Health Canada Santé Canada

Protected B (when complete)

Medical Device Licence Application Fee Form

(disponible en français)

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

1. This fee form is related to the medical device licence application form for the following device

Name Of The Device (as it appears on the label)

2. Licence Number To Be Amended (if applicable)

3. Manufacturer Information (as it appears on the label)

Contact Name and Title:	
Company Name:	
Company ID (if known):	
Street Address (incl. suite):	
City:	P.O. Box:
Province/State	Country
Postal/Zip Code	E-mail
Telephone #: (US/Canada)	Fax #: (US/Canada)
Telephone #: (International)	Fax #: (International)

4. Review Fees For Licence Applications

The fees for the review of licence applications or requests for the reinstatement of a licence are shown below. For further information on the applicable fees, refer to the Guidance Document - Fees for the Review of Medical Device Licence Applications

Category	**Fee**
Class II – New licence application	$414
Class III – New licence application	$5,922
Class III – New licence application for a near patient in vitro diagnostic device	$10,079
Class III – Amendment application - a significant change that relates to manufacturing	$1,492
Class III – Amendment application - a significant change or change that would affect the Class of the device that is not related to manufacturing	$5,546
Class IV – New licence application	$13,770
Class IV – New licence application for devices that contain human or animal tissue	$12,846
Class IV – New licence application for a near patient in vitro diagnostic device	$23,473
Class IV – Amendment application - a significant change that relates to manufacturing	$1,492

Canada

Class IV – Amendment application - a significant change or change that would affect the Class of the device that is not related to manufacturing	$6,319

5. Fee For Licence Application

Enter the appropriate fee in box **5.1** **If the fee is $5000 or less**, submit payment along with the licence application **If the fee is greater than $5000**, you are not required to send payment with the licence application. Health Canada will send out an invoice for the amount due.	**5.1**

6. 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

7. Fee Remission

7.1 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 following required documentation must be provided:

(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 fee indicated in box 5**.1** above is more than an amount equal to 2.5% of the anticipated gross revenue. For the purposes of fee remissions, 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.

(2) The applicant must present information to establish that the applicable fee 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 $100,000 or less)

2.5% of amount **(A)** = $ ____ = Applicable fee

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

7.2 Application for Fee Remission

Enter the anticipated gross revenue for this medical device during the fee verification period in box 7.1	**7.1**
Enter 2.5% of amount in box 7.1 in box 7.2	**7.2** $ 0.00

Enter $65 processing fee in box 7.3 (There is no processing fee for a remission application for a Class II medical device.)	**7.3** $65.00
Total fee to be paid: Enter the sum of boxes 7.2 and 7.3 in box 7.4	**7.4** $ 65.00

8. Method Of Payment (check method)

◯ MasterCard / Visa / American Express (AMEX)	◯ Cheque	◯ Money order	◯ International bank draft
◯ Payment using existing credit	◯ Wire	◯ e-Payment	◯ Invoice (for fees > $5000 only)

9. Payment By Credit Card

Company's Full (Legal) Name:		Application Name (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/Zip Code:
Cardholder's Telephone Number (including country and area codes):			

10. 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 (that is [i.e.], referenced on the cheque), otherwise they are NOT ACCEPTED.

11. 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:

Fédération des caisses Desjardins du Québec, 1 Complexe Desjardins, South Tower, 15th floor, Montreal QC Canada, H5B 1B3
SWIFT code: CCDQCAMM
Institution number: 815
Transit number: 98000
Beneficiary Name: Health
Account number: MFI09703350815CAD2
Description Field: Authorization Number: 022-25631 (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.

12. 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.

13. 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:
		$ 1,000.00
Total Device Licence Application Fee:		$ 1,000.00
Portion of Device Licence Application Fee to be Paid for by Credit:		$ 1,000.00
Remainder of Fee to be Paid by Another Method (check one of the methods above, see Items 9 to 12):		$ 1,000.00

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: 1918B, 18th Floor, Room 1804B, Jeanne-Mance Building, 161 Goldenrod Driveway, Tunney's Pasture, Ottawa, Ontario K1A 0K9.