



**APPLICATION FOR A NEW MEDICAL DEVICE LICENCE FOR A  
PRIVATE LABEL MEDICAL DEVICE**  
*(disponible en français)*

**1. NAME OF THE PRIVATE LABEL MEDICAL DEVICE (as it appears on the label)**

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**2. PRIVATE LABEL 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. ORIGINAL MANUFACTURER INFORMATION**

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. INFORMATION ON MEDICAL DEVICE MANUFACTURED BY THE ORIGINAL MANUFACTURER**

Name of Device:			
Device Class (II, III or IV):		Licence No.:	
Quality System Certificate Number:		Name of Registrar:	
<b>FOR HC USE ONLY</b>	Near Patient (Y/N):	Home Use (Y/N):	Point of Care (Y/N):

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

▶ Single device	<b>G</b>	▶ Test kit	<b>G</b>	▶ Medical device group	<b>G</b>
▶ System	<b>G</b>	▶ Medical device family	<b>G</b>	▶ Medical device group family	<b>G</b>





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7. ATTESTATIONS

I, the private label manufacturer, hereby attest that:

(1) I have included in this application a Declaration of Compliance with the Medical Devices Regulations signed by a senior official of the the private label manufacturer, in the format prescribed in Appendix 1 of the Guidance for Industry - How to Complete the Application for a New Medical Device Licence/Medical Device Licence Amendment for a Private Label Medical Device.

(2) I have included in this application a Letter of Authorization signed by a senior official of the original manufacturer, in the format prescribed in Appendix 2 of the Guidance for Industry - How to Complete the Application for a New Medical Device Licence/Medical Device Licence Amendment for a Private Label Medical Device;

(3) I have included in this application a copy of the device label; and

(4) I understand that all of the provisions of the Food and Drugs Act and Medical Devices Regulations and the Fees in Respect of Medical Devices Regulations apply to a private label medical device and private label manufacturer and are the responsibility of the private label manufacturer.

I, the private label manufacturer, also certify that the information and material included in this medical device licence application is accurate and complete.

Table with 2 columns: Name of Private Label Manufacturer's Authorized Signing Official, Signature, Title, Date.

LABELLING: The private label manufacturer must include in this application a copy of the device label. The application should include copies of all labelling, package inserts, product brochures and file cards to be used in connection with the private label medical device, as well as copies of information and instructions for use given to practitioners and/or patients.



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**CURRENCY: The dollar (\$) amounts on this form refer to Canadian dollars. All payments must be made in Canadian dollars.  
PAYMENT: Your payment must be included with the application.**

**8. FEE ASSESSMENT (check fee payable)**

<p><b>Class II application:</b> G Payment is in the amount of \$200</p> <p><b>Class III or IV application:</b> G Payment is in the amount of \$370*</p> <p><small>*\$200 base fee + \$170 for review of device label</small></p>	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 5px;">G A reduced fee of \$50 is requested (Class II application)</td> <td style="width: 50%; padding: 5px;">G A rationale for the fee reduction request is attached</td> </tr> <tr> <td style="padding: 5px;">G A reduced fee of \$ _____ is requested (Class III or IV application)</td> <td></td> </tr> </table>	G A reduced fee of \$50 is requested (Class II application)	G A rationale for the fee reduction request is attached	G A reduced fee of \$ _____ is requested (Class III or IV application)	
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**9. 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 II medical device licence applications is \$50.

The reduced fee for a Class III or IV medical device licence 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.**

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

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

**11. PAYMENT BY CREDIT CARD**

Company's Full (Legal) Name:		Application Name (e.g., product name, file name)	
Credit Card:    G Visa    G MasterCard    G 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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**12. 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**.

**13. 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 \$):	<b>G</b> Transaction Receipt Included (must attach)	
<p>Wire payments of fees will be accepted only when wired to:</p> <ul style="list-style-type: none"> <li>• Bank of Montreal, 1247 Wellington St., Ottawa, Ontario, Canada, K1Y 3A3</li> <li>• SWIFT code: B of M CAM2</li> <li>• Institution number 001</li> <li>• Transit number 03566</li> <li>• Account number 022101000</li> </ul> <p>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 Montreal at tel. 613-722-2954.</p>		

**14. 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 12 to 15):		\$

**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.