Medical Device Foreign Risk Notification Form for Industry

This form is intended to be used by authorization holders to report information concerning actions taken in certain foreign jurisdictions to eliminate or mitigate a **serious risk of injury to human health** related to the use of a medical device, as per sections 61.2 and 61.3 of the *Medical Devices Regulations* (the Regulations).

The requirement to submit foreign risk notification (FRN) reports applies to holders of a medical device licence for class II to IV devices, an establishment licence to import Class II to IV devices ("importer"), or an authorization under subsection 83(1) of the Regulations (Investigational Testing Authorization) for class II-IV devices. As a licence holder, a "private label manufacturer" (a person who sells a private label medical device under their own trademark) is also responsible for complying with the requirement to submit FRN reports.

All fields marked with an asterisk (*) must be filled prior to submission of the form.

For more information on how and when to fill out this form, see the instructions provided below and/or refer to the Foreign Risk Notification for Medical Devices Guidance Document.

How to submit the form

Completed forms should be submitted by email to Health Canada's Medical Devices Directorate at: mdd.postmarket-postcommercialisation.dim@hc-sc.gc.ca

* The email subject line should state: "**FRN report submission for medical device authorization # XXXXXX**"

Note: If a submitted FRN report meets requirements, Health Canada will **not** confirm receipt. Health Canada may, however, follow up with reporters if additional information is necessary. The authorization holder should have in place and maintain records of a monitoring process, which Health Canada may assess when verifying compliance.

Privacy Notice

The personal information you provide to Health Canada will be used by the Health Products and Food Branch under the authority of section 23(1)(c) of the Food and Drugs Act and Medical Devices Regulations and handled in accordance with the Privacy Act.

Why are we collecting your personal information? *We collect your name and contact information as part of the compliance and enforcement activities related to Foreign Risk Notification reports for medical devices.*

Will we use or share your personal information for any other reason? *Your personal information is used to follow up with you concerning your foreign risk notification report. Your personal information may be shared with other Branches in Health Canada who have similar mandates.*

What happens if you don't want to provide your personal information? *The collection of name and contact information for the organization is mandatory.*

What are your rights? *You have the right to access and request a correction and/or notation to your personal information. You also have a right to complain to the Privacy Commissioner of Canada if you feel your personal information has been handled improperly. For more information about these rights, or about how we handle your personal information, please contact the Medical Devices Directorate at mdd.postmarket-postcommercialisation.dim@hc-sc.gc.ca.*

For more information: *The collection of your personal information is described in Info Source at infosource.gc.ca. Refer to the personal information bank (PIB) HC PPU 405 – Compliance and Enforcement – Medical Devices. In addition to the requirements specified on the Treasury Board of Canada Secretariat Personal Information Request form, individuals requesting information described by this bank must provide the incident ID number, device name or company name.*

Medical Device Foreign Risk Notification Form

Clear Form

A. INFORMATION ABOUT THE REPORT

1. Type of report
   - ☐ Initial report
   - ☐ Update report

2. Is this the principal report?
   - ☐ Yes
   - ☐ No

3. Information about the related principal report (if this is not the principal report)
   - a. Date of submission of the principal report:
   - b. Authorization number (Section C1) from the principal report:

4. Reporter file number:

B. INFORMATION ABOUT THE REPORTER

1. Authorization holder name *

2. Authorization holder mailing address

3. Authorization holder email address *

4. Health Canada assigned authorization holder identification number:

5. Authorization holder type
   - ☐ Manufacturer
   - ☐ Importer
   - ☐ Other:

6. If an importer, is the report being submitted on behalf of the manufacturer?

C. INFORMATION ABOUT THE MEDICAL DEVICE(S)

1. Canadian authorization number *

Select all that apply.

- ☐ Medical Device Licence number (if applicable):
- ☐ Investigational Testing Authorization number (if applicable):

If additional Investigational Testing Authorization numbers apply, enter them here:

2. Legal manufacturer *
   a. Name:
   b. Mailing address:

3. Canadian product (#1)
   a. Trade/brand name: *
   b. Control/lot/serial number:
   c. Device classification: ☐ II ☐ III ☐ IV
   d. Device identification number:
   e. Manufacturer's medical device identifier (catalogue/model number):
   f. Global Medical Device Nomenclature (GMDN) code:
   g. Other:

4. Canadian product (#2) – Optional
   a. Trade/brand name:
   b. Control/lot/serial number:
   c. Device classification: ☐ II ☐ III ☐ IV
   d. Device identification number:
   e. Manufacturer's medical device identifier (catalogue/model number):
   f. Global Medical Device Nomenclature (GMDN) code:
   g. Other:

5. Canadian product (#3) – Optional
   a. Trade/brand name:
   b. Control/lot/serial number:
   c. Device classification: ☐ II ☐ III ☐ IV

d. Device identification number:

e. Manufacturer's medical device identifier (catalogue/model number):

f. Global Medical Device Nomenclature (GMDN) code:

g. Other:

6. Foreign product(s)

a. Trade/brand names of the foreign products:

b. If different:

D. INFORMATION ABOUT THE SERIOUS RISK(S) OF INJURY TO HUMAN HEALTH

1. Type(s) of serious risk(s) *

Select all that apply.

- ☐ Life-threatening
- ☐ Persistent or significant disability or incapacity
- ☐ Inpatient hospitalization and/or prolonged hospitalization
- ☐ Serious health consequence, such as loss of function or debilitating chronic pain
- ☐ Death

2. Brief description of the serious risk(s) and what is known about the root cause(s)

E. INFORMATION ABOUT THE FOREIGN NOTIFIABLE ACTION(S) TAKEN

1. Jurisdiction(s) in which the manufacturer or importer has taken a notifiable action and/or the regulatory agency/agencies that has/have taken or been notified of a notifiable action *
Select all that apply.

☐ Australia	☐ Therapeutic Goods Administration (TGA)
☐ Austria	☐ Austrian Agency for Health and Food Safety (AGES)
☐ Belgium	☐ Federal Agency for Medicines and Health Products (FAMHP)
☐ Brazil	☐ National Health Surveillance Agency (ANSIVA)
☐ Bulgaria	☐ Bulgarian Drug Agency
☐ China	☐ National Medical Products Administration (NMPA)
☐ Croatia	☐ Agency for Medicinal Products and Medical Devices of Croatia (HALMED)
☐ Cyprus	☐ Cyprus Medical Devices Competent Authority
☐ Czechia	☐ State Institute for Drug Control
☐ Denmark	☐ Danish Medicines Agency
☐ Estonia	☐ Health Board, Medical Devices Department
☐ Finland	☐ Finnish Medicines Agency (FIMEA)
☐ France	☐ National Agency for the Safety of Medicine and Health Products (ANSM)
☐ Germany	☐ Federal Institute for Drugs and Medical Devices (BfArM)
☐ Greece	☐ National Organization for Medicines (EOF)
☐ Hungary	☐ National Institute of Pharmacy and Nutrition (OGYEI)
☐ Ireland	☐ Health Products Regulatory Authority (HPRA)
☐ Italy	☐ Medical Devices and Active Implantable Medical Devices, Ministry of Health
☐ Japan	☐ Pharmaceuticals and Medical Devices Agency (PMDA) and the Ministry of Health, Labour and Welfare (MHLW)
☐ Latvia	☐ Ministry of Health of the Republic of Latvia- Health Inspectorate
☐ Lithuania	☐ State Health Care Accreditation Agency (VASPVT)
☐ Luxembourg	☐ State Health Care Agency, Ministry of Health
☐ Malta	☐ Malta Competition and Consumer Affairs Authority (MCCAA)
☐ Mexico	☐ Federal Commission for Protection Against Sanitary Risk (COFEPRIS)
☐ Netherlands	☐ Healthcare and Youth Care Inspectorate (IGZ)
☐ New Zealand	☐ Medicines and Medical Devices Safety Authority (MEDSAFE)
☐ Poland	☐ Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
☐ Portugal	☐ National Authority of Medicines and Health Products (INFARMED)
☐ Romania	☐ National Agency for Medicines and Medical Devices (NAMMDR)
☐ Russia	☐ Russian Ministry of Health
☐ Singapore	☐ Health Sciences Authority (HSA)
☐ Slovak Republic	☐ State Institute for Drug Control (SIDC)
☐ Slovenia	☐ Agency for Medicinal Products and Medical Devices of the Republic (JAZMP)
☐ South Korea	☐ Ministry of Food and Drug Safety
☐ Spain	☐ Spanish Agency for Medicines and Health Products (AEMPS)
☐ Sweden	☐ Medical Products Agency (MPA)
☐ Switzerland	☐ Swiss Agency for Therapeutic Products (Swissmedic)
☐ United Kingdom	☐ Medicines and Healthcare Products Regulatory Agency (MHRA)
☐ United States of America	☐ United States Food and Drug Administration (US FDA)

2. Type(s) of notifiable action(s) taken *

Select all that apply.

- ☐ Risk communication
- ☐ Label change that has been communicated to or requested by a relevant regulatory agency
- ☐ Recall (e.g., product withdrawal)
- ☐ Reassessment of authorization
- ☐ Suspension or revocation of authorization

3. Description of the notifiable action(s) taken *

4. Link(s) to information about the notifiable action(s), if available

F. INFORMATION ABOUT ACTION(S) BEING PLANNED IN CANADA

1. Type(s) of action(s) being planned in Canada in response to the serious risk(s) identified in Section D *

Select all that apply.

- ☐ Communication
- ☐ Label Change
- ☐ Recall (as defined in Sections 63-65 of the Canadian Medical Devices Regulations)
- ☐ Other:
- ☐ No action(s) taken or planned in Canada (Provide a rationale in section F6.)

2. Description of action(s) being planned in Canada, if any

3. Estimated or actual date of action initiation:	4. Estimated date of action completion:

5. Reference numbers or links to relevant information, if available

6. If no action has been taken or is planned in Canada, provide a rationale.

INSTRUCTIONS ON COMPLETING THE FOREIGN RISK NOTIFICATION FORM

Please read all form fields carefully and supply an answer. **All form fields marked with an asterisk (*) must be filled prior to submission.**

A. INFORMATION ABOUT THE REPORT

This section captures information about the Foreign Risk Notification (FRN) report being submitted to Health Canada. A **single FRN report** should be submitted related to serious risk of injury to human health, even if more than one notifiable action is taken and/or if notifiable actions are taken in more than one foreign jurisdiction.

A single form can be used to submit for up to three (3) medical devices if they are authorized:

- under a single Medical Device Licence number;
- under a single Medical Device Licence number *as well* as one or more Investigational Testing Authorization numbers; or
- only for Investigational Testing (i.e., no Medical Device Licence), even if there is more than one Investigational Testing Authorization number.

If, however, more than one (1) Medical Device Licence number or more than three (3) devices are implicated, submit additional forms. In some cases, an alternative approach may be possible, such that the burden on the reporter is reduced while continuing to ensure that the required information is provided for timely review by Health Canada. If a very large number of authorizations and/or devices are implicated, or if the implicated medical devices are authorized differently under various authorization numbers, please contact Health Canada for further guidance at: mdd.postmarket-postcommercialisation.dim@hc-sc.gc.ca.

As more is learned about the risk, it is possible that **additional notifiable actions** will be taken or that notifiable actions will be taken in **additional jurisdictions** following the submission of an initial FRN report. In this situation, additional FRN reports ("**update reports**") must be submitted to Health Canada within 72 hours of receipt or awareness of information about additional notifiable actions having been taken (i.e., new actions or new jurisdictions).

A1. Type of report: Indicate if the report being submitted is an initial report or an update report.

A2. Is this the principal report? Indicate if the form being submitted has been designated as the "principal report". The reporter should designate a single initial report of their choosing as the "principal report". If only one initial report is being submitted, it should be the principal report by default. The designation of a principal report is intended to allow for linkage of any reports related to the same identified serious risk(s), whether submitted at the same time as, or following the principal report. If the response in Section A2 is "no", then complete section A3.

A3. Information about the principal report (if this is not the principal report):

a. **Date of submission of the principal report:** Provide the date on which the principal report was submitted. If more than one form is being submitted on the same date (e.g., not all relevant

authorization numbers or devices can fit on a single form), the response in Section A3a will be the same as the date on which the additional report(s) is/are being submitted. If an update report is being submitted, the response in Section A3a will be the date on which the principal report was submitted.

b. **Authorization number (Section C1) from the principal report:** If an additional report or an update report is being submitted, provide the authorization number that was listed in Section C1 on the principal report. If a Medical Device Licence number AND one or more Investigational Testing Authorization numbers were listed on the principal report, provide the Medical Device Licence number. If there was no Medical Device Licence number on the principal report, provide the main Investigational Testing Authorization number that was provided on the principal report.

A4. Reporter file number: Indicate the manufacturer's or importer's file number for the case. This field is optional. If it is completed, the file number should be the same for all related reports (e.g., initial reports and update reports).

B. INFORMATION ABOUT THE REPORTER

This section captures information about the reporter (e.g., manufacturer or importer). This is the information that Health Canada will use if follow-up is required.

B1. Authorization holder name: Provide the name of the company submitting the report, if applicable. If the reporter is not a company, provide an alternate authorization holder name.

B2. Authorization holder mailing address: Provide the mailing address of the company submitting the report, if applicable. If the reporter is not a company, provide an alternate authorization holder mailing address.

B3. Authorization holder email address: Provide the e-mail address of the company submitting the report, if applicable. If the reporter is not a company, provide an alternate authorization holder email address.

B4. Health Canada assigned authorization holder identification number: Provide the Health Canada assigned authorization holder (e.g., company) identification number, if known. This number can be found on a medical device licence or a medical device establishment licence, if applicable.

B5. Authorization holder type: Indicate if the authorization holder submitting this report to Health Canada is a manufacturer, an importer, or other. If "other", please specify.

B6. If an importer, is the report being submitted on behalf of the manufacturer? Select "yes" or "no" to specify if the importer is submitting on behalf of the manufacturer.

Note: If a manufacturer wants to permit the importer of the device to submit FRN reports to Health Canada on the manufacturer's behalf, the manufacturer must give authorization to the importer, and notify Health Canada in writing. To notify Health Canada or to receive a copy of the form "**Authorization for medical devices mandatory problem, foreign risk notification, and recall reporting according to sections 61.1, 61.3, and 65.1 of the Medical Devices Regulations and/or designation to Act as the Canadian regulatory contact**", contact Health Canada's Regulatory Operations and Enforcement Branch at: MDCU_UCIM@hc-sc.gc.ca.

C. INFORMATION ABOUT THE MEDICAL DEVICE(S)

This section captures information about the implicated medical device(s). In some cases, **more than one form may need to be submitted** to capture the necessary authorization and device information. See the instructions for Section A for more information.

C1. Canadian authorization number: Provide the authorization number(s) issued by Health Canada on behalf of the Minister for class II, III and IV medical devices (i.e., Medical Device Licence number and/or Investigational Testing Authorization number). If there is more than one implicated licence number, submit additional forms. If the devices listed in Section C3 are authorized under more than one Investigational Testing Authorization number, select one "main" Investigational Testing Authorization number and enter additional numbers for reference.

C2. Legal manufacturer: Provide information about the legal manufacturer for the implicated device(s) under the authorization number(s) listed on the form:

a. **Name:** Provide the name of the legal manufacturer.
b. **Mailing address:** Provide the mailing address of the legal manufacturer.

C3. Canadian product (#1): Provide information about the implicated medical device that is authorized for sale in Canada:

a. **Trade/brand name:** Indicate the trade/brand name of the device and reported on the Canadian label.
b. **Control/lot/serial number:** Indicate the control number, lot number and/or serial number for the device.
c. **Device classification:** Indicate the class of the device (II-IV).
d. **Device identification number:** If available, indicate the device identification number assigned by Health Canada in the licence or Investigational Testing Authorization issued for the device.
e. **Manufacturer's medical device identifier (catalogue/model no.):** Indicate the unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the manufacturer and that identifies it and distinguishes it from similar devices. Examples of an identifier for a device are a catalogue, model, or part number.
f. **Global Medical Device Nomenclature (GMDN) code:** Provide the 5-digit standardized numeric code assigned to the device.
g. **Other:** Include any additional information that helps to identify the implicated medical device.

C4. Canadian product (#2) – Optional: Complete this section if there is a second implicated medical device under the authorization number.

C5. Canadian product (#3) – Optional: Complete this section if there is a third implicated medical device under the authorization number.

C6. Foreign product(s): Provide information about the implicated foreign product(s). This is captured to allow Health Canada to understand if information gathered about foreign risks or notifiable actions apply in Canada.

a. **Trade/brand name(s) of the foreign product(s):** If the trade/brand names for the implicated foreign products are the same as those listed in C3, C4, and C5, select "Same as the Canadian products". If the trade/brand names for the implicated foreign products are different from those listed in Sections C3, C4, and C5, select "Different from the Canadian products" and fill in Section C6b.
b. **If different:** Enter the trade/brand name(s) of the implicated foreign product(s), if different from those listed in Sections C3, C4, and C5.

D. INFORMATION ABOUT THE SERIOUS RISK(S) OF INJURY TO HUMAN HEALTH

This section captures information about the serious risk(s) of injury to human health being mitigated and what is known about the root cause(s).

A **serious risk of injury to human health** is defined as: A hazard associated with the medical device that is relevant to the safety of the medical device (including issues related to effectiveness or quality) and that, without risk mitigation, would likely:

- be life-threatening
- result in persistent or significant disability or incapacity
- require inpatient hospitalization or prolonged hospitalization
- result in a serious health consequence such as loss of function or debilitating chronic pain
- result in death

Note: If the notifiable action is **not** being taken in response to an actual or potential serious risk of injury to human health, submission of a FRN report is **not** required.

D1. Type(s) of serious risk(s): Select any types of risks that apply to the notifiable action being reported.

D2. Brief description of the serious risk(s) and what is known about the root cause(s): Provide a narrative to describe the serious risk(s) identified under section D1 and what is known about the root cause(s).

E. INFORMATION ABOUT THE FOREIGN NOTIFIABLE ACTION(S) TAKEN

This section captures information about the notifiable action(s) taken in the foreign jurisdiction(s). See Section 61.2(2) of the Medical Devices Regulations and the List of regulatory agencies and foreign jurisdictions for more information.

A **notifiable action** is defined as an action taken in one or more specified jurisdictions **for the purpose of mitigating or eliminating a serious risk of injury to human health** related to the use of a medical device. Notifiable actions include:

- **risks that have been communicated** by a regulatory agency or by any person who is authorized to manufacture or sell a medical device within the jurisdiction of a regulatory agency
- **changes to the labelling** that have been communicated to or requested by any regulatory agency
- **recalls** that have taken place within the jurisdiction of any regulatory agency
- **reassessments of authorizations** that have taken place within the jurisdiction of any regulatory agency
- **suspensions or revocations of authorizations** that have taken place within the jurisdiction of any regulatory agency

Regulatory requirements and definitions may differ in various foreign jurisdictions and from those in Canada. The definition of the action in the foreign jurisdiction(s) should be used.

E1. Jurisdiction(s) in which the manufacturer or importer has taken a notifiable action and/or the regulatory agency/agencies that has/have taken or been notified of a notifiable action: Select from among the list of regulatory agencies and jurisdictions to indicate all implicated jurisdictions and/or agencies. At least one selection must be made. Select all that apply.

E2. Type(s) of notifiable action(s) taken: Select from among the list of notifiable actions. Select all that apply.

E3. Description of the notifiable action(s) taken: Provide a narrative to describe the notifiable action(s) identified under section E2.

Note: It is not necessary to provide original documents that are issued to health care professionals or to the public as part of the foreign action. When describing the action in Section E3, give enough detail to allow Health Canada to understand what was shared in the foreign jurisdiction.

E4. Link(s) to online information about notifiable actions, if available: If information is available online related to the notifiable action(s) taken, provide links.

F. INFORMATION ABOUT ACTION(S) BEING PLANNED IN CANADA

This section captures information about any actions that are being planned in Canada to mitigate or eliminate the serious risk(s) of injury to human health that was/were identified in one or more foreign jurisdictions (i.e., Section D).

Note: Submission of a FRN report is not required if, **prior to** or **within 72 hours of receipt or awareness of a notifiable action**, another established method has been or will be used to notify Health Canada of action(s) taken in Canada to mitigate or eliminate the serious risk (e.g., submission of a recall notification as specified under Sections 63-65 of the Medical Devices Regulations).

F1. Type(s) of action(s) being planned in Canada in response to the serious risk(s) identified in Section D: Select from among the list of types of actions. If none apply, select "other" and indicate the type of action. If no action has been taken or is planned in Canada, provide a rationale in section F6.

F2. Description of the action(s) being planned in Canada, if any: Provide a narrative to describe any action(s) identified under section F1.

F3. Estimated or actual date of action initiation: Provide the estimated date of initiation of any planned action(s) or, if action(s) has/have already been initiated, provide the actual date of initiation.

F4. Estimated date of action completion: Provide the estimated date of completion of any planned action(s).

F5. Reference numbers or links to relevant information, if available: If reference numbers or links are available related to any actions that have been planned in Canada, provide them here.

F6. If no action has been taken or is planned in Canada, provide a rationale: If no action has been taken or is being planned in Canada to mitigate or eliminate the serious risk(s) of injury to human health identified in Section D, provide a rationale. The rationale should be sufficient for Health Canada to understand why action isn't necessary in Canada.