

NEW CLASS II MEDICAL DEVICE LICENCE APPLICATION FORM

(disponible en français)

Before completing this form, you must consult the document *Guidance for Industry – How to Complete the Application for a New Medical Device Licence* (available on the website).

1. NAME OF THE DEVICE (as it appears on the label)

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2. MANUFACTURER INFORMATION (as it appears on the label)

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:
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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.**

<input type="checkbox"/> I, the Manufacturer of this device, have objective evidence to establish that this device meets the safety and effectiveness requirements set out in the <i>Medical Devices Regulations</i> , Part 1, sections 10 through 20.
<input type="checkbox"/> I, the Manufacturer of this device, have met all the labelling requirements set out in the <i>Medical Devices Regulations</i> , Part 1, sections 21 through 23.
<input type="checkbox"/> The device IS a near patient IVDD (<i>In Vitro</i> 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.
<input type="checkbox"/> The device IS NOT a near patient IVDD.



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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:** A description of the medical conditions, purposes and uses for which the device is manufactured, sold or represented [Note: Failure to supply an appropriate level of detail may result in the application not being accepted for review.]

8. **LICENCE APPLICATION TYPE (check one only)**

▶ Single device	<input type="checkbox"/>	▶ Test kit	<input type="checkbox"/>	▶ Medical device group	<input type="checkbox"/>
▶ System	<input type="checkbox"/>	▶ Medical device family	<input type="checkbox"/>	▶ Medical device group family	<input type="checkbox"/>

9. **PLACE OF USE**

Is this device sold for home use?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Is this device used at a point of care, such as a pharmacy, bedside, or healthcare professional's office? (<i>In Vitro DIAGNOSTIC DEVICES [IVDD] ONLY</i>)	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is this device an IVDD?	<input type="checkbox"/> Yes <input type="checkbox"/> No		

10. **MEDICAL DEVICES CONTAINING DRUGS**

10.1 **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) and complete the information listed below. If the drug does not have a DIN or NPN, please provide the Drug Establishment Licence (DEL) number of the company from where the drug is sourced.

Brand / Trade Name of Drug:	DIN/NPN:
Active Ingredient(s):	
Drug Manufacturer:	
DEL Number:	



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10.2 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 <input type="checkbox"/>	No <input type="checkbox"/>
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. DEVICE HISTORY

Has this device been previously authorized for sale in Canada under the Investigational Testing or Special Access provisions of the <i>Medical Devices Regulations</i> ?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, provide the authorization number or the device identification number:		

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

15. REVIEW FEE FOR LICENCE APPLICATION: The fee for the review of a licence application or a request for the reinstatement of a licence is \$350. 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. (available on the website).

<input type="checkbox"/> Payment is in the amount of \$350	<input type="checkbox"/> A fee remission is requested	<input type="checkbox"/> A rationale for the fee remission application is attached
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16. 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

17. FEE REMISSION

17.1 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 \$350 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 \$350 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 \$350 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

The payment must be included in the licence application.

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

17.2 Application for Fee Remission

Enter the anticipated gross revenue for this medical device during the fee verification period in box 17.1	17.1
Enter 2.5% of amount in box 17.1 in box 17.2	17.2

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18. METHOD OF PAYMENT (check method)

<input type="checkbox"/> MasterCard / Visa / American Express (AMEX)	<input type="checkbox"/> Cheque	<input type="checkbox"/> Money order	<input type="checkbox"/> International bank draft
<input type="checkbox"/> Payment using existing credit		<input type="checkbox"/> Wire	

19. PAYMENT BY CREDIT CARD

Company's Full (Legal) Name:		Application Name (for example [e.g.], product name, file name):	
Credit Card: <input type="checkbox"/> Visa <input type="checkbox"/> MasterCard <input type="checkbox"/> 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):			

20. PAYMENT BY CHEQUE / MONEY ORDER / INTERNATIONAL BANK DRAFT

<p>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.</p>
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21. 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 \$):	<input type="checkbox"/> Transaction Receipt Included (must attach)
<p>Wire payments of fees will be accepted only when wired to:</p> <ul style="list-style-type: none"> 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*(<i>please ensure 12 digit #</i>) Description Field: Authorization Number: 022-22879 (<i>please ensure 8 digit # is provided</i>) <p>Please remit payments in CANADIAN FUNDS only. All other currencies will be rejected.</p> <p>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.</p> <p>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.</p>	

22. 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 17 to 20):		\$

<p>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.</p>
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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