

BSI Flex 5555

Version 1, January 2021

Community face coverings — Specification



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Version history

BSI Flex 5555 v1.0:2021-01 Published January 2021

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Foreword

The development of this BSI Flex was facilitated by BSI Standards Limited and it was released under licence from The British Standards Institution.

Acknowledgement is given to the following organizations and their representatives as well as individuals who contributed as members of the Advisory Group:

- Bolton Consultancy Ltd
- National Childrenswear Association
- Shirley Technologies Ltd
- Intertek
- The Cabinet Office
- CPIN
- University of Leeds, UK
- University of Huddersfield
- Nestle UK
- University College London
- Which?
- Pennine Healthcare
- UK Hospitality
- SMTL, NWSSP
- Rocialle Healthcare Limited

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Relationship with other publications

This BSI Flex was adapted from the CEN Workshop Agreement, *Community face coverings — Guide to minimum requirements, methods of testing and use*. The CEN Workshop Agreement is now being further developed as the basis for a CEN Technical Specification, and it is envisaged that this BSI Flex will be withdrawn once the CEN Technical Specification is published.

Use of this document

The provisions of this BSI Flex are presented in roman (i.e. upright) type. Its requirements are expressed in sentences in which the principal auxiliary verb is “shall”.

Commentary, explanation and general informative material is presented in smaller italic type, and does not constitute a normative element.

Where words have alternative spellings, the preferred spelling of the Shorter Oxford English Dictionary is used (e.g. “organization” rather than “organisation”).

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Introduction

In response to the COVID-19 pandemic, people were asked to wear simple face coverings to reduce the projection of exhaled air and hence reduce the spread of infection. Drawing on hospital experiences and data, community face coverings are being re-defined to include performance requirements.

The World Health Organization (WHO) have provided guidance on the factors which are to be considered for face coverings, as well as examples of where the general public are encouraged to use medical and non-medical masks (i.e. face coverings) in areas with known or suspected community transmission [1].

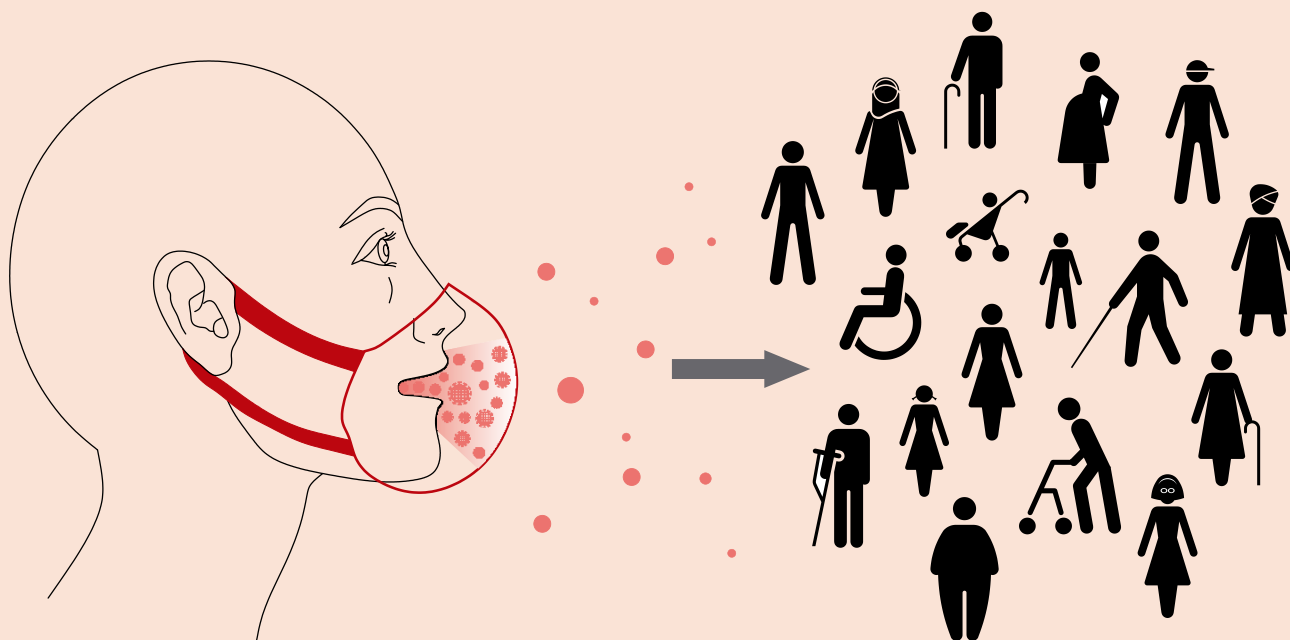
Community face coverings are intended for use by people not displaying any clinical symptoms of viral or bacterial infection and who do not come into contact with people displaying such symptoms.

Community face coverings are not suitable for children under 3 years of age. It is recommended that children between 3 and 11 years are supervised while wearing the community face covering.

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

Community face coverings minimize the projection of the wearer's respiratory droplets, saliva, sputum or respiratory secretions when talking, coughing or sneezing. Community face coverings are designed to offer a level of protection for those around the wearer, but they can also limit penetration by respiratory droplets from another person into the wearer's nose and mouth. A face covering can also minimize the amount wearers touch their nose and mouth. See Figure 1.

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



This document specifies the minimum performance requirements and associated test methods for community face coverings.

This document specifies a filtration level 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 recommendations [1].

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

Community face coverings might be legally required to be worn in a number of settings, and attention is drawn to national regulations.

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 might need to call upon a laboratory to verify the required performance.

IMPORTANT A community face covering will have maximum effectiveness if it is worn in direct contact with bare skin. Facial hair can influence the effectiveness of the face covering, and those with facial hair should take extra precautions of social distancing.

IMPORTANT The community face coverings specified in this document do not fall under medical devices within the meaning of Part II of the Medical Devices Regulations 2002 (No. 618) (as amended) [2] or Directive 93/42/CEE [3] or Regulation (EU) 2017/745 [4], nor as a personal protective equipment (PPE) within the meaning of Regulation (EU) 2016/425 [5].

1 Scope

This BSI Flex specifies the minimum requirements for reusable or single-use community face coverings intended for the general public. These minimum requirements include:

- a) design;
- b) performance;
- c) test methods;
- d) packaging;
- e) labelling; and
- f) information for use.

This BSI Flex is not intended for community face coverings for children under the age of 3 or for community face coverings that contain any valves.

This BSI Flex does not apply to PPE or medical grade face masks.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes provisions 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.

BS EN 149:2001+A1:2009, *Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking*

BS EN 13274-3, *Respiratory protective devices – Methods of test – Determination of breathing resistance*

BS EN 13274-7:2019, *Respiratory protective devices – Methods of test – Determination of particle filter penetration*

BS EN 14683:2019, *Medical face masks – Requirements and test methods*

BS EN ISO 3758, *Textiles – Care labelling code using symbols*

BS EN ISO 6330, *Textiles – Domestic washing and drying procedures for textile testing*

3 Terms and definitions

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

3.1 breathing resistance

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

3.2 community face covering

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

3.3 exhaled air

air exhaled by the wearer

3.4 inhaled air

air inhaled by the wearer

3.5 material

element of community face coverings forming the barrier

3.6 producer

- a) the manufacturer of the product, when they are established in the European Union, and any other person presenting themselves as the manufacturer by affixing to the product their name, trade mark or other distinctive mark, or the person who reconditions the product;
- b) 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;
- c) 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 [6]]

3.7 product(s)

item intended for use or likely, under reasonably foreseeable conditions, to be used by wearers

3.8 cleaning cycle

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

4 Designation

Community face coverings to be placed on the market that meet the requirements of this document shall be designated as follows: BSI Flex 5555.

5 Requirements

5.1 General

Community face coverings shall not contain any valves.

Community face coverings are intended to be reusable or for single use.

***NOTE 1** For single use community face coverings consideration should be given to using sustainable materials to reduce the environmental impact.*

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

The community face covering shall be able to be fixed and maintained over the nose, cheeks and chin of the wearer, during normal activities, for example when the wearer moves their head, and when the wearer's skin is dry or damp.

***NOTE 2** 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.*

The producer shall retain all necessary documentation in relation to the materials that are used in the manufacturing of community face coverings for a period appropriate to the product life cycle.

To comply with this document, products shall meet all the requirements specified in this document throughout their useful life as per the manufacturer's claims. Where no maximum cleaning cycles are stipulated, reusable community face coverings shall withstand a minimum of 5 cleansing cycles.

5.2 Dimensions/Sizing

Community face coverings shall have a means by which they can be fitted over the nose, mouth and chin of the wearer and which ensures that the mask fits closely to the face. Community face coverings shall be produced in a selection of sizes to fit the intended user population.

5.3 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 packaging are at the producer's discretion.

5.4 Materials

Materials used shall be suitable to withstand handling and wear over the period for which the community face covering is designed to be used.

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

- a) its breathability;
- b) the ability to absorb moisture or minimize the effects of condensation;
- c) materials which come into direct contact with the nose and mouth shall not be known to cause irritation, allergenic effects or other toxic effect. Inorganic materials that might cause a respiration risk shall be avoided. Biocides shall not be used. This evaluation is under the responsibility of the producer;
- d) for reusable community face coverings, the materials used shall withstand the cleaning cycles, detergents and methods specified by the producer.

Community face coverings shall be so designed and manufactured as to preclude risks and other nuisance factors under foreseeable conditions of use.

Community face covering materials and parts, including any of their decomposition products, shall not adversely affect user hygiene or health.

NOTE Consideration should be given to using sustainable materials to reduce the environmental impact.

5.5 Cleaning

Reusable community face coverings 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:

- a) the producer's detailed cleaning instructions; or
- b) the procedure described in BS EN ISO 6330.

Only cleaning products that do not present any health risk shall be used, e.g. any products leaving residual hazardous substances on the material shall be avoided. For this reason, domestic detergent should be used and fabric softener/conditioner shall not be used.

If any damage to the community face coverings is detected (e.g. tears, detachment of the fastenings, deformation, wear) after each cleaning cycle, the community face coverings are deemed non-compliant.

Community face coverings shall not be cleaned by professional wet or dry cleaning.

5.6 Surface condition of the parts

All parts of the community face covering shall be free of sharp edges or burrs. Staples for connecting parts shall not be used as they pose a safety hazard to the wearer.

Testing shall be carried out in accordance with 6.2.

5.7 Filtration efficiency of the material

Community face coverings shall have filtration efficiency of greater than or equal to 70% when tested in accordance with 6.4.

5.8 Fastenings

The fastenings shall be designed such that the community face coverings can be easily put on and removed.

Fastenings 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 fastening can go around the wearer's head or ears and each attachment point shall withstand a tensile load of 10 N.

Community face coverings shall be available in a selection of sizes or be self-adjusting.

NOTE 1 Fastenings can be laces, or 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.

Face coverings to be used for children shall only utilize earloops for fastening and shall not have an adjusting device.

NOTE 2 *A self-adjusting fastening 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.

5.9 Breathing resistance

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

- a) Requirement 1: Differential pressure:
Differential pressure of the material less than or equal to 70 Pa/cm²; or
- b) Requirement 2: Breathing resistance:
 - 1) Inhalation resistance of 2.4 mbar; and
 - 2) Exhalation resistance of 3 mbar.

Testing shall be carried out in accordance with 6.5.

6 Test methods

6.1 General

The producer shall ensure that verification and validation tests are performed 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 and manual inspection

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

All defects (e.g. tears, detachment of the fastening, sharp edges) shall be considered as non-compliant.

For reusable community face coverings, the visual and manual inspection shall be carried out on samples before and after cleaning as per the manufacturers' instructions.

6.3 Fastening strength test

Mount the face covering securely to a fixture as shown in BS EN 149:2001+A1:2009, Figure 9. Apply an axial tensile force of 10 N to the fastenings for 10 s, and record the results.

A total of three face coverings shall be tested: single-use face coverings shall be tested as received only, reusable face coverings shall be tested after five manufacturer's cleaning cycles.

6.4 Material filtration efficiency test

The filtration efficiency shall be tested in accordance with the sodium chloride test method in BS EN 13274-7:2019, Clause 6 with a flow through the face covering of 95 l/min.

A total of three face coverings shall be tested: single-use tested as received only, but if the face covering is reusable, then after five manufacturer's cleaning cycles as well.

6.5 Breathing resistance

To determine the breathing resistance, one of the following tests shall apply as appropriate to the selected requirements used in 5.9:

- a) Method 1: Differential pressure
Differential pressure: test in accordance with BS EN 14683:2019, Annex C on the material; or
- b) Method 2: Breathing resistance
Breathing resistance: test in accordance with BS EN 13274-3:2001, Clause 6, Method 1: Static breathing resistance using a constant flow of 95 l/min through the face covering.

A total of three face coverings shall be tested: single-use tested as received only, but if the face covering is reusable, then after five manufacturer's cleaning cycles as well.

7 Labelling and instructions for use to be provided with the community face covering

7.1 Labelling

Community face coverings to be placed on the market shall be clearly and durably labelled with the information below or shall be legible through the packaging if the packaging is transparent and contain the minimum information below.

NOTE National regulations might require additional information.

The text shall be printed in the official language(s) of the country or region of the wearer.

- a) The producer name, trademark, or other means of identification.
- b) The postal address at which the producer can be contacted.
- c) A means of product identification e.g. catalogue or model number.
- d) The designation "BSI Flex 5555" followed by the version of the document.
- e) The type of community face coverings i.e. "reusable" or "single-use".
- f) The type of user the face covering is intended for, i.e. "child" or "adult".
- g) The age appropriate restriction warning i.e. "Not suitable for children under 3 years of age due to suffocation hazard."

7.2 Instructions for use

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

- a) The cleaning instructions (washing and drying) in accordance with BS EN ISO 3758 and instructions to clean the reusable community face covering after each use. A reusable community face covering shall include instructions to be washed before first use unless recommended otherwise by the producer.
- b) For reusable community face coverings, the maximum number of cleaning cycles for which the community face covering is guaranteed to be compliant.

- c) The purpose of face covering, for example, to minimize the risk of the wearer transmitting the virus to others.
- d) The producer's recommendation on duration of use (e.g. number of hours);
- e) Instructions on how to fit, use, put on (don) and remove (doff) the community face covering, which may be informed by a pictogram.
- f) The instructions and warnings below, with the words "WARNING" in front of them:
 - 1) If you are ill, this community face covering is unsuitable. Seek advice from your doctor.
 - 2) 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; facial hair can reduce the filtration efficiency of the face covering.
 - 3) Community face coverings are not suitable for children under 3 years of age. It is recommended that children between 3 and 11 years are supervised while wearing the community face covering. It can take time to become comfortable with the community face covering.
 - 4) A community face covering which hinders the wearer's ability to breathe when first put on is deemed unsuitable. It can take time to become comfortable with the community face covering.
 - 5) This community face covering does not replace protective measures including regular hand-washing, physical separation, and reduced contact with other people. It can minimize the projection of wearer's respiratory droplets and saliva into the environment.
 - 6) Do not use when participating in vigorous physical activity.
 - 7) Stop using this product at the first signs of damage.
 - 8) Do not dry clean; do not use fabric conditioner/softener or scent boosters.

Bibliography

Other publications

- [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>
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- [3] EUROPEAN UNION. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. OJ L 169, 12.7.1993.
- [4] EUROPEAN UNION. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. OJ L 117, 5.5.2017.
- [5] EUROPEAN UNION. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC. OJ L 81, 31.3.2016.
- [6] EUROPEAN UNION. Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (Text with EEA relevance). OJ L 11, 15.1.2002.



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