# An Overview of Standards on Community Masks

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IFC International Finance Corporation WORLD BANK GROUP

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# “Community face coverings”

- Sometimes referred to as ‘Community face masks’, ‘Barrier Face Coverings’, or (in everyday speech) as ‘face masks’
- These are neither PPE (in the strict sense) nor medical devices. They are not usually subject to regulations other than those for General Product Safety.
- Typically made from one or multiple layers of fabric (woven, knitted, or nonwoven) and with a means of attachment to the head or ears.
- Whilst standards for respirators and medical face masks pre-dated the COVID-19 Pandemic, it is only recently (in late 2020 and 2021) that standards have been developed for Community Face Coverings.

# Typical Key Requirements*

*Taken from BSI Flex 5555:2021

- General (No valves; for single use or reusable)
- Dimensions / Sizing / Coverage (Nose and mouth)
- Filtration efficiency
- Breathing resistance
  - preferred WHO threshold for adults is ≤40 Pa/cm2; for children ≤20 Pa/cm2.
- Test criteria
  - Visual and manual inspection
  - Fastening strength test
  - Material filtration efficiency test
  - Breathing resistance
- Labelling and instructions for use
- Environmental considerations

# Summary Essential Fabric Mask Requirements

- Minimum 70% filtration
- 3µm particle size
- Challenge options
  - Solid: NaCl, latex spheres, talcum powder, holi powder, dolomite,
  - Liquid: Paraffin oil, Dioctyl sebacate
- Breathability
  - Pressure drop: ≤70 Pa/cm$^2$ (CEN CWA 17553)
  - Breathing resistance: ≤ 2,4 mbar for a flow of 95 l/min (inhalation), ≤3 mbar for a flow of 160 l/min (exhalation)
  - Air permeability: ≥ 96 l/s/m$^2$
- Minimum wash cycles: 5 cycles
- Other performance claims must be substantiated

World Health Organization

HEALTH EMERGENCIES programme

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# Standards available - examples

**CEN**

**WORKSHOP**

**AGREEMENT**

**CWA 17553**

June 2020

**ICS** 13.340.20

English version

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

- Swiss National Covid-19 Taskforce Recommendations
- Turkey (TSE K599)
- Morocco (similar to AFNOR S076)
- Bangladesh (Specs and QC Version – 2.01)
- South Korea (KF-AD, anti-droplet)
- Italy (UNI/PdR 90.1 and 90.2)
- Spain (UNE 0065)

**AATCC M14-2020**

**Guidance and Considerations for General Purpose Textile Face Coverings: Adult**

**BSI Flex 5555**

Version 2, March 2021

Community face coverings — Specification

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**AFNOR SPEC S76-001**

28 Avril 2020

Version 1.10

**Masques barrières**

—

**Guide d'exigences minimales, de méthodes d'essais, de confection et d'usage**

This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.

Designation: F3502 – 21

ASTM F3502-21

**Standard Specification for Barrier Face Coverings**[1]

This standard is issued under the fixed designation F3502; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

**INTRODUCTION**

This is the first ASTM standard to address this type of product. The standard was primarily established in response to the global COVID-19 pandemic beginning in 2019 to address a product that is neither a medical face mask per ASTM Specification F2100 for providing source control, nor a respirator for providing inhalation protection as defined by regulatory requirements specified in the United States under 42 CFR Part 84.

This specification is intended to establish a national standard baseline for a source control device. This standard brings value by specifying minimum design, performance, and testing requirements and allowing comparison of products by end users where current guidelines have been limited. Evolving literature suggests that barrier face coverings could reduce the potential for disease transmission, as well as offering a reduction of inhalation particulate matter by the wearer. The focus of this specification is to identify how the device should perform in terms of source control/protection, comfort, and re-use potential. The level of source control/protection depends on how well particles are blocked from going through the barrier face covering and minimizing the amount of leakage that may occur around the perimeter of the barrier face covering. The specific performance property for filtration efficiency provides a greater challenge than most other particulate filtration tests, including BFE, based on the use of smaller particles and more rigorous test conditions. Barrier face coverings must be comfortable enough for individuals to be willing to wear them for long periods of time. Requirements for breathing resistance were incorporated into the specification. The final performance criterion was the potential for re-use of the barrier face covering, so the possibility of re-use was identified in the specification.

Users of this standard are directed to Section 1 (Scope) and Section 4 (Significance and Use) to understand the specific areas addressed by this standard and its limitations, along with the reasons for choice of specific requirements. Users of this standard are further directed to the specific caveats for this standard that are included in 1.3 – 1.11. The subcommittee responsible for this standard intends to further evolve this specification for addressing new knowledge about disease transmission reduction and barrier face covering design, performance, labeling, conformity assessment, and other aspects of these products' safety, health, and environmental impact as this information becomes available.

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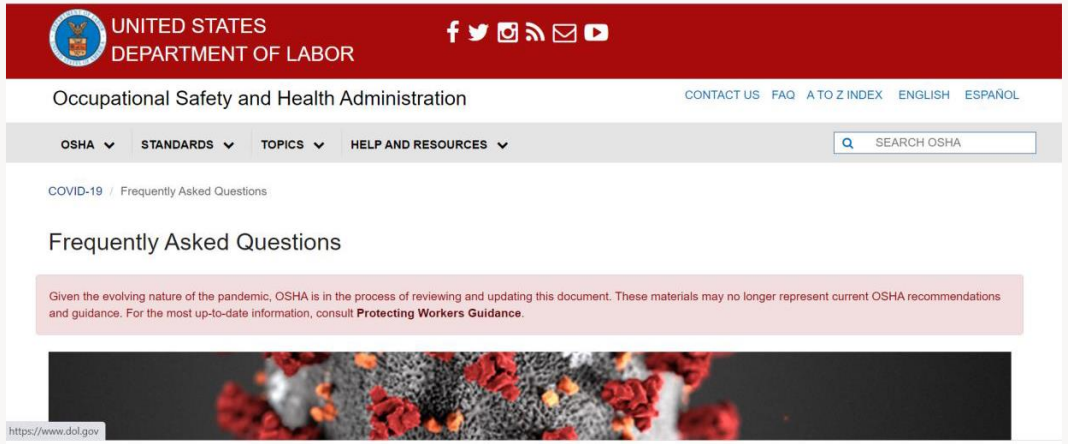
# Government Policies and "Enforcement" criteria for community face masks

- Regulatory
  - there are none; other than requirements to ***use*** a mask in certain settings! ("Anything is better than nothing")
- "Semi-voluntary"
  - Workplace, public buildings
    - Example: OSHA Guidance (US)
  - "Conditions of entry"
    - Bars, Theatres, Airlines etc
  - Peer/community pressure
    - But usually for "any kind of mask"

# Lack of alignment of standards

No ISO Standard
All other standards developed separately

| Market | Main product standards |
|---|---|
| Relevant ISO Standards | N/A |
| EU | **CWA 17553:2020** Community face coverings - Guide to minimum requirements, methods of testing and use |
| USA | **ASTM F3502-21** Standard Specification for Barrier Face Coverings |
| Australia | N/A |
| Brazil | **ABNT PR 1002:2020 Ed 2** Masks for non-professional respiratory protection – Guide with basic requirements for testing, manufacture and use |
| Canada | **BNQ 1922-900:2020** Masks intended for working environments — Attestation Document (for Province of Quebec) |
| Colombia | **NTC 6449:2020** Masks (face masks) for use in environments other than the health sector |
| India | N/A |
| Jordan | N/A (under development) |
| Kenya | **KS 2924:2020** Personal protective equipment — Face masks — Masks for public use — Specification |
| Malaysia | N/A |
| S. Africa | N/A (under development) |
| UK | **BSI Flex 5555:2021** Community face coverings — Specification |
| Vietnam | N/A |

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# Comparison EU/US

More stringent | Similar | Not comparable

| (Market) Standard | (EU) CWA 17553:2020 | | (US) ASTM F3502-21 | | COMPARISON/ COMMENTS |
|---|---|---|---|---|---|
| **Characteristic** | **Testing method** | **Requirement** | **Requirement** | **Testing method** | |
| Breathing Resistance | EN 14683:2019, Annex C or<br>EN 13274-3 | ≤ 70 Pa/cm$^2$<br>or<br>Inhalation resistance of 2.4 mbar Exhalation resistance 3 mbar | Level 1 ≤ 15 mm $H_2O$<br>Level 2 ≤ 5 mm $H_2O$ | Subpart K of 42 CFR Part 84, modified as per § 8.2 | 1 Alternate characteristic to breathing resistance in the EU is air permeability,<br>2 In the US breathing resistance of entire mask is measured (not per unit area) |
| Air permeability | EN ISO 9237 | ≥ 96 l/s/m$^2$ @ 100 Pa | n/a | | |
| Particle Filtration Efficiency (PFE) | EN 13274-7 or<br>EN ISO 16890-2 or<br>EN ISO 21083-1:2018 | Level 90% ≥ 90%<br>Level 70% ≥ 70% Particle size 3 (± 0.5) µm | Level 1 ≥20%<br>Level 2 ≥ 50%<br>Sub-micron particle size | Subpart K of 42 CFR Part 84, modified as per § 8.1 | Alternate characteristic to PFE in the EU is BFE test (see below) |
| Bacterial Filtration Efficiency (BFE) | EN 14683:2019, Annex B | Level 90% ≥ 90%<br>Level 70% ≥ 70% | Manufacturer may choose to provide the BFE results (as per ASTM F 2101) along with PFE | | |
| Inward leakage | | N/A | Results to be reported (no criteria are set) | Determined through design analysis or optional application of a modified form of ASTM F3407 (quantitative leakage test) | |

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# Comparison UK/EU/US

BSI Flex 5555 is…….  Less stringent  Same (or More stringent)  Not comparable

| (Market) Standard | (EU) CWA 17553:2020 | (UK) BSI Flex 5555 | (USA) ASTM F3502-21 | COMMENTS |
|---|---|---|---|---|
| | | | | |
| Breathing Resistance | EN 14683:2019, Annex C<br>(≤ 70 Pa/cm$^2$)<br>EN 13274-3 (Inhalation resistance of 2.4 mbar; Exhalation resistance 3 mbar) | Differential pressure ≤60 Pa/cm$^2$; (BS EN 14683:2019, Annex C)<br>OR<br>Inhalation resistance of 2.4 mbar; Exhalation resistance of 3 mbar (BS EN 13274-3:2001) | Subpart K of 42 CFR Part 84, modified by §8.2<br>(Level 1 ≤ 15 mm $H_2O$<br>Level 2 ≤ 5 mm $H_2O$) | For EU either breathing resistance or air permeability is measured. |
| Air permeability | EN ISO 9237<br>(≥ 96 l/s/m$^2$ @ 100 Pa) | n/a | n/a | |
| Particle Filtration Efficiency (PFE) | EN 13274-7:2019 OR<br>EN ISO 16890-2 OR<br>EN ISO 21083-1:2018,<br>OR measure BFE (see below)<br>(Level 90% ≥ 90%;<br>Level 70% ≥ 70%)<br>Particle size 3 (± 0.5) µm | ≥ 70%<br>in accordance with the NaCl test method in BS EN 13274-7:2019, Clause 6 with a flow of 95 l/min, Particle size 3 (± 0.5) µm;<br>OR | Subpart K of 42 CFR Part 84, modified by §8.1<br>(Level 1 ≥20%;<br>Level 2 ≥ 50%) | For EU and UK either PFE or BFE is measured.<br>For PFE, the CWA provides for alternative methods |
| Bacterial Filtration Efficiency (BFE) | EN 14683:2019<br>(Level 90% ≥ 90%;<br>Level 70% ≥ 70%) | ≥ 95%<br>BS EN 14683:2019, Annex B. | Manufacturer may choose to provide the BFE results (as per ASTM F 2101) along with PFE | UK Exceeds the requirements in EU |

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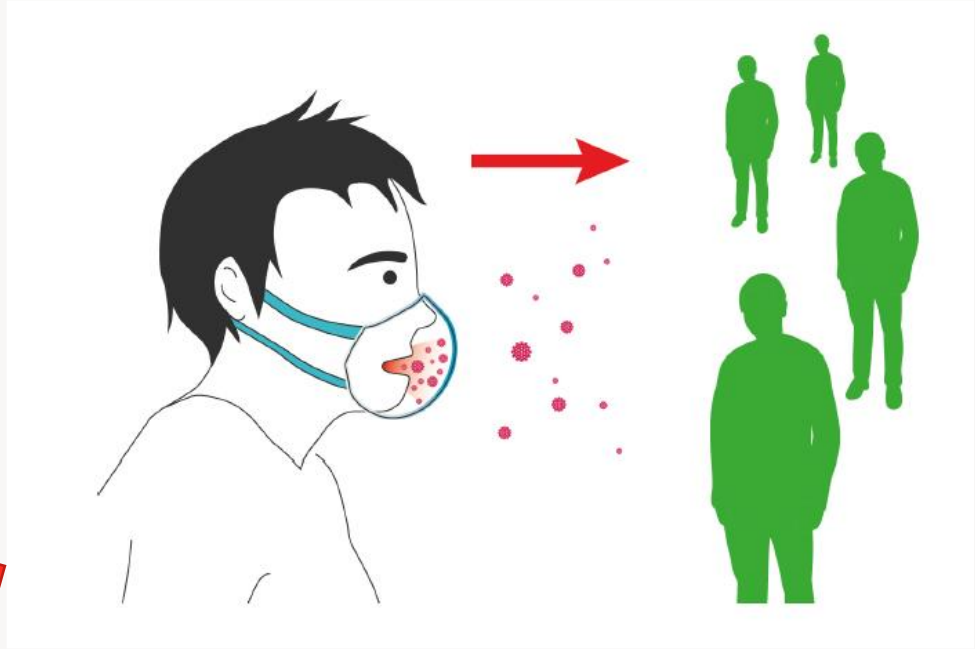
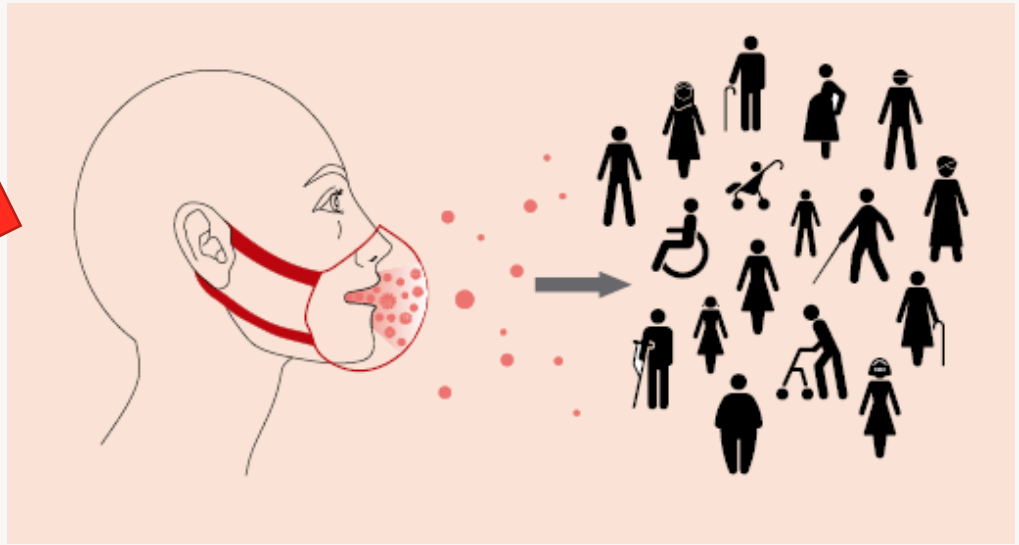
# Gender and inclusivity are important!.....

- Two different community face covering standards
- Same topic
- No comment needed!!





# Thank You!

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