

# CLASS II MEDICAL DEVICE LICENCE AMENDMENT APPLICATION FORM

(disponible en français)

Protected A when completed

**1. NAME OF DEVICE LICENCE BEING AMENDED**

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

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**3. MANUFACTURER INFORMATION** (as it appears on the label and the quality management system certificate)

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**

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

<p>Specific to Part 1, Section 32(2), item (c), (d), and (e) of the <i>Medical Devices Regulations</i> 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 (<b>check (T) the relevant attestations</b>):</p>
<p>I, <b>the Manufacturer</b> of this device (other than a decorative contact lens), have objective evidence establishing that it is compliant with section 10, subsections 11(1) and 12(1) and sections 13 to 20 of the <i>Medical Devices Regulations</i>.</p>
<p>I, <b>the Manufacturer</b> of this decorative contact lens, have objective evidence to establish that this device meets section 10, subsections 11(2) and 12(2) and sections 13 to 17 of the <i>Medical Devices Regulations</i>.</p>
<p>The device IS a near patient IVDD. I, <b>the Manufacturer</b> of this device, have evidence of investigational testing of this device using human subjects representative of the intended user and under conditions similar to the intended conditions of use of the device.</p>

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G The device IS NOT a near patient IVDD.
<b>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.</b>
<b>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. Please ensure that all information and documents set out in Section 32 of the <i>Medical Devices Regulations</i> that are relevant to the change has been enclosed.</b>
Name: _____ Title: _____
Signature: _____ Date: _____

**COMPLETE ITEMS 8 & 9 ONLY IF THEY HAVE CHANGED FROM THE PREVIOUS LICENCE**

**8. 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? ( <i>In Vitro Diagnostic Devices [IVDD] ONLY</i> )	Yes No
Is this device an IVDD?	Yes 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), if applicable. Otherwise, for combination products please complete the information listed below with respect to the drug substance.

Brand / Trade Name of Drug or Drug Substance:	DIN/NPN:
Active Ingredient(s):	
Manufacturer:	
USP Compliance	
GMP Compliance	
Compliance to other pharmacopeia and specify	

**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	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.

**10. RADIATION EMITTING MEDICAL DEVICES**

Do any of the devices contained in this application emit radiation?	Yes	No
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**11. DEVICE HISTORY**

Has this device been previously authorized for sale in Canada under the Investigational Testing or Special Access provisions of the <i>Medical Device Regulations</i> ?	Yes	No
If yes, provide the authorization number or the device identification number:		











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- 14. 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 the website [www.mdall.ca](http://www.mdall.ca))

Name of compatible device	Licence Number

**15. 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 <i>Guidance Document on Recognition and Use of Standards under the Medical Devices Regulations</i> , 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

- 16. REVIEW DOCUMENTS** – Indicate (Y) that labelling material is included as an attachment to this application. Manufacturers of a Class II medical device must submit their device label as required by section 32(2)(d) of the *MDR*. Refer to the documents *Guidance for the Labelling of Medical Devices* and *Guidance for the Labelling of In Vitro Diagnostic Devices*.

Labelling material	
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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.

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