



**LICENCE AMENDMENT FAX-BACK FORM - GUIDANCE
FOR CHANGES TO THE NAME OF A DEVICE LICENCE FOR
EXISTING *DEVICE LICENCES ONLY*.**

PLEASE READ CAREFULLY

1. The purpose of the attached form is to facilitate the approval of device licence amendments where the change involved consists of a change only to the device name on an *EXISTING* device licence(s). **No other changes to the device may be addressed in this Fax-Back form nor can an additional device be added to an existing licence.**
2. The attached form **must** be submitted **with** a copy of page 1 of the applicable licence(s).
3. **All boxes on the attached form must 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 authorization that your licence has been amended and therefore, the device(s) can be sold. 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 date of receipt.
6. **Please do not use both the Amendment Fax-Back Form and a regular Amendment Application for the same amendment.**



Licence Number to be Amended

Application Number

LICENCE AMENDMENT FAX-BACK FORM
For Changes To The Name of the Device Only

PLEASE SUBMIT TO THE MEDICAL DEVICES DIRECTORATE AT

hc.devicelicensing-homologationinstruments.sc@canada.ca

*NOTE: PLEASE PROVIDE ONE FAX-BACK FORM PER LICENCE TO BE AMENDED

1) NAME OF THE DEVICE AS IT APPEARS ON THE CURRENT LICENCE

Empty text box for device name

2) PROPOSED NEW NAME OF THE DEVICE (Please provide the reason for the change in device name)

Empty text box for proposed name and reason

3) IF APPLICABLE, PROPOSED NEW IDENTIFIER FOR THE DEVICE (i.e. Model or Catalogue Number)

Table with 4 columns: Device ID No., Model or Catalogue No., Device ID No., Model or Catalogue No.

Please attach additional pages if necessary using this same format (Note catalogues, computer printouts, etc. will not be accepted).

4) CERTIFICATION

I hereby certify that, in accordance with the Medical Devices Regulations, this amendment represents a legal change in the name of the device only and does not constitute a "significant change" as defined in section 1 of the Regulations.

Name of Manufacturer Senior Official/Signature Date

Date

5) E-MAIL ADDRESS TO WHICH MDD SHOULD SEND THE LICENCE, **ONLY IF DIFFERENT THAN THE E-MAIL ADDRESS OF THE REGULATORY CONTACT ON FILE WITH MDD:

Empty line for email address

FOR MEDICAL DEVICES DIRECTORATE USE ONLY:

Date Fax-Back Complete

Signature