



Final Recall Reporting Form for Medical Devices (FRM-0360B)

Under section 65 of the Medical Devices Regulations (MDR), manufacturers and importers are required to report to Health Canada as soon as possible after the completion of a recall.

This form is optional but all fields in this document are required. If you use your own version of this form, you must ensure that the information required under section 65 is provided. Health Canada may request additional information if necessary to help us properly evaluate the risk and other aspects of the recall.

Personal information you may provide to Health Canada is governed in accordance with the Privacy Act. It is collected to administer the Medical Device and Enforcement Program authorized under the Food and Drugs Act.

For more information, visit:

- [Guide for recalling medical devices \(GUI-0054\)](#)
- [Recalls and Safety Alerts Database](#)
- [Information page on medical devices shortages](#)
 - Shortage: [Report a medical device shortage](#)
 - Discontinuation: [Report a medical device discontinuation](#)
- [Guidance on how to interpret 'significant change' of a medical device](#)
- [Guidance on investigation of reported medical device problems](#)
- [Info Source](#) to learn how we collect and safeguard personal information.
 - refer to the personal information bank HC PPU 405
 - for questions about our privacy practices, email the director of the Privacy Management Division at Privacy-vie.privee@hc-sc.gc.ca

Complete and email this recall reporting form and attachments required under section 65 of the MDR to Health Canada's Medical Devices Compliance program at meddev-matmed@hc-sc.gc.ca.

Section 1: Submitter information

General information

Type of report:

New voluntary final report, as per section 65 of the MDR

Amended final report (ex: update or modification). Specify in the comments section below

Other. Specify in the comments section below

Comments or additional information about this recall submission (if applicable):

Health Canada file number:

Submitter file number: (if applicable)

Information about your company regarding this submission

Name of reporting company:

Company ID:

Street address:

City:

Province/state:

Postal/zip code:

Country:

Activity:

Manufacturer

Importer reporting on behalf of the manufacturer; we are authorized under section 65.1 to report recalls on behalf of the manufacturer

Importer only; we are not reporting this recall on behalf of the manufacturer

Other. Specify in the comments section above

Primary contact information (for correspondence about the recall submission)

Contact's first and last name:

Title:

Email:

Phone number:

Preferred language:

English French

Section 2: Results of the recall

Evaluation of the effectiveness of the recall communications

Note: Include information about the effectiveness of the recall notification, follow-ups and confirmation that all accounts have received the recall notice. You may send additional information as attachments.

Were all notifications and follow-ups with the consignees completed and deemed effective? (for example, reasonable response rate)

Provide a detailed rationale (add additional information as attachments):

Number of consignees who responded:

Total number of consignees:

Evaluation of the effectiveness of the recall actions

Confirm that all corrections have been completed. Provide a reconciliation of all devices affected by the recall and a rationale for any discrepancies. You may send additional information as attachments.

Number of devices that were corrected or retrieved:

Total number of affected devices:

Section 3: Actions taken to prevent recurrence of the problem**Root cause**

Name the root cause of the defect or problem and how you were able to identify it.

Corrective and preventive actions

Explain all actions undertaken by your company to correct the defect or the problem with the affected device or devices, prevent it from reoccurring and the effectiveness of those actions.

Were all corrective actions fully implemented and deemed effective?

Recall completion date (yyyy-mm-dd):

Section 4: Licence amendments and significant changes

Class II medical devices

Note: For Class II medical devices, refer to section 34 of the MDR to evaluate if the criteria to submit a licence amendment are met.

Did the actions undertaken during this recall lead to a change in the name of the manufacturer, of the devices or to their identifiers?

Did the actions undertaken during this recall lead to a change in the medical conditions, purposes or uses for which the device is manufactured, sold or represented?

Provide a detailed rationale (add additional information as attachments):

If yes, when was the licence amendment issued (yyyy-mm-dd)?

Class III and IV medical devices

Note: For Class III and IV medical devices, refer to section 34 of the MDR and to the Guidance on how to interpret 'significant change' of a medical device to determine if the criteria are met and how to update your Health Canada device licence.

Did the actions undertaken during this recall lead to a change in the name of the manufacturer, of the devices or to their identifiers?

Did the actions undertaken during this recall lead to a significant change to the medical devices?

Provide a detailed rationale (add additional information as attachments):

If yes, when was the licence amendment issued (yyyy-mm-dd)?

Submission checklist

Submission with **manufacturing** responsibilities (select all that apply):

Note: The documents that are required to be submitted depend on your role within this recall. This checklist is for manufacturers submitting a final recall report or importers submitting a final recall report on behalf of a manufacturer.

Final recall report

Consignee response tracker

Tracker for the completion of the corrective actions to the affected medical devices

CAPA (if applicable)

Submission with **importing** responsibilities only (select all that apply):

Note: This checklist is for importers only. If you are an importer who is submitting a final recall report on behalf of a manufacturer, complete the checklist named “submission with manufacturing responsibilities” above.

Final recall report

Consignee response tracker