



## Frequently asked questions on face mask requirements for the United States, Canada and European Union markets



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During our webinar for [Face Mask Requirements for the U.S., Canada and EU Markets](#), we received several questions from the audience. Please refer to this FAQ document for additional insights shared from our UL subject matter experts. If you have any additional questions, please contact UL today!

**Q: If we are starting a disposable mask making company, should we engage a certified lab to perform the required U.S. National Institute for Occupational Safety and Health (NIOSH) tests to have the masks U.S. Food and Drug Administration (FDA) certified?**

A: Respirators marketed in the U.S. require approval testing by NIOSH. Respirators intended for medical use, like N95 surgical respirators, also require FDA approval. There is a Memorandum of Understanding between NIOSH and the FDA to help streamline the process for surgical respirators requiring NIOSH and FDA approval (<https://www.fda.gov/about-fda/domestic-mous/mou-225-18-006>). ISO 17025 accredited laboratories can perform pre-approval testing to 42 CFR Part 84 in preparation for NIOSH submission.

Face masks that do not include respirator claims are not required to have NIOSH testing.

**Q: Is NIOSH testing mandatory to market respirators in Canada? If yes, is it only NIOSH testing or should we pursue NIOSH certification too?**

A: In Canada, respirators are regulated by Health Canada as Class I medical devices and are manufactured or imported by companies that hold a Medical Device Establishment License. They are also certified by the NIOSH.

**Q: When the emergency situation is revoked, what will happen to stock already imported into U.S.? Should the manufacturers recall the stock, or can they continue marketing until the imported stock is exhausted?**

A: As of the date of the webinar, masks that are not approved by the FDA under product codes FXX, OUK, or OXZ cannot be distributed within the U.S.

**Q: What are source control masks? Do they need different testing and labeling?**

A: Source control means preventing the transmission of infection through a person's respiratory secretions which are produced when speaking, coughing, or sneezing. Masks intended for source control are regulated differently in different countries and may therefore require different testing than non-medical or surgical masks.



**Q: For non-medical masks, are Class 1 and Class 2 masks both acceptable?**

A: The question refers to 16 CFR 1610 flammability testing on textile face coverings. Legally, both Class 1 and Class 2 results are acceptable. Class 2 is only for raised-surface textiles. However, most retailers/manufacturers/importers only accept a Class 1 result.



### Q: For disposable non-medical masks, can you claim intended use for source control?

A: Generally non-medical masks cannot claim source control use; however, the ability to make such a claim depends on each country's regulations. For example:

- Non-medical masks are not allowed to claim source control use in the USA because the FDA categorizes masks intended for source control as medical masks.
- Health Canada similarly considers source control masks as medical devices and therefore non-medical masks cannot claim source control use
- France, Portugal and Spain have special regulations for masks intended for source control.

### Q: Is it mandatory to follow the CEN Workshop Agreement (CWA) in the EU to sell face masks?

A: CWA 17553 is a guideline document and is not mandatory on its own. Compliance to CWA 17553 would be mandatory to distribute face masks in any EU member state that adopts CWA 17553.

### Q: There are many requirements for EU community masks. If we miss some information on the packaging, it still be sellable?

A: All of the regulations defined by an EU member state must be followed in order to sell product within that country. There have been many recalls on products that did not comply with performance or labeling requirements.

In some cases, additional labeling and use instructions can be provided on a separate leaflet that accompanies the product, for example, including a leaflet inside the packaging.

### Q: Are the EU/U.K. community mask requirements a permanent standard or expected to exist only while COVID-19 crisis exists (similar to the U.S. state of emergency FDA declaration to temporarily reduce requirements)?

A: To respond to the urgency of the situation, CEN agreed to develop this CWA with a fast-track approach. A CWA is valid for three years, after which the former Workshop Secretariat shall consult the former Workshop participants and the relevant CEN/CENELEC technical bodies to determine whether the CWA shall be: confirmed for another three years, revised, transformed into another deliverable or withdrawn.

Although the EU community mask requirements were developed in response to the COVID pandemic, there is no timetable for withdrawal.





**Q: If I am making masks for use in my own company facilities and not for sale to general public, do I have to meet any of the community or medical mask standards to ship masks to various locations worldwide?**

A: Local regulations need to be met in order to import and distribute masks, even within a single company.

**Q: Do all fabric face covers have to meet the EUA requirements? If they are intended only for general use -- non-medical, source control only? Thinking about common cotton and other covers that are now widely available.**

A: Any face mask distributed or sold in the U.S. that is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, including the spread of COVID-19 virus, is considered a medical device and therefore subject to FDA regulation. These masks may be distributed or sold pursuant to the FDA's EUA, temporary Enforcement Policy or as FDA approved medical devices. Face masks intended to provide protection from inhalation of dust and other inert particulates, e.g., construction dust, road pollution, are not subject to the FDA.

**Q: If there is an antimicrobial agent in a general-use fabric mask that is intended for odor control, how should that be presented?**

A: Antimicrobial protection claims cannot be made on non-medical masks because antimicrobial protection implies a medical benefit. Anti-odor claims can be made, however.

**Q: If the community face cover is not sold in retail, does it still need to meet all the test requirements? Face cover is given as a gift with purchase.**

A: Local regulations need to be met in order to import and distribute masks.

**Q: What needs to be considered if a community mask is equipped with antimicrobial substances?**

A: Masks treated with an antimicrobial agent are classified as medical devices and subject to additional testing and regulations.

- Antimicrobial agents are considered pesticides or biocides and are therefore subject to additional regulations, e.g. EPA in the U.S.A
- Additionally, antimicrobial claims must be verified



### Q: Why can't antimicrobial protection claims be made on reusable masks?

A: Antimicrobial protection claims cannot be made on non-medical masks because antimicrobial protection implies a medical benefit.

Antimicrobial agents can be used in medical masks and be marketed with antimicrobial protection claims provided they are approved by the appropriate regulatory body.

### Q: What is the FTC requirement?

A: • Care label: For a reusable textile face covering, care label is not required. However, since it is reusable, consumers need to be provided guidance on how to wash the fabric. Below is US CDC guideline for care of cloth face coverings.

<https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-to-wash-cloth-face-coverings.html>

- Fiber label [fiber content, Country of Origin and RN# (or full name of the company doing business)]: This label is not required unless it contains any amount of wool. If it contains any amount of wool, it needs to be disclosed under Wool Products Labeling Act. A point-of-sale label is fine in this case.
- Country of Origin label: All imported products need a Country of Origin label as per U.S. Customs. U.S. Customs says that the label should be permanent as the nature of the article will permit.
- There may be additional labeling requirements for children's products, such as tracking label for children's products which is enforced by U.S. Consumer Product Safety Commission.

### Q: Is fiber content for reusable masks only required if they contain wool?

A: Yes, for U.S. market, the mask is covered by the Wool Products Labeling Act if it contains any amount of wool.

### Q: Is there a regulatory difference between the terms "face mask" and "face cover?"

A: There is no regulatory difference between face masks and face covers. We use the two terms to distinguish medical products subject to additional regulation (face mask) from non-medical products exempt from medical regulations (face cover).

### Q: What does stuff labeling mean in reference to Quebec regulations?

A: The province of Quebec in Canada needs a stuffed article label if there is a filling material inside the product. Generally, we do not see filling material in a face mask.

<http://legisquebec.gouv.qc.ca/en/ShowDoc/cr/M-5,%20r.%201>

### Q: Is a durable water repellent finish classified as a liquid barrier?

A: Durable water repellent treatment does not create a liquid barrier.

If you have any questions on face mask compliance or testing, please [contact UL](#) today.



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