



# CLASS IV MEDICAL DEVICE LICENCE AMENDMENT APPLICATION FORM

(disponible en français)

**1. NAME(S) OF DEVICE LICENCE(S) BEING AMENDED**

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**2. LICENCE NUMBER(S) TO BE AMENDED (provide the latest valid licence number(s))**

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**3. MANUFACTURER INFORMATION (as it appears on the label)**

Contact Name and Title:		Company ID (if known):	
Company Name:			
Telephone:	Fax:	E-mail:	
Street:		Suite:	PO Box:
City:	Province/State:	Country:	Postal/Zip Code:

**4. 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:	PO Box:
City:	Province/State:	Country:	Postal/Zip Code:

**5. 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:	PO Box:
City:	Province/State:	Country:	Postal/Zip Code:

**6. QUALITY MANAGEMENT SYSTEM CERTIFICATE (ensure that certificate is attached)**

Quality Management System Certificate Number:	Name of Registrar:
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## 7. ATTESTATIONS

I, as a senior official of the manufacturer named in Item 3 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 3 of this application, hereby attest that I also providing the information and documents set out in Part 1, Section 32(4) of the *Medical Devices Regulations*.

Where a person is named in Item 4 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 4 of this application.

Name: \_\_\_\_\_ Title: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## COMPLETE ITEMS 8, 9 & 10 ONLY IF THEY HAVE CHANGED FROM THE PREVIOUS LICENCE

### 8. 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		

### 9. MEDICAL DEVICES CONTAINING DRUGS

#### 9.1 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:	

#### 9.2 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.

### 10. COMPLETE FOR DEVICES CONTAINING BIOLOGICAL MATERIAL

Does this device consist of recombinant material?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does this device contain, or is it produced using, any animal or human sourced material?	<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, provide the following: Country of Origin (for animals only): Species (e.g. human, bovine, ovine, etc.): Tissue Type (e.g. bone, heart valve, skin and hair): Derivative (e.g. tallow, media components such as casein and peptone):	_____ _____ _____ _____



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Country of Origin (for animals only): Species (e.g. human, bovine, ovine, etc.): Tissue Type (e.g. bone, heart valve, skin and hair): Derivative (e.g. tallow, media components such as casein and peptone):	_____ _____ _____ _____
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Country of Origin (for animals only): Species (e.g. human, bovine, ovine, etc.): Tissue Type (e.g. bone, heart valve, skin and hair): Derivative (e.g. tallow, media components such as casein and peptone):	_____ _____ _____ _____
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**11. REASON FOR AMENDMENT (✓ appropriate change)**

▶ A change to the classification of the device	<input type="checkbox"/>	From Class: _____ To Class: _____
▶ A change in manufacturer's name	<input type="checkbox"/>	Ensure that Item 1 is completed
▶ A change in the device name (i.e. previous device name no longer available for sale)	<input type="checkbox"/>	New device name: _____ (add attachment if more space is needed)
▶ A significant change in the manufacturing process, facility or equipment	<input type="checkbox"/>	
▶ A significant change in the manufacturing quality control procedures	<input type="checkbox"/>	
▶ A significant change in the design or performance specifications	<input type="checkbox"/>	
▶ A significant change in the materials	<input type="checkbox"/>	➤ Device contains ≥ 0.1% w/w of DEHP* <input type="checkbox"/> Yes <input type="checkbox"/> No ➤ Device is manufactured from materials containing or derived from BPA* <input type="checkbox"/> Yes <input type="checkbox"/> No

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▶ A significant change in the labelling of the device	<input type="checkbox"/>	
▶ Any change which could affect the safety and effectiveness of the device	<input type="checkbox"/>	
▶ An addition, deletion or change in device components or associated model, part or catalogue numbers	<input type="checkbox"/>	Complete below

\* Please consult the document "Guidance for Industry: How to Complete the Application for a New Medical Device Licence", which is available on the website, for the definition of DEHP and BPA.











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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

Note that, typically, each information component requires one review and therefore one fee. However, where a medical device has more than one indication for use, different designs or incorporates different materials (e.g. non-coated and coated total hip prostheses), the number of information components requiring review may increase and should be taken into consideration when calculating fees.

Fees for the review of information components previously reviewed by the Medical Devices Bureau are not required. This applies to devices that have received a Notice of Compliance (or Supplementary Notice of Compliance) or a licence for a Class III or IV device, and the information component remains relevant to the new device licence application. The manufacturer should clearly identify the previously reviewed information component(s) and should not assign a fee to this component(s).

## 16. FEES FOR LICENCE APPLICATION COMPONENTS

<p>If the application contains a description of the medical device and the materials used in its manufacture and packaging enter <b>\$140</b> in box 16.1.1. Enter the number of information components requiring review in box 16.1.2. The total fee for this component is equal to box 16.1.1 times box 16.1.2. Enter this amount in box 16.1.3.</p>	16.1.1	16.1.2	16.1.3
<p>If the application contains a risk assessment and description of the risk reduction measures adopted to satisfy the safety and effectiveness requirements of the <i>Medical Devices Regulations</i>, enter <b>\$1,000</b> in box 16.1.4. Enter the number of information components requiring review in box 16.1.5. The total fee for this component is equal to box 16.1.4 times box 16.1.5. Enter this amount in box 16.1.6.</p>	16.1.4	16.1.5	16.1.6
<p>If the application contains specifications of the materials used in the manufacture and packaging of the medical device enter <b>\$680</b> in box 16.1.7. Enter the number of information components requiring review in box 16.1.8. The total fee for this component is equal to box 16.1.7 times box 16.1.8. Enter this amount in box 16.1.9.</p>	16.1.7	16.1.8	16.1.9
<p>If the application contains a description of the manufacturing process of the medical device enter <b>\$1,360</b> in box 16.1.10. Enter the number of information components requiring review in box 16.1.11. The total fee for this component is equal to box 16.1.10 times box 16.1.11. Enter this amount in box 16.1.12.</p>	16.1.10	16.1.11	16.1.12
<p>In the case of an <i>in vitro</i> diagnostic device, if the application contains pre-clinical studies on which the manufacturer relies to ensure that the device meets the safety and effectiveness requirements of the <i>Medical Devices Regulations</i> enter <b>\$2,090</b> in box 16.1.13. Enter the number of information components requiring review in box 16.1.14. The total fee for this component is equal to box 16.1.13 times box 16.1.14. Enter this amount in box 16.1.15.</p>	16.1.13	16.1.14	16.1.15
<p>In the case of an <i>in vitro</i> diagnostic device, if the application contains clinical studies on which the manufacturer relies to ensure that the device meets the safety and effectiveness requirements of the <i>Medical Devices Regulations</i> enter <b>\$3,880</b> in box 16.1.16. Enter the number of information components requiring review in box 16.1.17. The total fee for this component is equal to box 16.1.16 times box 16.1.17. Enter this amount in box 16.1.18.</p>	16.1.16	16.1.17	16.1.18
<p>In the case of a medical device other than an <i>in vitro</i> diagnostic device, if the application contains pre-clinical studies on which the manufacturer relies to ensure that the device meets the safety and effectiveness requirements of the <i>Medical Devices Regulations</i> enter <b>\$3,270</b> in box 16.1.19. Enter the number of information components requiring review in box 16.1.20. The total fee for this component is equal to box 16.1.19 times box 16.1.20. Enter this amount in box 16.1.21.</p>	16.1.19	16.1.20	16.1.21
<p>In the case of a medical device other than an <i>in vitro</i> diagnostic device, if the application contains clinical studies on which the manufacturer relies to ensure that the device meets the safety and effectiveness requirements of the <i>Medical Devices Regulations</i> enter <b>\$4,400</b> in box 16.1.22. Enter the number of information components requiring review in box 16.1.23. The total fee for this component is equal to box 16.1.22 times box 16.1.23. Enter this amount in box 16.1.24.</p>	16.1.22	16.1.23	16.1.24
<p>If the application contains process validation studies on which the manufacturer relies to ensure that the medical device meets the safety and effectiveness requirements of the <i>Medical Devices Regulations</i> enter <b>\$850</b> in box 16.1.25. Enter the number of information components requiring review in box 16.1.26. The total fee for this component is equal to box 16.1.25 times box 16.1.26. Enter this amount in box 16.1.27.</p>	16.1.25	16.1.26	16.1.27



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<p>If the application contains software validation studies on which the manufacturer relies to ensure that the medical device meets the safety and effectiveness requirements of the <i>Medical Devices Regulations</i> enter <b>\$2,020</b> in box 16.1.28.</p> <p>Enter the number of information components requiring review in box 16.1.29.</p> <p>The total fee for this component is equal to box 16.1.28 times box 16.1.29. Enter this amount in box 16.1.30.</p>	16.1.28	16.1.29	16.1.30
<p>If the application contains a copy of the medical device label enter <b>\$170</b> in box 16.1.31.</p> <p>Enter the number of information components requiring review in box 16.1.32.</p> <p>The total fee for this component is equal to box 16.1.31 times box 16.1.32. Enter this amount in box 16.1.33.</p>	16.1.31	16.1.32	16.1.33
<p>In the case of a medical device, other than an <i>in vitro</i> diagnostic device, manufactured from or incorporating animal or human tissue or their derivatives, if the application contains objective evidence of the biological safety of the medical device enter <b>\$2,620</b> in box 16.1.34.</p> <p>Enter the number of information components requiring review in box 16.1.35.</p> <p>The total fee for this component is equal to box 16.1.34 times box 16.1.35. Enter this amount in box 16.1.36.</p>	16.1.34	16.1.35	16.1.36
<p>In the case of a near patient <i>in vitro</i> diagnostic device, if the application contains detailed information on investigational testing conducted on the device using human subjects representative of the intended users and under the conditions similar to the conditions of use of the device enter <b>\$2,410</b> in box 16.1.37.</p> <p>Enter the number of information components requiring review in box 16.1.38.</p> <p>The total fee for this component is equal to box 16.1.37 times box 16.1.38. Enter this amount in box 16.1.39.</p>	16.1.37	16.1.38	16.1.39

## 17. TOTAL FEE FOR LICENCE APPLICATION

<p>The total fee for the licence application is equal to the sum of boxes 16.1.3, 16.1.6, 16.1.9, 16.1.12, 16.1.15, 16.1.18, 16.1.21, 16.1.24, 16.1.27, 16.1.30, 16.1.33, 16.1.36, and 16.1.39. Enter this amount in box 16.2.</p> <p><b>Calculated fee of \$5000 or less:</b> The payment <b>must be included</b> in the licence application.</p> <p><b>Calculated fee is more than \$5000:</b> <b>Do not send payment</b> with the licence application. Health Canada will send out an invoice for the amount due.</p> <p>Consult the <i>Guidance Document on Cost Recovery – Fees in Respect of Medical Devices Regulations</i> (available on the website).</p>	16.2
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## 18. FEE REDUCTION REQUEST

### 18.1 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 (e.g., 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 IV Medical Device Licence Application is calculated as follows:

*Anticipated gross revenue for this medical device during the fee verification period* \_\_\_\_\_ \$CAN (A)

*5% of amount (A) = \$ \_\_\_\_\_ = Reduced fee*

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

The full fee, as indicated in box 16.2 above, must be greater than 5% of the anticipated gross revenue from sales of the medical device in Canada during the fee verification period.

### 18.2 Application for Reduced Fee

Enter the anticipated gross revenue for this medical device during the fee verification period in box 18.1	<b>18.1</b>
Enter 5% of amount in box 18.1 in box 18.2	<b>18.2</b>

## 19. 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		

## 20. PAYMENT BY CREDIT CARD

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



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## 21. 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.

## 22. 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)
Wire payments of fees will be accepted only when wired to: <ul style="list-style-type: none"> <li>The Bank of Nova Scotia, Toronto Business Service Centre, 40 King St., West, Toronto, Ontario, Canada, M5H 1H1</li> <li>SWIFT code: NOSCCATT</li> <li>Institution number: 002</li> <li>Transit number: 47696</li> <li>Account number: 400060277312 <i>*(please ensure 12 digit #)</i></li> </ul>	
Note that <b>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.</b> For further information on wire payment, contact Accounts Receivable at tel. 1-800-815-0506 or via e-mail at <a href="mailto:AR-CR@HC-SC.GC.CA">AR-CR@HC-SC.GC.CA</a> . If problems occur with the transaction, contact the Bank of Nova Scotia at tel. 613-829-8842.	

## 23. 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 19 to 22):		\$

**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  
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](mailto:device_licensing@hc-sc.gc.ca)