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.

Do not send payment with the licence application. Health Canada will send out an invoice for the amount due.

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
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** **Do not 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)** = $ 0.00 = 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**
Total fee to be paid: Enter the sum of boxes 7.2 and 7.3 in box 7.4	**7.4** $ 0.00