Health Canada Santé Canada

NEW CLASS III 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

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.

I, as a senior official of the manufacturer named in Item 2 of this application, hereby attest that I am also providing the information and documents set out in Part 1, section 32(3) of the *Medical Devices Regulations.*

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: _____

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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:	

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 (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])

Name of device, components, parts and/or accessories as per product label	Identifier for device (bar code, catalogue, model or part number)	DEHP	BPA	Preferred Name Code **(FOR HEALTH CANAD USE ONLY)**

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13. COMPATIBILITY OF INTERDEPENDENT DEVICES: For a Class III 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 licenced 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:
Please answer "Yes" to one, and only one, of the following.

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 am including with this application Declarations of Conformity that the medical device(s) comply with the following Recognized Standards:	
The medical devices subject to this application DO NOT conform with Recognized Standards but meet an equivalent or better standard.	☐ Yes ☐ No
If yes, I am including detailed information proving that the device(s) meet the following equivalent or better standards:	
The medical devices subject to this application DO NOT conform with Recognized Standards, NOR do they meet an equivalent or better standard, but I am including detailed information as evidence of the safety and effectiveness of these devices.	☐ Yes ☐ No

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15. REVIEW DOCUMENTS – Indicate (✔) which documents listed below are included as attachments to this application. For details regarding content and format, you are requested to consult the *Guidance Document – Preparation of a Premarket Review Document for Class III and Class IV Device Licence Applications* (available on the website).

Executive Summary	
Table of contents	
Background, which includes Device Description, Design Philosophy, and Marketing History	
Summary of Safety and Effectiveness Studies, which includes List of Standards, Method of Sterilization, Summary of Studies, and Bibliography	
Near Patient Diagnostic Device Testing Results (if applicable)	
Labelling material	

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

16. 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 III - Licence application	$ 5,151
Class III - Licence application for a near patient *in vitro* diagnostic device	$ 8,772

17. FEE FOR LICENCE APPLICATION

Enter the appropriate fee in box 17.1 **Do not send payment** with the licence application. Health Canada will send out an invoice for the amount due.	**17.1**

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

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19. FEE REMISSION

19.1 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 must be less than $100,000, and the full fee, as indicated in box 17.1 above, must be greater than 2.5% of the anticipated gross revenue from sales of the medical device in Canada during the fee verification period. 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.

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 fee indicated in box 17.1 above 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 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)** = $ _____ = Applicable fee*

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

19.2 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 in box 19.2	**19.2**
Enter $51 processing fee in box 19.3	**19.3**
Total fee to be paid: Enter the sum of boxes 19.2 and 19.3 in box 19.4	**19.4**

20. METHOD OF PAYMENT (check method)

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

21. 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):			

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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 (that is [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. 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 21 to 24):		$

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.

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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

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