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[U.S. FDA regulatory info](#)

N/A - non-medical face masks are not classified as medical devices

[European Union regulatory info](#)

N/A - non-medical face masks are not classified as medical devices according to EU/2017/745 or PPE according to EU/2016/425 [1]

[World Health Organization guidance:](#)

Advice on the use of masks in the context of COVID-19 [2]

Overview

The purpose of this technical guidance document is to provide the following information:

- A general overview of the purpose of non-medical face masks as well as an explanation of the differences between medical and non-medical face masks
- A concise introduction to the key design features of non-medical face masks, including a brief explanation of why each feature is important and how it is tested
- References to available resources that provide sample designs and construction guidance

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Introduction and Intended Use

Overview

Non-medical face masks are intended for use by the general population to cover the wearer’s nose and mouth as a method of source control. “Source control” refers to containing a person’s respiratory secretions – which are produced when speaking, coughing, or sneezing – as a means to prevent the transmission of infection [3]. In addition, masks can be used to provide some level of protection for the wearer [2].

The World Health Organization cautions that “the use of a mask alone is insufficient to provide an adequate level of protection or source control, and other personal and community level measures should also be adopted to suppress transmission of respiratory viruses. Whether or not masks are used, compliance with hand hygiene, physical distancing and other infection prevention and control (IPC) measures are critical to prevent human-to-human transmission of COVID-19 [2].”

The CDC recommends that people wear non-medical face masks in public settings, especially when other social distancing measures are difficult to maintain [4].

Non-Medical vs. Medical Face Masks

There are a range of options when it comes to face masks. For the purposes of this guidance document, face masks are considered to belong to either of the following high-level categories: non-medical face mask or medical face mask.

Non-Medical Face Mask

A non-medical face mask may also be referred to as a cloth face covering, fabric mask, cloth mask, or barrier mask. A non-medical face mask can be made from a variety of woven and non-woven fabrics, combinations of fabrics, layering sequences, and shapes [2]. Few of these combinations have been systematically evaluated, and the nearly unlimited combination of fabrics and materials results in variable filtration and breathability performance [2].

The World Health Organization recommends the use of a non-medical face mask for the following situations/settings and populations as a means of source control:

Table 1 - World Health Organization: Non-Medical Face Mask Guidance [2]

Situations/settings	Population
Areas with known or suspected widespread transmission and limited or no capacity to implement other containment measures such as physical distancing, contact tracing, appropriate testing, isolation and care for suspected and confirmed cases.	General population in public settings, such as grocery stores, at work, social gatherings, mass gatherings, closed settings, including schools, churches, mosques, etc.
Settings with high population density where physical distancing cannot be achieved; surveillance and testing capacity, and isolation and quarantine facilities are limited	People living in cramped conditions, and specific settings such as refugee camps, camp-like settings, slums
Settings where a physical distancing cannot be achieved (close contact)	General public on transportation (e.g., on a bus, plane, trains) Specific working conditions which places the employee in close contact or potential close contact with others e.g., social workers, cashiers, servers

Non-medical face masks should not be used as a substitute for medical/surgical masks or filtering facepiece respirators (FFRs) when protections such as the following are needed [3]:

- Liquid barrier protection
- Antimicrobial or antiviral protection, prevention, or reduction
- Respiratory protection
- Particulate filtration
- Protection in high-risk aerosol generating procedures

A non-medical face mask is not considered to be a medical device or personal protective equipment (PPE) [2].

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Medical Face Mask

A medical face mask (or simply “medical mask”) is defined as a surgical or procedure mask that is subject to performance characteristics (set forth by standards ASTM F2100-19, EN 14683:2019, or equivalent) that aim to balance high filtration, adequate breathability, and optionally, fluid penetration resistance [2] [5] [6].

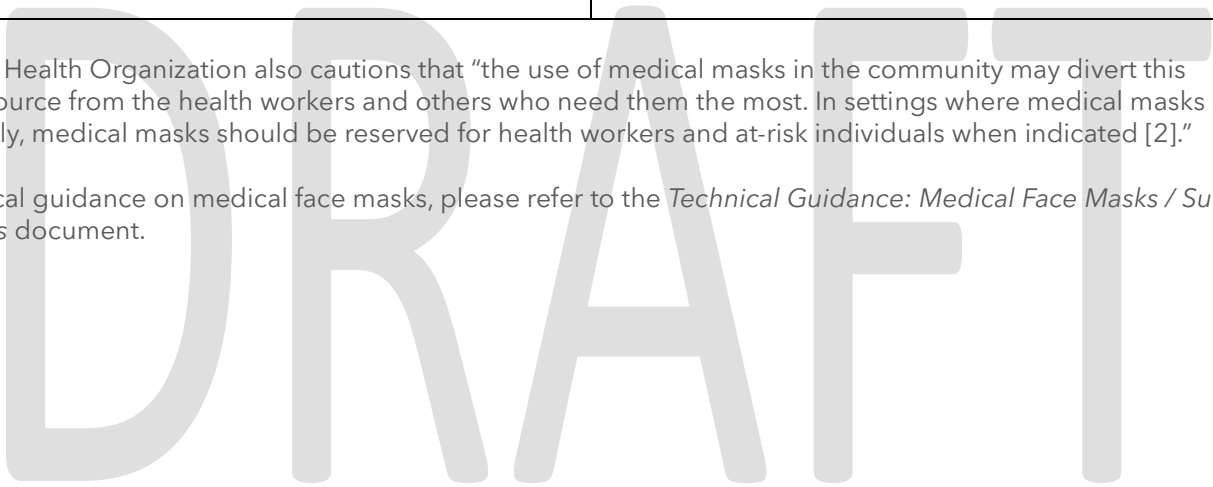
The World Health Organization recommends the use of a medical mask for the following situations/settings and populations as a means of source control and/or wearer protection:

Table 2 - World Health Organization: Medical Face Mask Guidance [2]

Situations/settings	Population
Settings where physical distancing cannot be achieved and increased risk of infection and/or negative outcomes	Vulnerable populations: <ul style="list-style-type: none"> • People aged ≥ 60 years • People with underlying comorbidities, such as cardiovascular disease or diabetes mellitus, chronic lung disease, cancer, cerebrovascular disease, immunosuppression
Any setting in the community (any transmission scenario)	Persons with any symptoms suggestive of COVID-19

The World Health Organization also cautions that “the use of medical masks in the community may divert this critical resource from the health workers and others who need them the most. In settings where medical masks are in short supply, medical masks should be reserved for health workers and at-risk individuals when indicated [2].”

For technical guidance on medical face masks, please refer to the *Technical Guidance: Medical Face Masks / Surgical Face Masks* document.



Technical Design and Test Criteria

This section provides a concise introduction to the key design features of non-medical face masks, including a brief explanation of why each feature is important and how it is tested (as applicable). Collectively, this set of technical features and test criteria are what ensure the safety and effectiveness of non-medical face masks.

Note: In some areas, multiple test methods are provided; it is not necessary to perform all test methods (one is sufficient).

General Construction

The construction of the non-medical face mask can be highly variable from one design to the next. As stated above, there is no single right or best design. The key aspects of the general construction to consider include the following:

Identification of Outer Layer vs. Inner Layer

To reduce the likelihood of inadvertent contamination (e.g. if the wearer momentarily takes the mask off, then puts it back on), it is important for the wearer to be able to distinguish between the outer layer and the inner layer of the mask. One way to accomplish this is to designate the outer and inner layer to be a different color. It is also possible to identify the outer surface vs. the inner surface by examining the seams. Ultimately, it is strongly encouraged to utilize a design that does not have an identical and indistinguishable outer surface and inner surface.

Test method: Verify by visual inspection that it is possible to identify the outer surface and inner surface of the non-medical face mask.

Seam Placement

Seams are inherently weak points for maintaining the integrity of a material's filtration efficiency. Therefore, it is not recommended to have a seam near the center of the face mask (vertically or horizontally).

Test method: Verify by visual inspection that a seam is not located near the center of the face mask.

Durability

The mask materials as well as the overall construction of it must be able to withstand the handling and wear throughout the expected lifetime of the mask [7].

Note: AFNOR SPEC S76-001:2020, Annex A, provides a list of recommended materials [7].

Test method: Qualitatively evaluate the mask's durability by donning and doffing the non-medical face mask at least 5 times [7].

Reuse

As a non-medical face mask is designed to be reusable, the materials as well as the overall construction must be able to withstand the anticipated type and cycles of cleaning and drying [7]. At a minimum, a non-medical face mask shall be able to withstand at least 5 wash cycles [7].

Test method: Visually inspect the mask before each wash cycle for any sign of damage (impact to fit, deformation, wear, etc.) [7].

Coverage and Fit

It is important for the mask to be able to appropriately cover the wearer's nose and mouth while comfortably securing to the ears or head.

Sizing

Anthropometric data, such as what may be found in ISO/TS 16976-2:2015 *Respiratory protective devices - Human factors - Part 2: Anthropometrics*, may be used to help determine the most appropriate sizing to fit the general population. It may be desirable to have one-size-fits-most for adults and a separate one-size-fits-most for children.




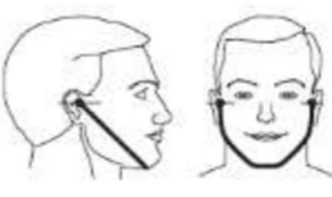
			
Bigonial breadth 132.5 – 144.5 mm	Menton-sellion length 123 – 135 mm	Interpupillary distance 65 – 71 mm	Bitragion chin arc 295 – 315 mm

Figure 1 - Anthropometric data from ISO/TS 16976:2015 [7]

Test method: Qualitatively evaluate the mask's fit and coverage on wearers of various face sizes and proportions.

Ties vs. Ear Loops

Whether a mask is provided with ear loops or ties is primarily a matter of preference. Ear loops are well suited for easy donning and doffing, while ties may be more comfortable for prolonged use (as the ear loops may irritate the ears).

Test method: Qualitatively evaluate the mask's securing mechanism (ties or ear loops) and coverage on wearers of various face sizes and proportions. Ensure that the mask may be secured with sufficient ease, the mask stays in place during foreseeable use, and that it may be worn without excessive tightness and discomfort [7].

Breathability (Differential Pressure)

The differential pressure (pressure drop) across the non-medical face mask material should be assessed to ensure it allows adequate breathability. When considering a candidate material, a qualitative breathability evaluation (go / no go) may aid in the selection/screening process. However, a more quantitative analysis of breathability, including tests of the pressure drop across the mask and CO₂ accumulation, is an important requirement to consider to ensure adequate usability (which will therefore influence compliance) [8].

EN 14683:2019

Test method: Determine breathing resistance (differential pressure) as directed in EN 14683:2019, Medical Face Masks - Requirements and Tests, Annex C[5].

AFNOR SPEC S76-001:2020

Test method: AFNOR SPEC S76-001:2020 provides three suggested methods/requirements for determining the inhalation resistance [7]:

- Method 1: Determined by experts consequent to the technical specifications for the single layer or composite multi-layer:
 - Splash resistance pressure of 160 mbar
 - Differential pressure of the material used shall not be greater than 0.6 mbar/cm².
- Method 2: Dynamic sinusoidal flow test, breathing machine set to 30 l/min
 - Inhalation resistance: 2.4 mbar
 - Exhalation resistance: 3 mbar
- Method 3: Constant flow test, 160 l/min
 - Inhalation resistance: 2.4 mbar
 - Exhalation resistance: 3 mbar

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Test method (approximation): Perform the DIY Mask Test for Breathability provided at <https://makermask.org/diy-mask-tests/>. This test assesses the breathability of mask materials by measuring how far an individual can blow a small object (high breathability = longest distances) [9].



Figure 2 - Overview of MakerMask.org Breathability Test [9]

Particulate Filtration Efficiency

There are a few different options available for evaluating a mask's ability to filter solid or liquid particles.

ASTM F2100-19

ASTM F2100-19 defines sub-micron particulate filtration efficiency as "the efficiency of the filter material in capturing aerosolized particles smaller than one micron, expressed as the percentage of a known number of particles that does not pass the medical face mask material at a given flow rate [5]."

Test method: Determine the particulate filtration efficiency as directed in ASTM F2299/F2299M-03, Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres [5].

AFNOR SPEC S76-001:2020

Test method: AFNOR SPEC S76-001:2020 sets the requirement for the filtering capacity at 70% for solid particles or for liquid particles as per the figure below:

	Solid particle	Liquid particle (droplet)
Test method	EN 13274-7, section 6 Sodium chloride test method	EN 13274-7, section 7 Paraffin oil test method
	In accordance with the test protocol of the French Directorate General of Armaments (DGA) circulated in a letter of 25 March 2020.	

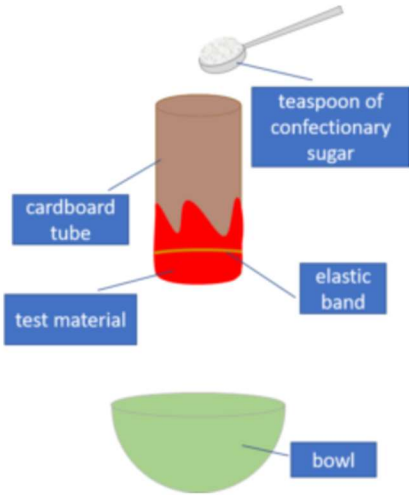
NOTE The particle size spectrum can extend to a limit of 3 μm .

Figure 3 - AFNOR SPEC S76-001:2020, Filtering Capacity [7]

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MakerMask.org

Test method (approximation): Perform the DIY Mask Test for Filtration provided at <https://makermask.org/diy-mask-tests/>. This test may be used to determine how well a material can keep particles (< 50 µm) from crossing from one side of the mask/material to the other [9].



Example of high particle filtration



Example of low particle filtration

Figure 4 - Overview of MakerMask.org Filtration Test [9]

Splash Resistance (Optional/Not Required)

Although not highly likely, members of the general population can be exposed to biological liquids capable of transmitting disease. Even though engineering controls cannot mitigate all possible exposures, it is possible to reduce the likelihood of direct skin and mucous membrane contact through the use of PPE that resists penetration [10]. There are various international standards that provide an appropriate level of guidance and expectations for demonstrating resistance to splashed or sprayed bodily fluids.

A lack of fluid resistance of the general use face mask material may be mitigated (if necessary) with the use of a face shield in conjunction with the non-medical face mask.

ASTM F2100-19

Test method: Determine the synthetic blood penetration resistance as specified in ASTM F1862/F1862M-17, Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)[5].

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MakerMask.org

Test method (approximation): Perform the DIY Mask Test for Water Resistance provided at <https://makermask.org/diy-mask-tests/>. This test assesses how well a material can keep water from crossing from one side of the mask/material to the other [9].



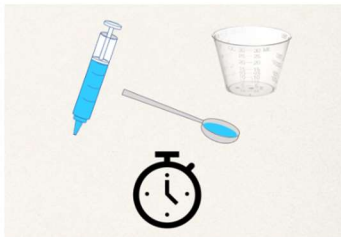
Prepare Tools & Supplies



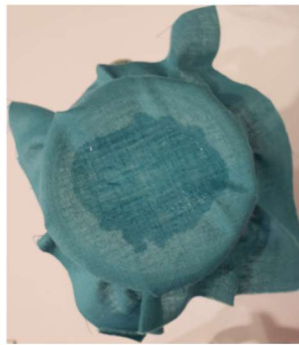
Place a square of material over the glass



Secure with a rubber band



Measure water and pour onto square covering glass



Hydrophilic cotton



Hydrophobic polypropylene

Figure 5 - Overview of MakerMask.org Water Resistance Test [9]

Biocompatibility

The skin-contacting materials of the non-medical face mask may be in contact with intact skin for a duration of ≤ 24 hours. To ensure biocompatibility, the skin-contacting materials shall not be associated with known risks for skin irritation, which is a tissue response characterized by inflammation, redness, swelling, and sometimes accompanied by heat and pain [11]. In addition, the use of natural rubber latex shall be avoided.

Natural Rubber Latex

Due to reports of allergic reactions, some medical device manufacturers started labeling products as "latex-free," "does not contain natural rubber latex," or "does not contain latex." However, it is not possible to reliably assure the complete absence of the allergens associated with the reactions to natural rubber latex. Therefore, the U.S. FDA advises manufacturers who want to indicate that natural rubber latex was not used in the manufacturing of their product to "inform users that a product, product container, or product packaging was not made with natural rubber latex [12]."

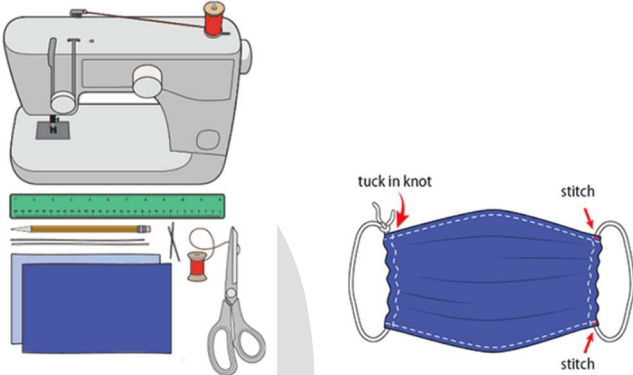
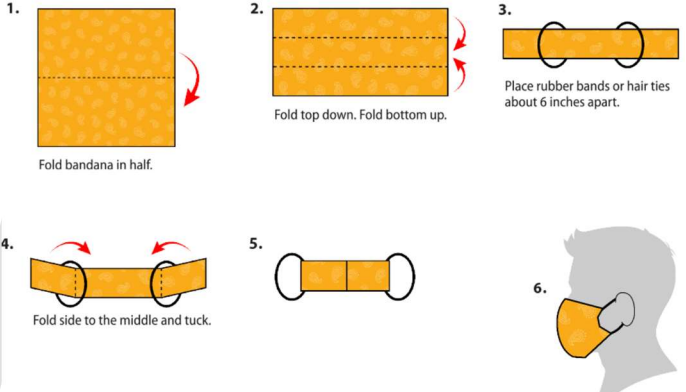
Sample Designs and Construction Guidance

This section provides references to available resources that provide sample non-medical face mask designs and construction guidance.

CDC on Homemade Cloth Face Coverings

The CDC provides two non-medical face mask designs: one that may be made with sewing and one that may be made without sewing [13]. Refer to <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-to-make-cloth-face-covering.html> for the latest detailed instructions.

Table 3 - Overview of CDC Face Covering Designs [13]

Sewn Face Covering	Non-Sewn Face Covering
	

MakerMask

MakerMask is a source for science-based mask designs; they use water-resistant nonwoven polypropylene (NWPP), are latex-free, and can be machine washed or disinfected by boiling or autoclaving [14]. Available MakerMask designs include the following:

MakerMask: Cover



The *MakerMask: Cover* is designed as a single layer NWPP cover to wear over a commercially available N95 to reduce external contamination and extend N95 use. The breathability of *MakerMask: Covers* (N=3) used with 3M N95 respirators was evaluated at ATOR Labs using ISO 16900 and NIOSH testing methodologies. ATOR Labs concluded that, "All three mask coverings would pass NIOSH/NPPTL testing for form, fit and function."

MakerMask: Surge



The *MakerMask: Surge* is a stand-alone face mask made from three-layers of breathable, water-resistant NWPP. Three layers of NWPP are recommended based on breathability analysis, however due to variability in alternatively sourced materials we recommended checking mask breathability prior to use. Optimal layering combinations may vary with intended use and specific materials used.

MakerMask: Fit (Beta)



The *MakerMask: Fit* is a multi-layer face mask design optimized for face fit. Optimal layering combinations are under investigation. The breathability of *MakerMask: Fit* prototypes (N=4) was evaluated at ATOR Labs using ISO 16900 and NIOSH testing methodologies. Mask designs using 3 layers of NWPP passed all of the breathability criteria.

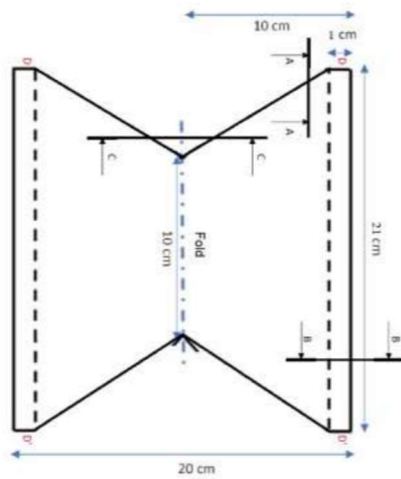
Figure 6 - MakerMask.org designs [14]

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AFNOR

AFNOR provides sample non-medical mask designs for a “duckbill” as well as a “flat-fold” design. Please refer to the following link for the patterns: <https://masques-barrieres.afnor.org/home/PdfMasquePatron?token=29935287-6e94-4ece-8b8d-8800a198bae0&culture=en-GB>

Pattern of “Duckbill” type barrier mask



Pattern of “Flat-fold” barrier mask

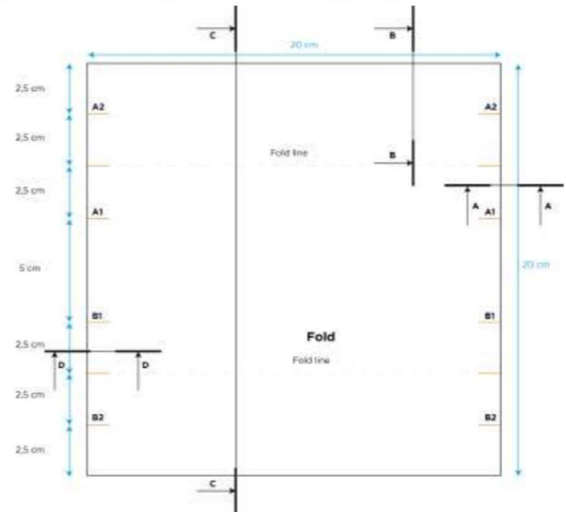


Figure 7 - AFNOR designs [7]

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