



**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. PRIVATE LABEL REGULATORY CORRESPONDENT INFORMATION (if applicable)**

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. 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:

**5. 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):

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

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



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**8. FEES**

Please indicate that the Medical Device Licence Application Fee Form has been included with this application form

**9. 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 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 (original letter only) 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* 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.**

Name of Private Label Manufacturer's Authorized Signing Official:	Signature:
Title:	Date:

<p><b><i>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.</i></b></p>
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