Health Canada Santé Canada

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)

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:

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, have objective evidence to establish that this device meets the safety and effectiveness requirements set out in the *Medical Devices Regulations*, Part 1, sections 10 through 20.
☐ I, **the Manufacturer** of this device, have met all the labelling requirements set out in the *Medical Devices Regulations*, Part 1, sections 21 through 23.
☐ 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.

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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	☐	▸ Test kit	☐	▸ Medical device group	☐
▸ System	☐	▸ Medical device family	☐	▸ Medical device group family	☐

9. **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		

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 ☐ 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. 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:	

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12. **IDENTIFIER OF DEVICE (Include a device identifier for each device or medical device group listed and indicate if it contains ≥ 0.1% w/w of DEHP or is manufactured from raw materials containing or derived from BPA)**

Name of device, components, parts and/or accessories as per product label	Identifier for device (bar code, catalogue, model or part number)	Device contains ≥ 0.1% w/w of DEHP (check if applicable)	Device is manufactured from raw materials containing or derived from BPA (check if applicable)	Preferred Name Code **(FOR HC USE ONLY)**

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13. **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: www.mdall.ca)

Name of compatible device	Licence Number

14. **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

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

15. **FEE ASSESSMENT:** The fee for the examination of a licence application or a request for the reinstatement of a licence is as follows (indicate applicable fee below). The payment **must be included** with the licence application. See *Guidance Document on Cost Recovery – Fees in Respect of Medical Devices Regulations* (available on the website).

☐ Payment is in the amount of $200.00	☐ A reduced fee of $50.00 is requested	☐ A rationale for the fee reduction request is attached

16. **ELIGIBILITY FOR REDUCTION**

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

For the purposes of **fee reduction**, 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.

Eligibility for reduction:

(1) The applicant must present information to support gross revenue from sales of the medical device in Canada during the fee verification period beginning on the date that the medical device is first offered for sale in Canada and ending two years after that date. 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 (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 (eg. United States, European Union, etc.)

(2) The full fee must be greater than 5% of the anticipated gross revenue from sales of the medical device in Canada during the fee verification period.

The reduced fee for a Class II medical device licence application is $50.

Refer to the *Guidance Document on Cost Recovery - Fees in Respect of Medical Devices Regulations* for more detailed information.

17. **METHOD OF PAYMENT (check method)**

☐ MasterCard / Visa / American Express (AMEX)	☐ Cheque	☐ Money order	☐ International bank draft
☐ Payment using existing credit	☐ Wire		

18. **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 Code/Zip Code:
Cardholder's Telephone Number (including country and area codes):			

19. **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.

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20. 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:

- Bank of Montréal, 1247 Wellington St., Ottawa, Ontario, Canada, K1Y 3A3
- SWIFT code: B of M CAM2
- Institution number 001
- Transit number 03566
- Account number 022101000

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 via e-mail at AR-CR@HC-SC.GC.CA. If problems occur with the transaction, contact the Bank of Montreal at tel. 613-722-2954.

21. 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):		$

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, 2005 Tower A Holland Cross, 11 Holland Avenue, Address Locator 3002B, Ottawa, Ontario, K1A 0K9, Canada.

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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
Room 1605 Main Building
150 Tunney's Pasture Driveway
Tunney's Pasture
Address Locator: 0301H1
OTTAWA, Ontario K1A 0K9

Phone: (613) 957-7285
Fax: (613) 957-6345
E-mail: device_licensing@hc-sc.gc.ca

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