



**MEDICAL DEVICES LICENCE AMENDMENT FAX-BACK
FORM - GUIDANCE FOR CHANGES TO THE
MANUFACTURER'S NAME AND / OR ADDRESS OF
EXISTING *DEVICE LICENCES ONLY***

PLEASE READ CAREFULLY

- 1) The purpose of the attached form is to facilitate the approval of device licence amendments to support a change to the manufacturer's name or address on an **EXISTING** device licence(s). Note that the term "manufacturer" is synonymous with the business or corporate entity who owns the **trade name** of the device licence. As there can be **only one manufacturer who owns the trade name for a device licence in Canada**, once a change to the manufacturer's name is processed, the **previous manufacturer must stop the sale of all devices in Canada for which ownership has been changed.**
- 2) The attached form **shall** be submitted **with** the following information:
 - a copy of page 1 of the applicable licence (s)
 - a valid Quality System Certificate that reflects the change in manufacturer name or address.
 - **** a completed F202 form**
(<https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/quality-systems-13485/form-f202-submission-new-modified-quality-management-system-certificate-medical-devices.html>)
 - a copy of the attached Attestation Letter if a change is being made to the manufacturing facility but the manufacturing specifications remain unchanged
- 3) **All sections of the attached form shall be completed for this fax-back form to be processed.** Incomplete forms will result in the licence amendment fax-back form being rejected.
- 4) Receipt of an amended licence is considered to be confirmation that your licence has been amended and therefore, the device(s) and specified catalogue number(s) can be offered for sale in Canada. The amended licence will follow by email.
- 5) It is the intention of the Medical Devices Directorate to process Licence Amendment Fax-Back forms within 7 calendar days from the receipt date of the amendment application.
- 6) **Do not use both the Amendment Fax-Back Form and a regular Amendment Application for the same amendment.**



**MEDICAL DEVICES LICENCE AMENDMENT FAX-BACK FORM
(FOR CHANGES TO THE MANUFACTURER'S NAME / ADDRESS)**

**PLEASE SUBMIT TO THE MEDICAL DEVICES DIRECTORATE AT:
hc.devicelicensing-homologationinstruments.sc@canada.ca**

1) REASON FOR CHANGE (*Specify the nature of the proposed change i.e. Acquisition, moving, etc.*)

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2) CHANGE IN MANUFACTURER'S NAME AND / OR ADDRESS

Please check (√) one or more of the boxes below:

- Change only in Manufacturer's Name (Complete columns 1 and 2).
- Change in Manufacturer's Name and Address (Complete columns 1 and 3).
- Change only in Manufacturer's Address (Complete columns 1 and 4).
- Change only to the name and/or address of the Manufacturing Facility (Complete letter in Appendix 1 or submit a full amendment).

| Column 1: Device Licence No. Affected. | Column 2: Name of new manufacturer | Column 3: Name and Address of new manufacturer as indicated in the following format: | Column 4: New Address of manufacturer as indicated in the following format: |
|---|--|--|---|
| | | Name: | Name: |
| | | Street: | Street: |
| | | City: | City: |
| | | Country: | Country: |
| | | Postal/ZIP Code: | Postal/ZIP Code: |
| | | Contact Name: | Contact Name: |
| | | Telephone: Ext: | Telephone: Ext: |

Use additional pages if necessary using this same format

3) IF THERE IS ALSO A CHANGE TO THE REGULATORY CORRESPONDENT'S NAME AND/OR ADDRESS, IDENTIFY THE CHANGES BELOW.

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4) ATTESTATION

| | |
|---|-------|
| This certifies that, in accordance with the <i>Medical Devices Regulations</i> issued July 1998, the amendment(s) described above represent(s) a legal change in the ownership of the above-noted licence(s) or a change in the manufacturer's address. | |
| _____ | _____ |
| Name of Manufacturer Senior Official/Signature Date | Date |



5) EMAIL ADDRESS TO WHICH MDD SHOULD SEND THE AMENDED LICENCE(S)**only if different than the e-mail address of the regulatory contact on file with MDD: _____

FOR MEDICAL DEVICES DIRECTORATE USE ONLY:

Date Fax-Back Complete _____

Signature _____

Appendix - Template for Attestation Letter declaring the manufacturing specifications are the same in the new manufacturing facility

If the manufacturer can make the attestation below, an amended licence can be issued without further evidence of safety and effectiveness. The attestation cannot be forward-looking. If the below attestation cannot be made, a review of evidence that the device specifications are identical if there were any changes in the process, equipment, etc. will be required.

(Manufacturer's Letterhead)

Manager, Device Licensing Services Division
Medical Devices Directorate
Health Products and Food Branch
Health Canada
11 Holland Avenue
Address Locator: 3002A
Ottawa, Ontario
K1A 0K9

Dear Sir or Madam

RE: Changes to manufacturing facility for licence number(s): *(list licence numbers)* to *(identify new manufacturing facility)*

I, the manufacturer, hereby declare that the device specifications, performance specifications, materials, manufacturing process, quality assurance methods, quality control activities and labelling of the devices licensed in the above listed licences, are identical to that of the approved manufacturing facility, except for a change in the name and/or address of the manufacturing facility.

As a senior official of the manufacturer, having responsibility for this Attestation Letter and the regulatory compliance of the medical devices with the requirements of the *Medical Devices Regulations*, I hereby declare that the information I have provided in support of this application is accurate and complete.

I, the manufacturer, also acknowledge that any false statement made with respect to the manufacturing specifications, could result in the suspension of any medical device licence which has been issued for the medical devices subject of this Attestation Letter.

Yours sincerely,

(Signature of authorized senior official)
(Name and title of authorized senior official)