



Health Canada

Health Products and Food Branch
Medical Devices Directorate

April 7, 2020

Notice – Important Regulatory Considerations for the Reprocessing of Single Use N95 Respirators during the COVID-19 Response

Context:

Single Use N95 respirators are disposable filtering face pieces covering the mouth, nose and chin that capture airborne particles from the air on the filter. They are considered single use medical devices because scientific evidence has not been submitted to Health Canada to support decontamination and reuse methods. However, given the current crisis, decontamination of these respirators for reuse is being considered along with other conservation strategies, such as the use of expired masks, as a capacity strategy to ensure the continued availability of these devices.

Health Canada is currently monitoring and assessing the acceptability of various decontamination and sterilization methods/strategies for the reprocessing of single use N95 respirators in the context of the COVID-19 outbreak. As SARS-CoV-2 (the virus causing COVID-19) is a novel virus, no current data exists to support the effectiveness of sterilization methods specifically against the virus itself, yet some technologies have achieved a reduction in some related viruses.

Due to potential critical shortages of personal protective equipment (PPE) during the COVID-19 response, Health Canada is looking for innovative solutions from re-processors of normally disposable N95 respirators and from manufacturers of reprocessing equipment to meet current needs. In its publication [Decontamination and Reuse of Filtering Facepiece Respirators](#), the United States Center for Disease Control (CDC) is encouraging efforts to be focused on ultraviolet germicidal irradiation (UVGI), vaporous hydrogen peroxide (VHP), and moist heat, since these technologies have shown the most promise as potential methods to decontaminate face filtering respirators (FFRs). Further, the CDC is not recommending the use of ethylene oxide as a decontamination method since there are potential risks associated with it that may have negative effects on the wearer. As with all COVID-19 related products, these technologies and accompanying submissions are given priority and expedited review by Health Canada.

With regard to reprocessing and decontamination on-site by hospitals, Health Canada will continue to respect the current oversight provided at the provincial and territorial level and guidance provided by the Public Health Agency of Canada.

Regulatory Requirements:

This notice applies to the regulatory requirements for two separate reprocessing strategies for single use N95 respirators:

1. Sterilization devices that are manufactured and sold to reprocess N95 respirators
2. Companies who reprocess and distribute N95 respirators to healthcare facilities



1. Sterilization devices that are manufactured and sold to reprocess N95 respirators

Sterilization devices are classified as Class II medical devices, and the device manufacturers are required to comply with the corresponding licensing requirements of the [Medical Device Regulations](#), or through the [Interim Order pathway](#).

2. Companies who reprocess and distribute N95 respirators to healthcare facilities

Under the federal regulatory framework, companies that reprocess and distribute medical devices to Canadian healthcare facilities originally authorized and labelled for single use, will be held to the same requirements as manufacturers of new devices.

In accordance with Health Canada's [Notice to Stakeholders - Health Canada's Regulatory Approach to Commercial Reprocessing of Medical Devices Originally Labelled for Single Use](#), a company that reprocesses N95 respirators becomes the manufacturer of the reprocessed N95 respirators. As the manufacturer of these devices, the reprocessor is required to continue to meet appropriate standards for safety, effectiveness and labelling. As such, although the devices are Class 1, please submit any applications for reprocessed N95 respirators through the [Interim Order](#) pathway as opposed to the Medical Device Establishment Licence (MDEL) regulatory pathway given the requirement for a scientific review in advance of authorization.

Health Canada is also evaluating the guidance of the U.S. Food and Drug Administration (FDA) with respect to FDA's [Intended Approach for Emergency Use Authorizations \(EUAs\) for Masks and Respirators](#) and the [strategies of the US Centers for Disease Control and Prevention \(CDC\)](#) for optimizing the reuse of respirators.

Health Canada Reprocessor Application Requirements:

During the COVID-19 response, Health Canada will align with the FDA's Intended Approach for EUAs for Masks and Respirators (Section VI, Part A) which is part of FDA's [Enforcement Policy for Face Masks and Respirators During the COVID-10 Public Health Emergency – Guidance for Industry and FDA Staff \(March 2020\)](#). This includes proposed evidence requirements for reprocessed N95 respirators (as much as is available) in order to facilitate the application and evaluation process.

In either instance presented above, the manufacturer/reprocessor is required to provide the following information to Health Canada to support its application for authorization:

- a description of the process for disinfection/reprocessing controls, including scientific rationale,
- microbial testing for the validation of bioburden reduction/disinfection,
- a description of chain of custody and safeguards to prevent inadvertent exposure,
- material compatibility,
- testing for performance characteristics including filtration performance, fit test data, (airflow resistance, exhalation valve leakage), and



- a copy of the reprocessed device product labelling including the maximum number of times that the device can be reprocessed, the method for tracking the number of times the device has been reprocessed.

Health Canada has identified the following **minimum requirements** within the current context and key data/test requirements for sterilization and decontamination processes:

1. Reduce pathogen burden
 - Bacterial sporicidal testing (e.g. *Geobacillus stearothermophilus* spores), and
 - Viral inactivation testing (e.g. SAR-CoV-2, MERS-CoV, SARS-CoV, H1N1, Influenza A/PR/8/34), including the use of surrogates. Level-2 bacteria or viruses as surrogates, or other microorganisms, not required to handle in BSL-3 class containment laboratories can be considered.
 - Use of the same disinfectant parameters as specified in your labelling.
 - For sterility indications: sterility assurance level (SAL) of 10^{-6} is generally accepted for sterilization procedures.
2. Maintain performance
 - For particle filtration efficacy: breathability and valve leak (where applicable) as per Original Equipment Market (OEM) product label claim (e.g. N95), and respirator fit testing. Maximum suggested re-sterilisation cycles must be indicated and an acceptable performance needs to be demonstrated at maximum cycles. Available scientific literature, stating that certain respirators can be re-sterilized without significant change of their effectiveness can be considered.
 - For fit testing: alternative proposals can be considered and demonstrated. Users will require some direction as to whether an acceptable fit can be achieved or whether alternative uses are recommended for the reprocessed respirator.
 - For counting and identifying the re-sterilisation cycles: a method to indicate the number of cycles a specific respirator has undergone must be provided. Masks can be marked directly (on the elastic for example).
3. Present no residual chemical hazard
 - Quantitation and risk assessment of chemical extracts, or scientific rationale in lieu.
4. Provide adequate labelling to users/reprocessors, including:
 - Validated methods and reprocessing conditions (e.g. temperature, RH, disinfectant concentration, contact time, density).
 - Warnings including any original performance / safety testing that has not been validated.

Health Canada will continue to update this notice as more information becomes available.

To obtain further information regarding medical device licensing, or to submit an application for authorization under the [Interim Order](#) for COVID-19 medical devices, please contact the Medical Devices Directorate at hc.devicelicensing-homologationinstruments.sc@canada.ca.



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Related links:

- [About medical devices](#)
- [Optimizing the use of masks and respirators during the COVID-19 outbreak](#)
- [Decontamination and Reuse of Filtering Facepiece Respirators](#)
- [Guidance on Medical Device Establishment Licensing \(GUI-0016\) – Summary](#)

Approved by

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