Health Canada Santé Canada

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Medical devices licence amendment minor change form: Guidance for changes to the manufacturer's name and/or address of existing *device licences and/or COVID-19 medical device authorizations*

Please read carefully

1) The purpose of the attached form is to facilitate the approval of device licence and/or COVID-19 medical device authorization amendments to support a change to the manufacturer's name or address on an ***EXISTING*** device licence(s) and/or COVID-19 medical device authorization. Note that the term "manufacturer" is synonymous with the business or corporate entity who owns the **trade name** of the device licence and/or COVID-19 medical device authorization. **Only 1 manufacturer can own the trade name for a device licence and/or COVID-19 medical device authorization in Canada**. Once a change to the manufacturer's name is processed, the **previous manufacturer must stop selling all devices in Canada for which the 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) and/or COVID-19 medical device authorization
   - a valid Quality Management System Certificate that reflects the change in manufacturer name or address.
   - **a completed F202 form** (https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/md-im/qualsys/f202_rev0-eng.pdf)
   - a copy of the attached Attestation Letter if a change is being made to the manufacturing facility but the manufacturing specifications stay the same
3) **All sections of the attached form shall be completed in order to be processed.** Incomplete forms will be rejected.
4) Receipt of an amended licence or authorization is considered to be confirmation that your licence or authorization has been amended and the device(s) and specified catalogue number(s) can thus be offered for sale in Canada.
5) It is the intention of the Medical Devices Directorate (MDD) to process Licence Amendment Minor Change forms within 7 calendar days from the date that the amended application is received.
6) **Do not use both the Amendment Minor Change Form and a regular Amendment Application for the same amendment.**

Please submit to the Medical Devices Directorate at: qs.mdb@hc-sc.gc.ca

1) Reason for change **(Specify the nature of the proposed change (for example, acquisition, moving))**

Canada

2) Change in manufacturer's name and/or address

Please check 1 or more of the boxes below:

- ☐ Change only in manufacturer's name (complete rows 1 and 2)
- ☐ Change in manufacturer's name and address (complete rows 1 and 3)
- ☐ Change only in manufacturer's address (complete rows 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)

Row 1: Device licence No. or COVID-19 medical device authorization No. affected	
Row 2: Name of new manufacturer	
Row 3: Name and address of new manufacturer as indicated in the following format:	Name: Street: City: Province/State: Country: Postal/ZIP Code: Contact Name: Telephone: Ext:
Row 4: New address of manufacturer as indicated in the following format:	Name: Street: City: Province/State: Country: Postal/ZIP Code: Contact Name: 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

4) Attestation	
This certifies that, in accordance with the *Medical Devices Regulations* issued July 1998, the amendment(s) described above represent(s) a legal change in the ownership of the above-noted licence(s) and/or COVID-19 medical device authorization or a change in the manufacturer's address.	
Name of manufacturer's senior official:	
Signature	Date: (yyyy/mm/dd)
5) Email address to which the MDD should send the amended licence(s) and/or authorization(s):	
For Medical Devices Directorate (MDD) use only:	
Date Minor Change 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 or authorization 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, Quality Systems Section
Medical Devices Directorate
Health Products and Food Branch
Health Canada
11 Holland Avenue
Address Locator: 3002°
Ottawa, Ontario
K1A 0K9

Dear Sir or Madam

RE: Changes to manufacturing facility for licence and/or authorization number(s): *(list licence and/or authorization 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/authorized in the above listed licences and/or authorizations, 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 and/or the cancellation of COVID-19 medical device authorization, 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*)