Draft New Class II Medical Device Licence Application Form

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

Before completing this form, you must consult the document *Draft Guidance for Industry - How to Complete the Application for a New Medical Device Licence*.

Contact: Device Licensing

Currency: The dollar ($) amounts on this form refer to Canadian dollars. All payments must be made in Canadian dollars.

Application Form

1. **Name of The Device (as it appears on the label)**

2. **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:

3. **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:

4. **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:

5. **Quality Management System Certificate (ensure that certificate is attached)**
   Quality Management System Certificate Number:
   Name of Registrar:

6. **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 2 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 3 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 3 of this application.

Name
Title:
Signature:
Date:

7. **Purpose / Intended Use of Device:** Provide a description of the medical devices covered by this application and their intended use. The intended use statement should be verbatim as it appears on the device labelling. Please indicate the document, document date and version number where the formal intended use appears, if applicable.

8. **Licence Application Type (check one only)**
   Single device
   System
   Test kit
   Medical device family
   Medical device group
   Medical device group family

9. **Place of Use**
   Is this device sold for home use?
   - ❑ Yes
   - ❑ No

   Is this device an IVDD?
   - ❑ 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

10. **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.

11. **Radiation Emitting Medical Devices**
    Do any of the devices contained in this application emit radiation?
    - ❑ Yes
    - ❑ No

12. **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:

13. **Identifier of Device (Include a device identifier for each device or medical device group listed and indicate (by a check mark) if it contains = 0.1% w/w of Di** (2-Ethyl hexyl) Pthalate [DEHP] **or is manufactured from raw materials containing or derived from** bisphenol A (BPA)). If the device contains material of a particle size of 1000 nanometers or less, 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 Health Canada use only)**

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 ?

17. **Review Fee for Licence Application:** The fee for the review of a licence application or a request for the reinstatement of a licence is $373. The payment must be included with the licence application. See *Guidance Document - Fees for the Review of Medical Device Licence Applications* for further information on fees.
    Fees are updated the 1st of April each year.
    Payment is in the amount of $373

A fee remission is requested
A rationale for the fee remission application is attached

18. **Deferred Payment:** If a manufacturer has not completed its first fiscal year on the day that the medical device licence application is submitted, the manufacturer will be granted a one-year deferral of payment from the day the application is submitted. The deferral will also be applicable to fees associated with a licence amendment for the medical device that become payable within that one-year period. **In order to qualify for the deferral period, a statement signed by the individual responsible for the manufacturer's financial affairs specifying the commencement date of the fiscal year must be submitted with the application.** At the end of the one-year period, the manufacturer must pay all of the applicable fees.
    Please indicate if the applicant is applying for a deferred payment:
    - ❑ A deferred payment is requested

19. **Fee Remission**

    1. **Eligibility for Remission and Necessary Documentation**

        When applying for a fee remission, the necessary documentation must accompany the licence application. Failing to do so will result in the rejection of the fee remission application.

        In order to be eligible for a remission, the anticipated gross revenue during the fee verification period must be less than $100,000, and the $373 fee must be greater than 2.5% of the anticipated gross revenue. For the purposes of fee remission, the fee verification period is the period beginning on the date that the medical device is first offered for sale in Canada and ending two years after that date.

        There is no processing fee for a remission application for a Class II medical device.

        Necessary Documentation:

        1. The applicant must provide a statement signed by the individual responsible for the applicant's financial affairs indicating that the anticipated gross revenue during the fee verification period is $100,000 or less, and certifying that the normal payment amount of $373 is more than an amount equal to 2.5% of the anticipated gross revenue.

        2. The applicant must present information to establish that the applicable fee of $373 is greater than 2.5% of the anticipated gross revenue from sales of the medical device in Canada during the fee verification period. The information should provide an accurate measure of the current market situation for the proposed product. Information to support the anticipated revenue should include as a minimum:
            - marketing plan/product plan for the medical device;
            - sales history prior to product upgrades or sales history of similar products;
            - estimated market share (that is [i.e.], product's market potential compared to the total market for similar products in Canada);
            - average sale price and demand; and
            - comparison to similar products on the Canadian market or other similar markets (for example [e.g.], United States, European Union, etc.)

The calculation for the applicable fee following remission is as follows:

Anticipated gross revenue for this medical device during the fee verification period $CAN ***(A)*** *(if amount is less than $100,000)*

2.5% of amount ***(A)*** *= $ = Reduced fee*

Refer to the *Guidance Document- Fees for the Review of Medical Device Licence Applications* for further information on fee remissions.

2. **Application for Fee Remission**
   Enter the anticipated gross revenue for this medical device during the fee verification period in box 19.1 / **19.1**
   Enter 2.5% of amount in box **19.1** inbox **19.2** / **19.2**

20. **Method of Payment (check method)**
    - ❑ MasterCard / Visa / American Express (AMEX)
    - ❑ Payment using existing credit
    - ❑ Cheque
    - ❑ Wire
    - ❑ Money order
    - ❑ e-Payment
    - ❑ International bank draft
    - ❑ Invoice (for fees ≥ $5000 only)

21. **Payment by Credit Card**
    Company's Full (Legal) Name:
    Application Name (for example [e.g.], product name, file name):
    Credit Card:
    - ❑ Visa
    - ❑ MasterCard
    - ❑ AMEX

    Credit Card Number (full number):
    Credit Card Valid Date:
    Credit Card Expiry Date:
    Cardholder's Name and Address:
    Street:
    City:
    Province/State:
    Country:
    Postal Code/Zip Code:
    Cardholder's Telephone Number (including country and area codes):

22. **Payment by Cheque / Money Order / International Bank Draft**
    Cheques, money orders or international bank drafts must be made payable to the "Receiver General for Canada". All cheques are to be in Canadian funds **drawn from a Canadian Bank**. Cheques drawn from non-Canadian banks **must** be issued in coordination with a referenced Canadian bank (i.e., referenced on the cheque), otherwise they are **not accepted**.

23. **Payment by Wire**
    Company's Full (Legal) Name:
    Application Name (e.g., product name, file name):
    Name of Originator Bank:
    Date Funds Wired:
    Amount of Funds Wired (Canadian $):
    Transaction Receipt Included (must attach)
    Wire payments of fees will be accepted only when wired to:
    - The Bank of Nova Scotia, Toronto Business Service Centre, 40 King St., West, Toronto, Ontario, Canada, M5H 1H1

SWIFT code: NOSCCATT
- Institution number: 002
- Transit number: 47696
- Beneficiary Name: HEALTH CANADA - CFOB (Department Name)
- Account number: 476961242210***(please ensure 12 digit #)***
- Description Field: Authorization Number: 022-22879 ***(please ensure 8 digit # is provided)***

Please remit payments in **Canadian Funds** only. All other currencies will be **rejected**.

Note that the wire standards used in Canada offer 4 lines of description fields, each with a maximum of 35 characters. For customer identification and ease of reconciliation, it is recommended that you also request that your customers input other pertinent information in these fields, e.g. invoice number, payment period, contact information. Please be aware that wires are often passed through intermediary financial institutions, especially in the case of wires originated outside of Canada, and it is possible that details within the description fields might be truncated.

Note that **your bank may deduct a fee for this service which may then result in an unexpected balance owing. You must ensure that all service charges are covered by your payment.** For further information on wire payment, contact Accounts Receivable at tel. 1-800-815-0506 or 613-957-1052 or via e-mail at ar-cr@hc-sc.gc.ca

24. **e-Payment (only available to Manufactures with a Health Canada Company Id# Who use a Canadian Financial Institutions. (**** All Fields must be completed for application to be processed ****)**
Manufacturer's Full Name:
Name of the Device (as it appears on the label):
Manufacturer's ID:
Name of Canadian Financial Institution:
Amount of Funds sent via e-Payment: $
Date Funds Sent:
The Client ID (Manufacture ID) Number is used when creating a PAYEE at a Financial Institution.
Example:
    - Log in into your Online Bank Account.
    - Click Pay bills and Select - Add a bill (Payee)
    - Type **Health Canada** into the Name of Organization field.
    - Select Government of Canada from the drop down list.
    - Click Search.
    - Select Health Canada - Health Product and Food Branch (HPFB).
    - Click OK.
    - Type your Client Reference Number = Client ID number.
    - Click OK.

    If you need help finding your Client ID number, or have any other questions about our electronic bill payment option, please contact us by calling our toll-free number 1-800-815-0506 or email at ar-cr@hc-sc.gc.ca.

25. **Payment Using Existing Credit (attach to the application a copy of the most recent statement)**
Account # Containing Credit:
Account Owner's Name:
Existing Credit Amount:
Total Device Licence Application Fee:
Portion of Device Licence Application Fee to be Paid for by Credit:
Remainder of Fee to be Paid by Another Method (check one of the methods above, see Items 19 to 22):

Credits: Overpayment of fees will be automatically credited to account. **Refunds** of credit balances must be requested in writing by the account owner and must be on company letterhead. Address: Health Canada, Accounts Receivable, P/L 3203B, Room B350 Ottawa, Ontario, K1A 0K9, Canada.

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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Top of Page

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