Regulatory requirements for medical and non-medical face masks

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Masks have become an essential component of daily life, for everyone from medical professionals to grocery shoppers. With so many kinds of masks, manufacturers and retailers can find it challenging to differentiate between the various types. Companies should verify the specific safety requirements for their products but global guidelines for face mask testing may leave retailers, brands and manufacturers confused or unaware of the latest requirements.

Quality assurance programs can evaluate the manufacturing process and provide product and facility inspections and trainings. Third-party face mask testing services take the complexity out of the supply chain, leaving retailers confident that the face coverings they offer for sale meet legislative requirements. It should be noted that some countries have initiated additional specific requirements for face coverings, so understanding the end market is essential.

Differences between masks

Respirators such as N95, FFP2 and KN95, are intended to help protect the user from inhaling airborne particulates. These are available in surgical mask, half-face and full-face styles. They are form-fitting around the nose and mouth for a close facial fit to limit air exchange around the mask and bypassing the filter.

Face masks are intended to help protect those near the user by blocking the user's bodily fluids that are spread by coughing and sneezing. Mask may be made out of paper, woven fabric or nonwoven materials. Many masks are intended to help reduce the spread of disease such as source control masks, barrier masks or community masks. Splash resistant face masks, commonly known as surgical masks, also have a liquid barrier to protect the user from blood and bodily fluid sprays. Generally, face masks are loose fitting around the nose and mouth.

Government agencies typically classify products as intended for medical use if they are labeled or otherwise intended for use by a healthcare professional, labeled for use in a healthcare facility or environment, or include any drugs, biologics or anti-microbial/anti-viral agents.

Face masks are intended to help protect those near the user by blocking the user's bodily fluids spread by coughing and sneezing. These may be paper, woven fabric or nonwoven materials.

Medical use requiring liquid protection, i.e., surgical mask

Surgical masks require liquid protection. These are intended to reduce the spread of disease from sneezing and coughing and protect a user from blood spray and other fluids. They are disposable and subject to specific government oversight for medical devices.

Medical use not requiring a liquid protection, i.e., non-surgical mask

Masks intended for nonsurgical medical use can help reduce the spread of disease from sneezing and coughing. Without liquid protection, they do not protect from blood spray or other bodily fluids. These may be disposable or reusable and are subject to specific government oversight for medical devices.

Source control/barrier/community mask

Masks intended for use by members of the general public to cover their noses and mouths to prevent the spread of disease from sneezing and coughing. These masks are not intended to be used in clinical settings where the infection risk level through inhalation exposure is high. Like non-surgical masks, these masks do not include a barrier for liquid protection so they will not protect from blood spray or other bodily fluids. Some governments consider source control masks as medical devices subject to specific government oversight while other governments treat source control masks as non-medical general-use masks.

Non-medical general use face cover or mask

Masks intended for non-medical general use provide protection from inhalation of dust and other particulates such as from construction or road pollution. These can include disposable paper and non-woven face covers as well as reusable textile face covers and fashion masks. Because these masks are not intended for medical use, they cannot claim to prevent disease, spread of disease or offer anti-microbial or viral protection.

Specific requirements by country or jurisdiction

U.S.

Medical face masks

Regulatory requirements

FDA approval
- Performance testing at an ISO 17025 accredited laboratory
- Submission of a 510(k) premarket notification[1]
- Manufacturing under a Quality System Regulation[1]
- Unique Device Identification number[1]
- FDA registration and approval (FDA Product Code FXX)[1]

NIOSH approval required for respirator claims, e.g., N95

FTC compliance

[1]These requirements are temporarily waived during the State of Emergency

Mandatory performance requirements
- Synthetic blood penetration resistance
- Particle filtration efficiency (PFE)
- Differential pressure (Delta P)
- Bacterial filtration efficiency (BFE)
- Flammability
- U.S. Food and Drug Administration (FDA) label compliance review
- Toxics in packaging

Recommended related services
- Biocompatibility
- Microbial cleanliness
- Virus filtration efficiency (VFE)
- Strap attachment strength
- Elongation and tensile strength of straps
- Mask dimensions and weight
- Product and packaging description

Non-surgical medical and source control face masks*

Regulatory requirements

FTC and FDA compliance

NIOSH approval required for respirator claims, e.g., N95

Mandatory performance requirements
- FDA label compliance review
- Toxics in packaging
- Flammability (if necessary)
- Respirator (if applicable)

Recommended related services
- Biocompatibility
- Particle filtration efficiency (PFE)
- Differential pressure (Delta P)
- Bacterial filtration efficiency (BFE)
- Virus filtration efficiency (VFE)
- Bacterial filtration efficiency
- Strap attachment strength
- Elongation and tensile strength of straps
- Mask dimensions and weight
- Product and packaging description

**Only during the State of Emergency*

Non-medical face masks

DISPOSABLE

Regulatory requirements

FTC requirements

FDA label requirements include:

1. Product must be labeled for non-medical use
2. Product cannot claim it prevents infection or spread (including COVID-19)
3. No anti-microbial or anti-viral protection claims

NIOSH approval required for respirator (e.g. N95) claims.

Mandatory performance requirements

- Federal Trade Commission (FTC) and FDA label compliance review
- Fiber content (if if containing any amount of wool)
- Flammability (if textile material)
- Total lead (if applicable)
- Toxics in packaging
- Country of origin for imported products

Recommended related services

- Biocompatibility
- Particle filtration efficiency (PFE)
- Differential pressure (Delta P)
- Strap attachment strength
- Elongation and tensile strength of straps
- Mask dimensions and weight
- Product and packaging description

REUSABLE

Regulatory requirements

CPSC and FTC requirements for softlines

FDA label requirements include:

1. Product must be labeled for non-medical use
2. Product cannot claim it prevents infection or spread (including COVID-19)
3. No anti-microbial or anti-viral protection claims

Mandatory performance requirements

- CPSC, FTC and FDA label compliance review
- Children's usage requirements (if intended)
- Fiber content (if if containing any amount of wool)
- Flammability
- Total lead (if applicable)
- Toxics in packaging
- Country of origin for imported products

Recommended related services

- Biocompatibility
- Particle filtration efficiency (PFE)
- Differential pressure (Delta P)
- Strap attachment strength
- Elongation and tensile strength of straps
- Mask dimensions and weight
- Product and packaging description
- Care label testing
- Softlines apparel performance and appearance testing

Canada

Medical face masks

Regulatory requirements

- RSQ, SOR, CRC, and Health Canada
- Full Health Canada authorization:
  - Performance testing at an ISO 17025 accredited lab
  - Manufacturers, importers, and distributors must have a Medical Device Establishment License (MDEL)
  - Manufacturing under a Quality Management System
  - Health Canada registration and approval (Product Code 79FXX)
- NIOSH testing required for respirator (e.g. N95) claims

Mandatory performance requirements

- Synthetic blood penetration resistance
- Particle filtration efficiency (PFE)
- Differential pressure (Delta P)
- Bacterial filtration efficiency (BFE)
- Flammability
- RSQ, SOR, CRC, Health Canada label compliance review
- Lead regulation

Recommended related services

- Biocompatibility
- Virus filtration efficiency (VFE)
- Strap attachment strength
- Elongation and tensile strength of straps
- Mask dimensions and weight
- Product and packaging description

Non-medical face masks

Regulatory requirements

Competition Bureau, Health Canada and RSQ requirements for softlines

Recommended label requirements include:

1. Product must be labeled for non-medical use
2. Product cannot claim it prevents infection or spread (including COVID-19)
3. No anti-microbial or anti-viral protection claims

Mandatory performance requirements

- Health Canada, Competition Bureau, RSQ compliance
- Textile flammability
- Fiber content
- Stuffed article labeling for Quebec (if containing filling material)
- Children's requirements (if intended)
- Country of origin for imported products
- Bilingual labeling requirement – English and French Canadian

Recommended related services

- Biocompatibility
- Particle filtration efficiency (PFE)
- Differential pressure (Delta P)
- Strap attachment strength
- Elongation and tensile strength of straps
- Mask dimensions and weight
- Product and packaging description
- Care label testing
- Softlines apparel performance and appearance testing

EU and UK

Medical face masks

Regulatory requirements

- Reach and POP requirements
- European Medical Devices Regulation 2017/745
  - EU Council Directive 93/42/EEC (MDD)
  - CE mark (can be self-certified)

Mandatory performance requirements

- EU medical device and general product label compliance review
- Splash resistance (only for surgical masks)
- Breathability
- Bacterial filtration efficiency (BFE)
- Microbiological cleanliness
- Biocompatibility
- REACH and POP requirements
- Toxics in packaging
- Product and packaging description

Recommended related services

- Virus filtration efficiency (VFE)
- Strap attachment strength
- Elongation and tensile strength of straps

Non-medical face masks

Regulatory requirements

EU requirements for softline products

Label compliance review

Additional label requirements include:

1. Product must be labeled for non-medical use
2. Product cannot claim it prevents infection or spread (including COVID-19)
3. No anti-microbial or anti-viral protection claims

Mandatory performance requirements

- REACH and POP requirements
- Toxics in packaging
- Children's usage requirements (if intended)
- Fiber content (if applicable)
- Flammability (if applicable)

Recommended related services

- Particle filtration efficiency (PFE)
- Air permeability
- Strap attachment strength
- Elongation and tensile strength of straps
- Mask dimensions and weight
- Softlines apparel performance and appearance tests
- Product and packaging description

China

Medical face masks

Regulatory requirements

- Testing to YY 0469-2011
- Register and approved by the National Medical Products Administration (NMPA)

Mandatory performance requirements

- Appearance
- Structure and size
- Nose clip
- Strap strength
- Blood penetration
- Bacterial filtration efficiency (BFE)
- Particle filtration efficiency (PFE)
- Flammabiity
- Differential pressure (Delta P)
- Microbial cleanliness
- Biocompatibility
- Ethylene oxide residue
- Marking, labelling and packaging

Recommended related services

- Virus filtration efficiency (VFE)
- Elongation and tensile strength of straps

Non-medical face masks

Regulatory requirements

China requirements for softline products

SAMR approval and supervision

Label compliance review

Additional label requirements include:

1. Product must be labeled for non-medical use
2. Product cannot claim it prevents infection or spread (including COVID-19)
3. No anti-microbial or anti-viral protection claims

Mandatory performance requirements

- Similar to other textile products
- GB 18401 for adults
- GB 31701 for children

Recommended related services

- Dependent on product type
- If the face mask is made of woven fabric, it is recommended to use FZ/T 82006-2018 Woven Accessories
- If the face mask is made of knitted fabric, it is recommended to use FZ/T 73049-2014 Knitted Mask
- Enterprise standards or other applicable group standards can also be used

For more information, contact UL's Consumer and Retail Services at CRS.UL.com/contact.

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