THE MDEL BULLETIN

PRODUCED BY THE MEDICAL DEVICES COMPLIANCE PROGRAM

This bulletin provides MDEL holders with updates from Health Canada.

June 9, 2020

KN95 Respirators - Update on actions required

As part of its ongoing surveillance and assessment of KN95 respirators that may not meet filtration standards, Health Canada has determined that KN95 Particle Respirators manufactured by the companies listed below do not meet the required standards for filtration or the design features related to achieving an adequate fit. As a result, KN95s manufactured by these companies may pose a health and safety risk in settings where a 95% filtration is required. These products must be relabeled as face masks for use in settings where 95% filtration is not required. Under the *Medical Devices Regulations*, this re-labeling is considered a recall.

The KN95 Respirator manufacturers identified are:

1.Anhui Subolun Garment Co. Ltd
2.Bengbu Hongjie Medical Equipment Co Ltd
3.Donnaturel; Wanwei Chuangda Medical Technology (Shandong) Co Ltd
4.Guangzhou Folunsi Industrial Co., Ltd.
5.Hangzhou Unibear Medical Deveices Co. Ltd.
6.KMP
7.Luoyang Haoyang Clothing LTD
8.Ningbo Kangqi Medical Supplies Co. Ltd.
9.Qingdao Caiyang Childrens Articles Co.Ltd
10.Qingdao Hongshunyi Project Co., Ltd(ICK)
11.Quzhou Benneng Vehicle Co. Ltd.
12.Sichuan Fogu Medical Technology Co Ltd
13.Tianjin Benmo Medical Equipment Co., Ltd.
14.Wonder Medical Technology Co., Ltd(DONNATUREL)
15.Yiwu Wells Knitting Co. Ltd.
16.Zhejiang Beilan Protective Equipment Co. Ltd.

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. These medical devices can only be distributed in Canada if they are re-labelled as face masks for use in settings where 95% filtration is not required.

If you have sold or distributed KN95 respirators by the identified manufacturers noted above, Health Canada is directing you to:

1. Immediately stop sale of the KN95 respirators from the listed manufacturers and relabel current stock of respirators:

    a. as face masks (not respirators) that can be distributed to healthcare and non-healthcare settings, where a 95% filtration is not needed; and

    b. Remove all references to KN95, GB2626-2006 or 95% filtration efficiency from all labels.

2. Inform Canadian customers, within 2 business days of this bulletin, that:

    a. Filtering facepiece respirators from the manufacturers listed above may not provide consistent and adequate respiratory protection to healthcare personnel exposed to COVID-19

    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 (You) will:

        i) 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, and

        ii) inform customers to remove references to KN95, GB2626-2006 or 95% filtration efficiency;

    or

    c. They can choose to return the current stock to the MDEL holder (You).

3. To continue selling products as respirators, you are encouraged to submit an application for authorization under Health Canada's Interim Order (IO) for the Importation and Sale of Medical Devices. 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

These actions meet the definition of a recall, as stated in Section 1 of the *Medical Devices Regulations*.

Section 64 of the *Medical Devices Regulations* (Annex A) requires the manufacturer and importer of a device to provide the Minister with information on or before undertaking a recall of a device.

If you have imported or sold respirators from these companies, please immediately notify Health Canada at hc.meddev-matmed.sc@canada.ca. You will then be sent a letter outlining more details for required actions under the recall.

Continued updates to the NIOSH assessments

As previously communicated, Health Canada has determined that certain 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 when used in a setting where a 95% filtration rate is required.

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 check the NIOSH website noted 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 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 of the above noted 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 .

Counterfeit Products

Health Canada continues to monitor and address cases of counterfeit products, products of substandard specifications, and those of inferior quality. Medical Device Establishment Licence (MDEL) and Submission Number (SN) holders are responsible for ensuring imported and sold products that meet the definition of a medical device are compliant with the *Medical Devices Regulations* (MDR). Health Canada will conduct inspections to verify compliance with the MDR, and that all required procedures are in place. Health Canada will also conduct spot checks to verify compliance and will refuse shipments at the border or take any necessary action to address any risk to health, including any misleading claims or false information submitted in the application form. When non-compliance is confirmed, Health Canada will take immediate action to stop the importation and sale of any products that are found to pose a risk to health to Canadians. Specifications for the various types of Personal Protective Equipment (PPE) products can be found at Buyandsell.gc.ca.

A counterfeit health product is one that is represented as, and likely to be mistaken for, an authentic product. Counterfeit medical devices could relate to a product's identity or source, could include products with similar components, with the wrong components, or with misleading packaging or labelling. Health Canada considers a medical device counterfeit when it:

- is comprised of fraudulent components,
- is fraudulently labelled with respect to identity, composition, origins, and/or source
- has falsifications which may look genuine, or

- contains forgeries (i.e. printed).

Counterfeit medical devices may pose serious risks to health. In addition, counterfeit products have a negative impact on the reputations of genuine brands and reduce consumer confidence in the supply chain.

Counterfeited medical devices are placed on the market without a Health Canada assessment for safety, effectiveness and quality, and may pose health risks to Canadians. The importation and sale of counterfeit medical devices constitute violations of the *Food and Drugs Act* (FDA) and its Regulations. **All applicable requirements of the FDA and the MDR must be met at the time of importation into Canada of medical devices.**

Counterfeit Respirators / Misrepresentation of NIOSH-Approval

Health Canada has identified counterfeit respirators in Canada and continues to take action to stop the import and sale of such products. Counterfeit respirators include products that are falsely marketed and sold as being NIOSH-approved and may not be capable of providing adequate respiratory protection for consumers, including healthcare professionals.

Medical Device Establishment Licence (MDEL) and Submission Number (SN) holders are responsible for ensuring that all medical devices imported and distributed in Canada meet the requirements of the *Medical Device Regulations*, including verification of the authenticity of medical devices.

The National Institute for Occupational Safety and Health (NIOSH) - National Personal Protective Technology Laboratory (NPPTL) of the Centers for Disease Control and Prevention (CDC) provides information on how to verify the authenticity of N-95 masks, including examples of commonly counterfeited N-95 masks:

https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html

Following the guidance provided on the NIOSH website will help companies identify counterfeit products and prevent them from being imported and distributed.

Action Required

Verify that any respirators you have imported or distributed are not counterfeit. If you have imported, sold and/or distributed any suspect counterfeit respirators, you must:

1. Immediately Stop Sale and Recall the implicated products. These medical devices cannot be imported, distributed or sold in Canada by any person. Within 2 business days of this bulletin, you must inform Health Canada of the findings of your counterfeit verifications, including images and/or documentation that provide evidence of suspect-counterfeit, by emailing hc.meddev-matmed.sc@canada.ca.

2. Within 2 business days of this bulletin, inform your Canadian customers:
    a. to immediately stop use of the suspected counterfeit respirator, as they may not be capable of providing appropriate respiratory protection to consumers.

b. to return the current stock to yourself, the MDEL/SN holder.

3. Within 3 business days of this bulletin, submit a completed Section 64 Recall Report to hc.meddev-matmed.sc@canada.ca. Section 64 of the *Medical Devices Regulations* (Annex A) requires the manufacturer and importer of a device to provide the Minister with information on or before undertaking a recall of a device.

Please include the following in the S. 64 recall report to Health Canada:

A) The field notification letter sent to consignees informing them (as noted above):

i) to immediately stop use of the counterfeit respirator, as they are suspected counterfeit and may not be capable of providing appropriate respiratory protection to workers

ii) return the current stock to the MDEL or SN holder

B) A detailed proposed strategy for conducting the recall, including progress reports to Health Canada and the anticipated recall closure date.

i) The first progress report is to be provided to Health Canada is due by the end of 5 business days from now and subsequently every Friday or until the recall is considered closed. The progress reports should include an update on the contact with customers, response from customers, effectiveness checks, and any other pertinent information.

C) Detailed actions on how a 100% effectiveness check will be achieved.

4. As soon as possible following the completion of any necessary recall, you will be required to **supply the information defined within Section 65** of the *Medical Devices Regulations* (Annex B).

Contact Us

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

Annexes

Annex A: Section 64 of the Medical Device Regulations

64 The manufacturer and the importer of a medical device shall, on or before undertaking a recall of the device, each provide the Minister with the following:

(a) the name of the device and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
(b) the name and address of the manufacturer and importer, and the name and address of the establishment where the device was manufactured, if different from that of the manufacturer;
(c) the reason for the recall, the nature of the defectiveness or possible defectiveness and the date on and circumstances under which the defectiveness or possible defectiveness was discovered;

(d) an evaluation of the risk associated with the defectiveness or possible defectiveness;
(e) the number of affected units of the device that the manufacturer or importer
(i) manufactured in Canada,
(ii) imported into Canada, and
(iii) sold in Canada;
(f) the period during which the affected units of the device were distributed in Canada by the manufacturer or importer;
(g) the name of each person to whom the affected device was sold by the manufacturer or importer and the number of units of the device sold to each person;
(h) a copy of any communication issued with respect to the recall;
(i) the proposed strategy for conducting the recall, including the date for beginning the recall, information as to how and when the Minister will be informed of the progress of the recall and the proposed date for its completion;
(j) the proposed action to prevent a recurrence of the problem; and
(k) the name, title and telephone number of the representative of the manufacturer or importer to contact for any information concerning the recall.

Annex B: Section 65 of the Medical Devices Regulations

65 The manufacturer and the importer of a medical device shall, as soon as possible after the completion of a recall, each report to the Minister
(a) the results of the recall; and
(b) the action taken to prevent a recurrence of the problem.