

CSA Group Medical PPE Certification and Testing

Frequently Asked Questions (FAQs)

With global recognition and state-of-the-art labs, we provide reliable testing & certification for your PPE products.

The following are answers to some of the most frequently asked questions about CSA Group's certification and testing of Personal Protective Equipment (PPE). The questions and answers are divided into three sections: **General** questions, **Technical** questions, and questions related to the testing and/or certification **Process**. At the end, you'll see a section with frequently used **Acronyms and Initialisms**.

General

Q: What does "Medical PPE" stand for?

A: Medical PPE stands for Medical Personal Protective Equipment, and refers broadly to a range of coverings and devices aimed at protecting individuals in healthcare, industrial and other settings from exposure to harmful airborne, liquid or other contaminants.

Q: Is it mandatory for medical personal protective equipment to be tested?

A: Yes. Health Canada mandates that all medical devices (PPE are considered to be medical devices) intended for use in Canada be tested, and that manufacturers and distributors of these products be authorized.

As part of the process for obtaining the required authorization, a manufacturer or distributor must submit an application to Health Canada attesting to the safety, effectiveness and quality of the medical device to be sold in Canada.

Fast Facts



There are five major types of medical PPE currently in use in the Canadian market: Medical masks; Medical examination gloves; Respirators and medical respirators; Face shields; Medical gowns / drapes.



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Manufacturers and distributors with certified PPE have a competitive edge over those whose PPE has been tested but not certified. And the rigor of the CSA Group certification program ensures products' continued compliance with the required standards – which will appeal to potential and existing clients alike.

Q: What types of medical personal protective equipment (PPE) does the CSA Group test and certify?

A: There are five major types of medical PPE currently in use in the Canadian market:

- Medical masks
- Medical examination gloves
- Respirators and medical respirator
- Face shields
- Medical gowns / drapes

CSA Group tests and certifies these five major types of PPE.

Q: Is a ventilator considered medical PPE?

A: No, a ventilator is a piece of electronic medical equipment, and is not considered PPE.

Q: Does CSA Group plan to test other medical PPE, such as goggles, hair coverings and fashion masks?

A: Currently, we're focused on testing and certifying the five major medical PPE types.

Q: Do I have to test each individual PPE or can I test a representative sample from the production line?

A: CSA Group requires a set of samples from the broader production for testing and certification based on the applicable standard and testing requirements.

Q: What's the difference between testing and certification?

A: Testing is a process that verifies that the product provides the measure of protection required by law (with respect to the percentage of particulate filtration, the strength of materials, breathability, etc.) according to the relevant standards. With testing, it's only the product itself that is tested.

Certification is a much more involved process than testing is, though testing is a component of the certification process. Certifying a product involves evaluating not only the efficiency and safety level of the product itself, but also all aspects of the manufacturing process, including the facility in which the manufacturing takes place. As well, certification is an ongoing process, with in-process quality checks, quarterly inspections of the facility and sampling product throughout the year.

Another difference is that certified PPE bears the CSA Group's mark of certification – an instantly recognizable emblem. Manufacturers and distributors with certified PPE may provide a competitive edge over those whose PPE has been tested but not certified. The CSA Group certification program also helps ensure products' continued compliance with the required standards – which may appeal to potential and existing clients alike.

Q: Is it mandatory for personal protective equipment (PPE) to be certified as well as tested?

A: Not at the moment. Health Canada mandates only that all PPE intended for use in Canada be tested. But many manufacturers and distributors will choose to certify their products because it may give them a competitive edge over their competitors and helps prepare them for the possibility that certification may be mandated in the future.



Q: What is an "Interim Order"?

A: An "Interim Order", or IO, is a legally binding proclamation by a Minister or department of the federal government, often issued in response to a pressing or emergent situation. The interim order allows the government to respond quickly, when the time required to pass legislation may fail to address the imminent need.

With respect to PPE during this global pandemic, on March 18, 2020, the federal Minister of Health signed the *Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19*. This is the document that provides guidance for manufacturers on the minimum technical requirements for various types of respirators and other medical PPE entering Canada.

Q: What happens if or when the Interim Order is updated?

A: The Interim Order, or supporting documents, can be updated by Health Canada at any time to include new data, regulations or findings. To ensure compliance, it is recommended to check the Interim Order webpage regularly.

Q: Where will the CSA Group certification and testing lab be built?

A: The lab is located at the CSA Group headquarters in Toronto, but it will provide testing and certification for all suppliers of medical-grade PPE intended for use across Canada.

Q: When will the CSA Group start certifying and testing medical PPE?

A: CSA Group has been testing medical PPE since July 2020 and started certifying medical PPE in October 2020.

Q: Why should my company choose CSA Group to test and/or certify my PPE?

A: CSA Group is at the forefront of certification development for medical PPE in Canada. In fact, our parent organization developed the first set of standards for PPE in Canada more than 70 years ago. CSA Group has been, and continues to be, a leader in this field.

Q: Does CSA Group offer its services to companies outside of Canada?

A: Yes, we offer testing services to companies outside of Canada, provided that they intend to sell their products in Canada.

Technical

Face Shields, Masks and Respirators

Q: What does "N95" mean?

A: "N95" is a government rating. It denotes two characteristics of a mask. The "N" indicates that the mask is "Not resistant to oil". The number "95" indicates that the respirator (mask) is capable of filtering out 95% of particulate matter that is 0.3 microns or larger.

N95 is a designation used only by NIOSH for labeling respirators that meet the 42 CFR Part 84 standard. CSA Group will test and certify to the 42 CFR Part 84 standard but will not be able to designate a respirator as N95.

Q: What is the difference between a respirator and a surgical mask?

A: A respirator is used mainly to filter particles from the air. It has a set of testing requirements specific to that purpose. A surgical mask, on the other hand, protects the wearer and patient from large droplets, splashes or sprays of bodily fluid and other hazardous fluids.

Q: Can CSA Group test dual-canister painters' respirators?

A: CSA Group only tests N95 respirators, and the dual-canister type of respirator does not fall under that category.

Q: What are the requirements for the face-shield impact test?

A: The impact test is not mandatory, per Health Canada requirements. If the mask or face shield is intended only to provide a physical barrier to virus transmission, the impact test is not considered to be critical. The impact test was intended to convey a message that the shield material needs to be structurally solid.

Gowns and Drapes

Q: What is the difference between a medical gown and a medical drape?

A: A medical gown is worn by medical professionals during surgery, while a drape is the material used to cover a patient during surgery. The items have the same test requirements up to barrier level 3, but differ at barrier level 4.

Q: What are barrier-level tests?

A: Barrier levels 1 to 3 test the product for resistance to water penetration. Barrier level 4 for gowns test the product for resistance to penetration by blood-borne pathogens while level 4 for drapes test the product for resistance to blood penetration.



Q: Will CSA Group offer testing and certification for medical gowns and drapes for barrier level 4?

A: Yes, we are able to perform testing and certification services for level 4 drapes and gowns.

Process**Q: What is the process for submitting a PPE product for certification or testing by CSA Group?**

A: If a manufacturer is interested in submitting a medical PPE product for certification or testing they should contact (certinfo@csagroup.org or +1 866 797 4272) or their CSA Group sales representative who will guide them through the quote process. The quote process will include the following information:

- Test to be performed
- Number of samples required
- Location for samples to be sent
- Estimated time of project
- Estimated cost

Once the quote is agreed to and samples are sent, the certification or testing project can begin.

Q: What do I do once I receive the testing report?

A: Once you receive the test report, you may submit it to Health Canada to receive authorization for your medical PPE to be used in Canada.

Q: What do I receive after certifying medical PPE?

A: Once your medical PPE passes the certification process, the CSA mark can be placed on the medical PPE to indicate that it has been certified.

Acronyms and Initialisms

FFR	Filtering facepiece respirator
NIOSH	(U.S.) National Institute of Occupational Safety and Health
NRC	National Research Council
PHAC	Public Health Agency of Canada
PFE	Particulate filtration efficiency
PPE	Personal protective equipment
IO	Interim Order from Health Canada

Resources

For more information on the medical PPE products included in the new certification program, visit the links below:

New CSA Certification Program for Protective Apparel
<https://www.csagroup.org/wp-content/uploads/OccuHealthSafety131.pdf>

New CSA Certification Program for Protective Drapes for use in Healthcare Facilities
<https://www.csagroup.org/wp-content/uploads/OccuHealthSafety132.pdf>

New CSA Certification Program for Medical Face Masks
<https://www.csagroup.org/wp-content/uploads/OccuHealthSafety133.pdf>

New CSA Certification Program for Filtering Facepiece Respirators (FFR)
<https://www.csagroup.org/wp-content/uploads/OccuHealthSafety134.pdf>

New CSA Certification Program for Medical Filtering Facepiece Respirators (FFR)
<https://www.csagroup.org/wp-content/uploads/OccuHealthSafety135.pdf>

New CSA Certification Program for Medical Gloves
<https://www.csagroup.org/wp-content/uploads/OccuHealthSafety136.pdf>

Health Canada's Interim Order in respect for items sold in relation to COVID
<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/interim-order-importation-sale-medical-devices-covid-19.html>

Let's work together

To learn more about our PPE testing & certification services, contact us today.

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