

THE MDEL BULLETIN

PRODUCED BY THE
MEDICAL DEVICES
COMPLIANCE PROGRAM

This bulletin provides MDEL holders with information on upcoming updates from Health Canada.



> Recall of KN95 Respirators

Issue

Health Canada has determined that KN95 Filtering Facepiece Respirators (“respirators”) being manufactured by manufacturers listed on the National Institute of Occupational Safety and Health (NIOSH) website and possibly being imported by you, pose a health and safety risk to end users. Manufacturers of concern are only those that failed to meet 95% filtration specifications. The list of manufacturers can be found here:

<https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html>

Based on the testing done by the NIOSH’s National Personal Protective Technology Laboratory (NPPTL), Health Canada cannot reasonably conclude that the benefits associated with having the KN95 Filtering Facepiece Respirator available in Canada, as currently labelled, outweigh the risks. Health Canada has deemed this a Type 2 risk, meaning, the use of (or exposure to) a recalled device may cause temporary adverse health consequences, or where there is not a significant probability of serious adverse health consequences.

In addition to this bulletin, Health Canada will be sending regulatory letters to the implicated Medical Device Establishment Licence (MDEL) holders informing them of this same information. Regardless, it is the responsibility of all implicated MDEL and Submission Number (SN) holders to self-identify and follow the below protocol to notify Health Canada if they have imported or sold KN95 respirators from these manufactures by contacting hc.meddev-matmed.sc@canada.ca.

Required Recall Action for Implicated MDEL Holders

As an MDEL holder, it is your responsibility to verify the on-line list of manufacturers noted above to determine if any of them are your suppliers. The KN95 Respirators manufactured by the identified manufacturers can no longer be imported, distributed or sold in Canada by any person as currently labelled. If you have sold or distributed KN95 Respirators by the identified manufacturers noted above, Health Canada is requesting you to immediately take the following actions:

1. **Stop Sale** of KN95 respirators and **Relabel** current stock of respirators as face masks (not respirators) that can be distributed to healthcare and non-healthcare settings, where a 95% filtration is not needed; and
2. **Inform** Canadian customers, by close of business on **May 12, 2020**, that:



- a. certain filtering facepiece respirators from the Chinese manufacturers listed at the link above, may not provide consistent and adequate respiratory protection to healthcare personnel exposed to COVID-19 based on additional filtration performance testing conducted by the National Institute for Occupational Safety and Health (NIOSH) - National Personal Protective Technology Laboratory (NPPTL) of the Centers for Disease Control and Prevention (CDC).
 - b. they can continue using the masks as face masks instead of medical respirators, where a 95% filtration is not needed. In this situation the MDEL holder will provide stickers to the customer, indicating they can be used as face masks (not respirators), for application by the customer to allow for the existing stock to be maintained and used for alternate purposes while also preventing confusion about acceptability for use in COVID-19; or
 - c. return the current stock to the MDEL holder.
3. To continue selling products as respirators, you are encouraged to **submit an application** for authorization under **Health Canada's Interim order (IO) respecting the importation and sale of medical devices for use in relation to COVID-19**. If you want to continue selling the products as medical respirators, independent laboratory performance testing results would be required to accompany the submission to demonstrate the respirators' effectiveness. More information on the IO can be found at:

<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/interim-order-importation-sale-medical-devices-covid-19.html>

Contact Us

If you have any questions regarding the contents of this bulletin, please contact *hc.meddev-matmed.sc@canada.ca*.