coverings can be easily put on, used and removed.

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 wearer's head or ears.

The head harness should be adjustable in order to ensure a close fit to minimize the leak at the face. 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.

Ear loops are the preferred options for head harnesses on children's community face coverings in order to reduce the risk of strangulation (see A.7). Where ear loops are provided with adjusting devices, the cord shall pass through the toggle(s) such that they are captive. However, for certain children, who, for example have essential articles worn on the head, alternative head harness styles might be necessary (see A.7).

Verification of the fulfilment of these requirements shall be made by visual inspection (6.2).

When the head harness is locally attached to the main body of the community face covering (Figure 3 and Figure 4), the attachment strength for the community face covering head harness shall withstand a load of 50 N for reusable community face coverings (see A.7) and 10 N for single use community face coverings, when testing is carried out in accordance with 6.5. Figure 5 shows examples of head harness attachments, made of continuous cords (*in red*) which are not to be tested, unless any loop has a joint as in Figure 4.