Government of Canada Gouvernement du Canada

Optimizing the use of masks and respirators during the COVID-19 outbreak

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Importance of masks and respirators

Masks and respirators (personal respiratory protective devices) are essential during the COVID-19 outbreak. They help slow the spread of the disease in Canada and protect health care providers. Both masks and respirators need to be used in combination with appropriate eye protection (e.g., face shield, goggles) to achieve full protection of the eyes, nose and mouth.

There are a number of different types of masks and respirators. They each have a particular use in a particular setting. A definition for respirators and masks is provided on the Public Health Agency of Canada' s (PHAC) website.

N95 respirators for medical applications

N95 respirators (or particulate filtering face-piece respirators) are Class I medical devices. They are manufactured and/or imported by companies that hold a Medical Device Establishment Licence (MDEL) and include those that are authorized by Health Canada under the Interim Order for COVID-19 medical devices. See below for more information on expedited review and approval pathways for masks and respirators in relation to COVID-19.

N95 respirators achieve a minimum filtration efficiency of 95% when worn properly. The edges of the mask form a seal around the nose and mouth. N95 respirators (not medical masks) are designed to reduce the risk of inhaling hazardous airborne particles and aerosols.

N95 respirators are produced in many different styles, such as cup-style (see image), flatfold or duckbill. They may or may not have an exhalation valve.

In a healthcare setting, N95 respirators protect against exposure to respiratory viruses and bacteria.

The U.S. National Institute for Occupational Safety and Health (NIOSH) evaluates, tests and certifies N95 respirators. The masks must pass minimum performance requirements, such as filter efficiency and breathing resistance. All N95 respirators certified by NIOSH must have an approval number stamped on the mask, represented as TC-84A-####n.

Health Canada, the regulator for medical devices in Canada, accepts the NIOSH certification as an appropriate quality standard for N95 respirators used by healthcare providers. Equivalent alternate standards are also acceptable (see below for information on respirators approved in other countries).

The N95 respirator is the U.S./NIOSH standard for respirators and KN95 is the Chinese standard. Commercial-grade (non-medical) and medical-grade N95 and KN95 respirators are similar with respect to design, filtration, performance and material standards. In Canada, it is the labelling, indications for use and claims that contribute to the classification of a product as a medical device.

Use of N95 and equivalent respirators beyond their shelf life

Most respirators have a limited shelf life; after which they should be discarded. The length of time a respirator is stored beyond its shelf life or recommended conditions of storage may affect its performance. This includes not only the filter media but also headbands and nose foam components, which may affect the seal that is created.

N95 and equivalent respirators that are past their designated shelf life are no longer NIOSH-certified, as all manufacturer-designated conditions of use must be met to maintain the NIOSH approval. However, in times of increased demand and decreased supply, consideration can be made to use these expired N95 respirators. An expired respirator can still be effective at protecting health care provider if:

- the straps are intact
- there are no visible signs of damage
- they can be fit-tested

Health care providers should inspect the respirator and perform a seal check.

There is no specific timeframe beyond the expiry dates for N95 and equivalent respirators at which they would no longer be considered suitable for use.

Masks (surgical, procedure or medical masks)

Masks, for example surgical masks, are worn by operating room personnel during surgical procedures (see image). They protect both the patient and operating room staff from the transfer of micro-organisms, body fluids and particulate material.

There are 3 classifications under the American Society for Testing and Materials (ASTM):

- Level 1 (low) - venous pressure splash
- Level 2 (moderate) - arterial pressure splash
- Level 3 (high) - high-velocity procedures, orthopedic surgery

Unlike N95 respirators, masks are looser in fit. As a result, they do not provide the same level of filtration.

Use of surgical masks beyond their shelf life

Masks can still be used beyond their shelf life to protect health care providers. Health care providers should check that the straps are intact and there are no visible signs of damage.

There is no specific timeframe beyond the expiry dates for masks at which they would no longer be considered suitable for use.

Non-medical N95 respirators

Commercial-grade (non-medical) and medical-grade N95 respirators are similar with respect to design, filtration, fit, performance, and material standards. In Canada, it is the labelling, indications for use and claims that make a product a medical device.

There is a subset of medical N95 respirators labelled as surgical respirators. These devices are sold sterile and are tested for fluid resistance (penetration by synthetic blood) under ASTM F1862. Because COVID-19 is transmitted by respiratory droplets, the use of surgical N95 respirators in most instances is not considered essential.

Use of commercial-grade N95 respirators

Health care institutions may, at their discretion, purchase and use commercial-grade N95 (or P95 etc.) respirators (or equivalents such as commercial-grade KN95 (or KP95) respirators) in a health care setting during the COVID-19 outbreak when medical N95 (or equivalent) respirators are not available.

Commercial-grade (non-medical) respirators do not qualify as a medical device and therefore, an authorization under the Interim Order (IO) or a Medical Device Establishment Licence (MDEL) is not necessary. It is important that the label be limited to a filtration indication, and that no medical claim can be made.

Respirators Approved Under Standards Used in Other Countries That Are Similar to NIOSH-Approved N95 Respirators

To expand the availability of medical and non-medical N95 respirators during the pandemic, equivalent alternate standards may also be acceptable. This includes respirators that are approved or certified under standards used in other countries that are similar to NIOSH-approved N95 respirators.

For example, this includes both medical and commercial (non-medical) KN95 or medical FFP2 respirators (including those with head band or ear loops) that meet standards:

- EN 149-2001 (Medical FFP2)
- GB 2626-2006* (Commercial KN95) *(standard will be replaced with GB 2626-2019 on July 1, 2020)
- GB 19083-2010 (Medical KN95)

The United States Food and Drug Administration (FDA) also issued a revised guidance on May 7, 2020, indicating that certain filtering face-piece respirators from China may not provide adequate respiratory protection. The FDA will still consider KN95 respirators medical devices equivalent to N95s (as the FDA and U.S. Centers for Disease Control and Prevention (CDC) consider GB2626-2006 to be equivalent to NIOSH N95) but authorization for KN95 respirators will require additional validation and review by the FDA.

Recent testing performed by the CDC resulted in concerns with some KN95 respirators (specifically those with ear loop design) that pose a difficulty in achieving a proper fit, which is essential for use. This is in contrast to N95s that use a head band design (not ear loops), which appears easier to achieve a proper fit and seal. In addition, several models of respirators, including some KN95 respirators, failed to meet the filtration criteria of 95%.

In response to these findings, Health Canada has asked manufacturers and importers to stop the sale of any products that did not meet the filtration criteria of 95% and re-label them as face masks, as they could be used in settings where 95% filtration is not needed. KN95s that meet the filtration criteria may continue to be sold and used as respirators.

This action does not implicate KN95 respirators purchased by the Government of Canada and tested by the Public Health Agency of Canada (PHAC). Before allocating any personal protective equipment to the provinces or territories for frontline healthcare workers, PHAC conducts a quality verification. For KN95 respirators, this includes a visual inspection to check for defects in design and construction, and testing to confirm that they meet filtering specifications. KN95 respirators distributed to provinces and territories by PHAC meet the Government of Canada's technical specifications for healthcare settings for COVID-19 response.

Manufacturers wishing to sell KN95s as respirators in Canada are invited to submit an application for authorization under Health Canada’s Interim Order for the Importation and Sale of Medical Devices.

Health Canada will continue to authorize KN95 medical respirators in Canada through the Interim Order pathway. As of May 7, 2020, Health Canada will request test results from independent testing facilities to validate the effectiveness of these respirators.

The Government of Canada has developed detailed specifications for personal protective equipment such as disposable N95 respirators.

Reporting complaints to Health Canada

Health care institutions are encouraged to verify orders of masks, respirators and other personal protective equipment to ensure they meet specifications before dissemination within their facility. If non-compliant products are found, these can be reported to Health Canada for verification via Health Canada's voluntary complaint process. During the COVID-19 response, some products may have design differences between usually seen products. For example, some imported KN95 respirators that are not able to form an adequate face seal in some individuals but may still be useable for low risk activities and should not be discarded. Users should seek advice from their local public health organizations in these cases.

Reprocessed N95 Respirators

Due to critical shortages of personal protective equipment (PPE) during the COVID-19 response, decontamination of N95 respirators for reuse is being considered as a strategy to ensure the continued availability of these devices. Health Canada is looking for innovative solutions for reprocessing N95 respirators from re-processors of normally disposable N95 respirators and from manufacturers of reprocessing equipment to meet current needs. Industry requirements are outlined in the Notice to Stakeholders on Reprocessing of Single Use N95 Respirators during the COVID-19 Response. As with all COVID-19 related products, applications for these products are given priority and are expedited by Health Canada**.** The Medical devices for use against coronavirus (COVID-19): List of products authorized under Interim Order, as discussed further below, includes Health Canada authorizations for sterilization machines and reprocessed devices for use against COVID-19.

Learn more about the products and services needed along with related specifications.

Expedited Review and Approval Pathways for Masks and Respirators in relation to COVID-19

1) Interim Order Authorizations for the sale and importation of medical devices used in relation to COVID-19:

Health Canada has developed the *Interim Order (IO) Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19* to allow the Department to issue expedited authorization for sale or import of medical devices to deal with the current significant risk of COVID-19 to the health and safety of Canadians. This pathway is intended for all classes of devices, including Class I devices such as masks and respirators (including KN95) that are not approved in Canada and are needed in relation to COVID-19. Medical devices authorized via the Interim Order are posted in the Medical devices for use against coronavirus (COVID-19): List of products authorized under Interim Order.

In order for Health Canada to conduct a scientific review in advance of authorizing the sale of these devices, manufacturers are encouraged to submit applications through the Interim Order pathway as opposed to the Medical Device Establishment Licence (MDEL) regulatory pathway.

2) Expedited review and issuance of MDELs for Class I devices in relation to COVID-19:

As another option for authorization, Health Canada is expediting the review and issuance of MDELs for companies requesting to manufacture, import or distribute Class I medical devices (such as masks and N95 respirators) in relation to COVID-19. Current fees apply.

Companies that need an MDEL application expedited should:

- Review Guidance 0016 - Medical Device Establishment Licensing and Medical Device Establishment Licensing Fees.
- Complete the MDEL Application Form (FRM-0292) available on Health Canada's website.
- Email the completed MDEL application form to hc.mdel.application.leim.sc@canada.ca, indicating the following in the subject line of the email: ***URGENT - COVID-19 - MDEL application for -[name of company]***

For any questions related to the MDEL process, please email hc.mdel.questions.leim.sc@canada.ca.

Related links

- List of KN95s that were tested by NIOSH
- Reprocessing of N95 Respirators for Healthcare Professionals - Notice
- Fraudulent and unauthorized N95 respirators may not protect consumers against COVID-19
- Notice - Important Regulatory Considerations for the Reprocessing of Single Use N95 Respirators during the COVID-19 Response
- Medical devices for use against coronavirus (COVID-19): List of products authorized under Interim Order
- Council of Chief Medical Officers of Health Communication: Use of Non-Medical Masks (or Facial Coverings) by the Public
- About medical devices
- Considerations in the use of homemade masks to protect against COVID-19
- FDA - Certain Filtering Facepiece Respirators from China May Not Provide Adequate Respiratory Protection - Letter to Health Care Providers
- CDC - International Assessment Results - Not NIOSH-approved

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