THE MDEL BULLETIN

PRODUCED BY THE MEDICAL DEVICES COMPLIANCE PROGRAM

This bulletin provides MDEL holders with updates from Health Canada.

June 26, 2020

Update on Counterfeit Respirators / Misrepresentation of NIOSH Approval

Further to Health Canada's ongoing efforts to identify counterfeit respirators in Canada and to take action to stop the import and sale of such products, the Department would like to inform you that the **DTC3X N95 PARTICULATE RESPIRATOR** sold by **Shanghai Lansheng Light Industrial Products Imp. & Exp. Corp., Ltd**. is suspected of having misrepresented NIOSH approval and consequently their respective Interim Order Authorization is now cancelled. The product is labelled as NIOSH-approved, but the configuration of a respirator with ear Loops, is not conforming to NIOSH specifications.

Sale of misrepresented devices is in violation of Section 20(1) of the *Food and Drugs Act*:
No person shall label, package, treat, process, sell or advertise any device in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its design, construction, performance, intended use, quantity, character, value, composition, merit or safety.

Action Required

If you have imported, sold and/or distributed any **DTC3X N95 PARTICULATE RESPIRATORS** from **Shanghai Lansheng Light Industrial Products Imp. & Exp. Corp., Ltd**.:

1. Immediately Stop Sale, Recall, and destroy 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 that you have imported, sold and/or distributed the affected product and that you are in agreement to recall, 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 it 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 affected product, as it is suspected counterfeit and may not be capable of providing appropriate respiratory protection

   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.

The first progress report is to be provided to Health Canada is due by the end of 5 business days from the date of this bulletin 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).

Reminder

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.

Contact Us

For more information, 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.