Health Canada Santé Canada

MEDICAL DEVICES LICENCE AMENDMENT FAX-BACK FORM - GUIDANCE FOR *NON-SIGNIFICANT* ADDITIONS/DELETIONS

PLEASE READ CAREFULLY

Please note that in order to add a catalogue number the device must already exist on a licence. The purpose of the attached fax-back form is to extend the *same product line*.

1. The purpose of the attached form is to facilitate the approval of device licence amendments where the change involved consists of the addition or deletion of new catalogue or model numbers that represent ***non-significant changes*** (**Section 34**) and that are ***within the guideline of the various application types*** (**Sections 28 to 31**) of the *Medical Devices Regulations*. To determine whether your amendment represents a *non-significant change* and for more information on the various application types please refer to the following guidance documents:

Guidance Document:	Website URL Address:
Guidance for the Interpretation of Significant Change	https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-document-interpretation-significant-change-medical-device.html
Guidance For the Interpretation of Sections 28 to 31: Licence Application Type - DRAFT	https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-interpretation-sections-28-31-licence-application-type.html

2. The attached form **must** be submitted **with** a copy of page 1 of the applicable licence to be amended.
3. **All sections below 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 and specified catalogue numbers 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. **Do not use both the Amendment Fax-Back Form and a regular Amendment Application for the same amendment.**
7. Please note that this form is not to be used for Private Label licences.
8. Please identify the device(s) being added (include the trade name).

Health Canada Santé Canada

Medical Devices Directorate use

Licence Number to be Amended

Application Number

LICENCE AMENDMENT FAX-BACK FORM FOR *NON-SIGNIFICANT* ADDITIONS/DELETIONS OF CATALOGUE NUMBERS 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) RATIONALE (*Please specify the nature of the proposed change. In addition, please confirm that the proposed change does not alter the original range of sizes licensed, or original indications for use, etc.*)

2) CATALOGUE NUMBERS (*Which catalogue numbers are being added/deleted? If a catalogue number is added and the associated device contains ≥ 0.1% w/w of DEHP or is manufactured from raw materials containing or derived from BPA, please check the appropriate box. Please consult the document "Guidance for Industry: How to Complete the Application for a New Medical Device Licence", which is available on the website, for the definition of DEHP and BPA.*)

Device ID No.	Model or Catalogue No.	Add = A Change = C Delete = D	Device contains ≥ 0.1% w/w of DEHP (check if applicable)	Device is manufactured from materials containing or derived from BPA (check if applicable)

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

3) CERTIFICATION

This certifies that, in accordance with the *Medical Devices Regulations* issued July 1998, the amendment(s) described above does not constitute a significant change.

Name of Manufacturer Senior Official/Signature Date

Date

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

FOR MEDICAL DEVICES DIRECTORATE USE ONLY:

Date Fax-Back Complete

Signature

(March 2020)