THE MDEL BULLETIN

PRODUCED BY THE MEDICAL DEVICES COMPLIANCE PROGRAM

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

May 19, 2020

Health Canada is updating the list of medical devices for mandatory reporting of shortages in relation to COVID-19

On March 30, 2020, the Minister of Health signed the *Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in relation to COVID-19* (the Interim Order).

The Interim Order makes it **mandatory** for manufacturers and importers to report to Health Canada shortages of specified medical devices (including their components, accessories, parts or consumable materials) related to COVID-19. The requirements are outlined in the Interim Order. The List of Medical Devices – Notification of Shortages, which is incorporated by reference (IBR) in the Interim Order, is maintained by Health Canada and is regularly updated. Manufacturers and importers must report shortages by completing the electronic reporting form. More information on medical device shortage reporting may be found on Health Canada's website.

This notification is to inform licence holders that The List of Medical Devices – Notification of Shortages was updated on May 19, 2020 to include additional medical devices that require mandatory reporting by manufacturers and importers. The list now includes:

Class I Medical Devices

- Masks (surgical, procedure or medical masks) - Level 1, 2, 3 (ATSM)
- N95 respirators for medical use
- Face shields
- Gowns - Level 2, 3 and 4

Class II Medical Devices

- Infrared thermometers
- Digital thermometers
- Oxygen Concentrators
- Pulse Oximeters (single measurement)

Class III Medical Devices

- Ventilators (including bi-level positive airway pressure machines)
- Pulse Oximeters (continuous monitoring)

Manufacturers and importers are responsible for periodically reviewing The List of Medical Devices – Notification of Shortages to ensure that they are submitting mandatory shortage reports for the required medical devices. Health Canada will not notify companies each time this list is updated. For inquiries, please contact: hc.meddev-matmed.sc@canada.ca.

Ongoing KN95 Respirator Recall

As previously communicated, Health Canada has determined that KN95 Filtering Facepiece Respirators ("respirators") which have failed to demonstrate a 95% filtration rate, as per the National Institute of Occupational Safety and Health (NIOSH) website (https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html) and which are possibly being imported into Canada, pose a health and safety risk to end users.

Since the issuance of those communications, there have been and continues to be updates made to the above NIOSH assessments, resulting in newly added manufacturers and medical devices of concern to Health Canada. It is the responsibility of Medical Device Establishment Licence (MDEL) and Submission Number (SN) holders to visit the NIOSH website above on a regular basis and to notify Health Canada if they are importing or selling any of the affected products.

As more information becomes available, the Department is committed to further assessing those respirators and informing Canadians of any updates to the recall through the following webpage:

https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/73137a-eng.php

As an MDEL or SN holder, it is your responsibility to verify both the above webpages on a regular basis to determine if you are impacted by the recall and to inform Health Canada at hc.meddev-matmed.sc@canada.ca.