An Overview of Standards on Community Masks

Dr Nigel H Croft
March 15th 2022
“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/cm² (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/m²
- Minimum wash cycles: 5 cycles
- Other performance claims must be substantiated
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

ASTM F3502-21

Standard Specification for Barrier Face Coverings

Introduction

This is the first ASTM standard to address this type of product. The standard was primarily established by a group of US manufacturers to create a specification for barrier face coverings (BFCs) that require a product that is not a medical face mask per the ASTM Specifications F95-20 for providing wearer comfort, and a material that provides a barrier to respiratory infection. This standard describes a method for fabricating such a product and the tests to release the fabric to the market.

The Committee on who are responsible for this standard specifies that the standard was intended to fill a gap in the market for barrier face coverings, and any testing required by this standard must be conducted in accordance with the relevant standard for that type of product.

Users of this standard are directed to the relevant sections of the standard for additional information, along with the use of the standard for barrier face coverings. This standard is intended to be used in conjunction with other standards for barrier face coverings, and any testing required by this standard must be conducted in accordance with the relevant standard for that type of product.
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

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

No ISO Standard
All other standards developed separately.
## Comparison EU/US

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>(EU) CWA 17553:2020</th>
<th>(US) ASTM F3502-21</th>
<th>COMPARISON/COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breathing Resistance</td>
<td>EN 14683:2019, Annex C or EN 13274-3 ≤ 70 Pa/cm² or Inhalation resistance of 2.4 mbar Exhalation resistance 3 mbar</td>
<td>Level 1 ≤ 15 mm H₂O Level 2 ≤ 5 mm H₂O Subpart K of 42 CFR Part 84, modified as per § 8.2</td>
<td>1 Alternate characteristic to breathing resistance in the EU is air permeability, 2 In the US breathing resistance of entire mask is measured (not per unit area)</td>
</tr>
<tr>
<td>Air permeability</td>
<td>EN ISO 9237 ≥ 96 l/s/m² @ 100 Pa</td>
<td>n/a</td>
<td>Alternate characteristic to PFE in the EU is BFE test (see below)</td>
</tr>
<tr>
<td>Particle Filtration Efficiency (PFE)</td>
<td>EN 13274-7 or EN ISO 16890-2 or EN ISO 21083-1:2018 Level 90% ≥ 90% Level 70% ≥ 70% Particle size 3 (± 0.5) μm</td>
<td>Level 1 ≥ 20% Level 2 ≥ 50% Sub-micron particle size Subpart K of 42 CFR Part 84, modified as per § 8.1</td>
<td></td>
</tr>
<tr>
<td>Bacterial Filtration Efficiency (BFE)</td>
<td>EN 14683:2019, Annex B Level 90% ≥ 90% Level 70% ≥ 70%</td>
<td>Manufacturer may choose to provide the BFE results (as per ASTM F 2101) along with PFE</td>
<td></td>
</tr>
<tr>
<td>Inward leakage</td>
<td>N/A</td>
<td>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)</td>
<td></td>
</tr>
</tbody>
</table>

**More stringent** | **Similar** | **Not comparable**
<table>
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<tr>
<th>(Market) Standard</th>
<th>(EU) CWA 17553:2020</th>
<th>(UK) BSI Flex 5555</th>
<th>(USA) ASTM F3502-21</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breathing Resistance</td>
<td>EN 14683:2019, Annex C (≤ 70 Pa/cm²) EN 13274-3 (Inhalation resistance of 2.4 mbar; Exhalation resistance 3 mbar)</td>
<td>Differential pressure ≤60 Pa/cm²; (BS EN 14683:2019, Annex C) OR Inhalation resistance of 2.4 mbar; Exhalation resistance of 3 mbar (BS EN 13274-3:2001)</td>
<td>Subpart K of 42 CFR Part 84, modified by §8.2 OR Inhalation resistance of 2.4 mbar; Exhalation resistance of 3 mbar (BS EN 13274-3:2001)</td>
<td>For EU either breathing resistance or air permeability is measured. For EU and UK either PFE or BFE is measured. For PFE, the CWA provides for alternative methods</td>
</tr>
<tr>
<td>Air permeability</td>
<td>EN ISO 9237 (≥ 96 l/s/m² @ 100 Pa)</td>
<td>n/a</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Particle Filtration Efficiency (PFE)</td>
<td>EN 13274-7:2019 OR EN ISO 16890-2 OR EN ISO 21083-1:2018, OR measure BFE (see below) (Level 90% ≥ 90%; Level 70% ≥ 70%) Particle size 3 (± 0.5) μm</td>
<td>≥ 70% 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; OR</td>
<td>Subpart K of 42 CFR Part 84, modified by §8.1 OR Inhalation resistance of 2.4 mbar; Exhalation resistance of 3 mbar (BS EN 13274-3:2001) (Level 1 ≥20%; Level 2 ≥ 50%)</td>
<td>For EU and UK either PFE or BFE is measured. For PFE, the CWA provides for alternative methods</td>
</tr>
<tr>
<td>Bacterial Filtration Efficiency (BFE)</td>
<td>EN 14683:2019 (Level 90% ≥ 90%; Level 70% ≥ 70%)</td>
<td>≥ 95% BS EN 14683:2019, Annex B.</td>
<td>Manufacturer may choose to provide the BFE results (as per ASTM F 2101) along with PFE</td>
<td>UK Exceeds the requirements in EU</td>
</tr>
</tbody>
</table>
Gender and inclusivity are important!........

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

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