# 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

## When to use this form

This form authorizes the organization named in **Section B** (importer) to act on behalf of the organization named in **Section A** (manufacturer) in regard to **mandatory problem, foreign risk notification** and/or **recall** reporting and/or to act as the **Canadian Regulatory Contact** for medical devices to Health Canada.

In addition, this form can also be used by the manufacturer to designate an organization to act as the Canadian Regulatory contact for all complaints originating from the Canadian market and authorize Health Canada to handle all other complaints information and follow-up through the designated company.

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|  | Please note that the manufacturer can authorize an importer to report mandatory problems, foreign risk notifications, and/or recalls on its behalf solely in situations where the manufacturer has a unique Canadian importer. |

## How to complete this form

**Section A** of the form should be completed by the manufacturer. The manufacturer specifies the authorization given to the importer by checking the appropriate box.

**Section B** of the form should be completed by the importer. The importer confirms that he will be reporting on behalf of the manufacturer.

## How to submit your form

The completed form should be the sent to the Medical Devices and Clinical Compliance Directorate of Health Canada at the following address:

Medical Devices Compliance and Licensing Unit

14th Floor, Jeanne Mance Building
Address Locator 1914D
200 Eglantine Driveway, Tunney's Pasture
Ottawa, Ontario
K1A 0K9

E-mail: MDCU\_UCIM@hc-sc.gc.ca

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|  | Manufacturers must also provide in writing any amendments / modifications to their authorization letter to the above mentioned coordinates. |

| Section A (manufacturer) (Check all that apply) |
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| * I hereby authorize the organization named in **Section B** to prepare and submit the preliminary and final reports for **mandatory problem reporting** according to the requirements defined in the Canadian Medical Devices Regulations on my behalf.
* I hereby authorize the organization named in **Section B** to prepare and submit reports for **foreign risk notification** according to the requirements defined in the Canadian Medical Devices Regulations on my behalf.
* I hereby authorize the organization named in **Section B** to prepare and submit the information and documents with respect to **recall reporting** for medical devices according to the requirements defined in the Canadian Medical Devices Regulations on my behalf, when those devices are made available on the Canadian market.
* I hereby designate the organization named in **Section B** to act as the Canadian Regulatory contact for all complaints originating from the Canadian market and authorize Health Canada to handle **all other complaints information and follow-up** through the designated company.
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| Company name: |
| Address: | City: |
| Province/State: | Postal code/Zip code: |
| Phone: | Fax: |
| Email: |
| Name of authorized representative: | Title: |
| Signature: | Date (yyyy-mm-dd): |

| Section B (importer) (Check all that apply) |
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| * I hereby accept the authorization in regard to **mandatory problem reporting** on behalf of the organization named in **Section A**.
* I hereby accept the authorization in regard to **foreign risk notification** on behalf of the organization named in **Section A**.
* I hereby accept the authorization in regard to **recall reporting** on behalf of the organization named in **Section A**.
* I hereby accept the designation as the Canadian regulatory contact for the organization named in **Section A** and accept that Health Canada will be contacting our organization for **all other complaints information and follow-up** related to this organization.
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| Company name: |
| Address: | City: |
| Province/State: | Postal code/Zip code: |
| Phone: | Fax: |
| Email: |
| Name of authorized representative: | Title: |
| Signature: | Date (yyyy-mm-dd): |