Draft Class II Medical Device Licence Amendment Application Form

Notice to the reader: This form is for consultation only.

Before completing this form, you must consult the document *Consultation on the Proposed Amendments to the Medical Devices Regulations*.

Contact: Device Licensing

Application Form

1. **Name of Device Licence Being Amended**

2. **Licence Number to be amended** (provide the **latest valid** licence number)

3. **Manufacturer Information** (as it appears on the label and the quality management system certificate)
   Contact Name and Title:
   Company ID (if Known):
   Company Name:
   Telephone:
   Fax:
   E-mail
   Street:
   Suite:
   P.O. Box
   City:
   Province/State:
   Country:
   Postal/Zip Code:

4. **Regulatory Correspondent Information**
   Same as Manufacturer
   Other (specify below)
   Contact Name and Title:
   Company ID (if Known):
   Company Name:
   Telephone:
   Fax:
   E-mail
   Street:
   Suite:
   P.O. Box
   City:

Province/State:
Country:
Postal/Zip Code:

5. **Invoicing Information**
   Same as Manufacturer
   Same as Regulatory Correspondent
   Other (specify below)
   Contact Name and Title:
   Company ID (if Known):
   Company Name:
   Telephone:
   Fax:
   E-mail
   Street:
   Suite:
   P.O. Box
   City:
   Province/State:
   Country:
   Postal/Zip Code:

6. **Quality Management System Certificate**
   Quality Management System Certificate Number:
   Name of Registrar:

7. **Attestations**
   Specific to Part 1, section 32(2), item (c), (d), and (e) of the *Medical Devices Regulations* relevant to the licensing of Class II medical devices, a senior official shall submit an application to the Minister that contains the following attestations as applicable: **Check (?) the relevant attestations.**

   - ❑ I, **the Manufacturer** of this device (other than a decorative contact lens), have objective evidence establishing that it is compliant with section 10, subsections 11(1) and 12(1) and sections 13 to 20 of the *Medical Devices Regulations*.
   - ❑ I, **the Manufacturer** of this decorative contact lens, have objective evidence to establish that this device meets section 10, subsections 11(2) and 12(2) and sections 13 to 17 of the *Medical Devices Regulations.*
   - ❑ The device **is** a near patient IVDD (*In Vitro* Diagnostic Device). I, **the Manufacturer** of this device, have evidence of investigational testing of this device using human subjects representative of the intended users and under conditions similar to the intended conditions of use of the device.
   - ❑ The device **is not** a near patient IVDD.

   I, as a senior official of the manufacturer named in Item 3 of this application, hereby attest that I have direct knowledge of the items checked above and declare that these identified statements are true and that the information provided in this application and in any attached documentation is accurate and complete.

   Where a person is named in Item 4 of this application, I hereby authorize that person to submit this application to the Minister on my behalf. I further authorize the Medical Devices Bureau to direct all correspondence relating to this application to the person named in Item 4 of this application. Please ensure that all information and documents set out in Section 32 of the Medical Devices Regulations that are relevant to the change have been enclosed.

Name
Title:
Signature:
Date:

Complete items 8 and 9 only if they have changed from the previous licence

8. **Place of Use**

Is this device sold for home use?

- ❑ Yes
- ❑ No

Is this device used at a point of care, such as a pharmacy, bedside, or healthcare professional's office? *(In Vitro Diagnostic Devices [IVDD]* ***only****)*

- ❑ Yes
- ❑ No

Is this device an IVDD?

- ❑ Yes
- ❑ No

9. **Medical Devices Containing Drugs**

1. **Non-IVD Devices Containing Drugs**

If the device contains a drug and is not an IVDD, indicate the Drug Identification Number (DIN) or the Natural Product Number (NPN), if applicable. Otherwise, for combination products, please complete the information listed below with respect to the drug or drug substance.

Brand / Trade Name of Drug or Drug Substance:
DIN/NPN:
Active Ingredient(s):
Manufacturer:
USP Compliance ?
GMP Compliance ?

2. **IVDD Test Kits containing Controlled Substances**

If this device is an IVDD test kit containing a substance listed in Schedule I, II, III, or IV of the Controlled Drugs and Substances Act, complete the section below.

Is this an IVDD Test Kit containing a controlled substance?

- ❑ Yes
- ❑ No

Test Kit Number (T.K. Number):

Please note: The manufacturer will need to contact the Office of Controlled Substances to obtain a T.K. Number if one has not yet been issued.

10. **Radiation Emitting Medical Devices**

Do any of the devices contained in this application emit radiation?

- ❑ Yes
- ❑ No

11. **Device History**

Has this device been previously authorized for sale in Canada under the Investigational Testing or Special Access provisions of the *Medical Devices Regulations*?

- ❑ Yes
- ❑ No

If yes, provide the authorization number or the device identification number:

12. **Reason for Amendment**

1. **Please select (?) the appropriate change(s):**

- A change to the classification of a device ?
  From Class:
  To Class:

- A change in the manufacturer's name (ensure that quality management system certificate is attached) ? Ensure that item 1 is completed
- A change in the licence and/or device name (i.e. previous device name no longer available for sale) ? New licence and/or device name: (add attachment if more space is needed)
- A change to the purpose/indication of a Class II device ? A description of the medical conditions, purposes and uses for which the device will now be manufactured, sold or represented (Note: failure to supply an appropriate level of detail may result in an unsuccessful application)
- An addition, deletion or change in device components or associated model, part or catalogue numbers ? Complete below

2. Please specify the nature of the proposed change, and indicate the Health Canada assigned Device ID number(s) that are impacted by the change, where applicable. Please indicate the document, document version number and the date where the formal intended use appears, if there is a change in the device labeling.

13. Before completing this section, please consult the document "Draft 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.

A. **Additions** If the device contains material of a particle size between 1 and 1000 nanometers, please specify the type and size range.
Name of device, components, parts and/or accessories as per product label
Identifier for device (bar code, catalogue, model or part number)
DEHP
BPA
If device contains nano-scale material enter YES and specify Type. If not, enter **none**
Size range of nano-scale material particles
Preferred Name Code **(For HC Use Only)**

B. **Deletions**
Name of device, components, parts and/or accessories as per product label
Identifier for device (bar code, catalogue, model or part number)
Device ID Number

C. **Changes**
Name of device, components, parts and/or accessories as per product label
Old Identifier for device (bar code, catalogue, model or part number)
New Identifier for device (bar code, catalogue, model or part number)
Device ID Number

14. **Compatibility of Interdependent Devices:** For a Class II medical device intended to be used with another Class II, III, or IV device, provide a list of all medical devices that this device is intended to be used or function with, including their medical device licence number. See *Notice to Industry - Licensing Requirements of Interdependent Medical Devices (April 30, 2002)* available on the website. For a complete list of licensed medical devices, refer to the MDALL website.
Name of compatible device
Licence Number

15. **List of Recognized Standards Complied with in the Manufacture of the Device**
The medical devices subject to this application conform with Recognized Standards as set out in the Guidance Document on Recognition and Use of

Standards under the Medical Devices Regulations, which is available on the website.

- ❑ Yes
- ❑ No

If yes, I attest that the medical device(s) comply with the following Recognized Standard(s):

If no, I attest that I possess objective evidence that the device(s):

- meet an equivalent or better standard, or
  - ❑ Yes
  - ❑ No
- has been tested and I have alternate evidence of safety and effectiveness:
  - ❑ Yes
  - ❑ No

16. **Review Documents** - Indicate (?) that labelling material is included as an attachment to this application. Manufacturers of a Class II medical device must submit their device label as required by section 32(2)(d) of the MDR. Refer to the documents *Draft Guidance for the Labelling of Medical Devices* and *Guidance for the Labelling of In Vitro Diagnostic Devices*.

    Labelling material ?

Licence Application Disclosure Request

As you are aware, Health Canada is striving to add transparency to the medical device review process. One area we would like to address is the requests from interested parties regarding whether or not a licence application has been received by the Medical Devices Bureau (MDB).

The purpose of this form is to request your signed authorization - in advance - if we receive such a request, to disclose the date on which a licence application has been received by the MDB. No other information would be supplied.

Please indicate your consent by completing this form and sending it with your application for a new medical device licence, or any time after a licence has been granted.

Disclosure Statement: In the case where the Medical Devices Bureau (MDB) has received requests concerning the status of the new licence application, amendment application, or fax-back application for (enter device name) from interested parties:

- this certifies that *(enter the manufacturer's name)* has **no objection** to the disclosure to the requester, by the MDB, of the date when an application for the device entered above, has been received by the MDB.
- this certifies that *(enter the manufacturer's name)* **objects** to the disclosure to the requester, by the MDB, of the date when an application for the device entered above, has been received by the MDB.

In accordance with the *Access to Information Act*, confidential, third party information will not be disclosed without your expressed consent.

Manufacturer's authorized signing official

Application forms should be sent to:

Device Licensing Services Division
Medical Devices Bureau
Therapeutic Products Directorate
Health Canada
2934 Baseline Road
Address Locator: 3403A
Ottawa, Ontario K1A 0K9

Phone: 613-957-7285

Fax: 613-957-6345
E-mail: device_licensing@hc-sc.gc.ca

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