Health Canada Santé Canada

DRAFT CLASS III MEDICAL DEVICE LICENCE AMENDMENT APPLICATION FORM

(disponible en français)

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

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

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:

7. ATTESTATIONS

Specific to Part I, Section 32(3) of the *Medical Devices Regulations* relevant to the licensing of Class III medical devices, a senior officer shall submit an application to the Minister that contains the following attestation as applicable **(check (✓) the relevant attestations)**:
☐ If the device contains a drug, I, **the Manufacturer** of this device, attest that the drug meets acceptable standards of safety, efficacy, and quality.

For Therapeutic Directorate Use
Device Licence Application No. _____

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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.

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 *Medical Devices Regulations* that are relevant to the change has been enclosed.

Name: _____ Title: _____

Signature: _____ Date: _____

COMPLETE ITEMS 8 and 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? *(In Vitro Diagnostic Devices [IVDD] ONLY)*	☐ 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) 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 ☐ 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.

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10. REASON FOR AMENDMENT (✔ appropriate change)

1.	A change to the classification of the device	☐	From Class:_____ To Class:_____
2.	A change in the Manufacturer's name	☐	Ensure that Item 1 is completed
3.	A change in the device licence name (that is [i.e.] previous device name no longer available for sale)	☐	New device licence name: _____ (add attachment if more space is needed)
4.	A significant change in manufacturing process, facility of equipment	☐	
5.	A significant change in manufacturing quality control procedures	☐	
6.	A significant change in design or performance specifications	☐	
7.	A significant change in the materials	☐	➢ Device contains ≥ 0.1% w/w of Di (2-Ethyl hexyl) Pthalate [DEHP]* ☐ Yes ☐ No ➢ Device is manufactured from materials ☐ Yes ☐ No containing or derived from bisphenol A (BPA)*
8.	A significant change in the labelling of the device	☐	
9.	Any change which could affect the safety and effectiveness of the device	☐	
10.	An addition, deletion or change in device components or associated model, part or catalogue numbers	☐	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.

DRAFT CLASS III MEDICAL DEVICE LICENCE AMENDMENT APPLICATION FORM

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11A. ADDITIONS (Before completing this section, 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)

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 CANADA USE ONLY)**

DRAFT CLASS III MEDICAL DEVICE LICENCE AMENDMENT APPLICATION FORM

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11B. DELETIONS

Name of device, components, parts and/or accessories as per product label	**Identifier for device (bar code, catalogue, model or part number)**	Device ID Number

DRAFT CLASS III MEDICAL DEVICE LICENCE AMENDMENT APPLICATION FORM

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11C. CHANGES

Name of device, components, parts and/or accessories as per product label	**Old** Identifier for device (bar code, catalogue, model or part number)	**New** Identifier for device (bar code, catalogue, model or part number)	Device ID Number

DRAFT CLASS III MEDICAL DEVICE LICENCE AMENDMENT APPLICATION FORM

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12. 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 licensed medical devices, refer to: www.mdall.ca.)

Name of compatible device	Licence Number

13. LIST OF RECOGNIZED STANDARDS COMPLIED WITH IN THE MANUFACTURE OF THE DEVICE

Please answer "Yes" where applicable.

The medical devices subject to this application conform with Recognized Standards listed in the List of Recognized Standards for Medical Devices which is available on the Health Canada website. I am including with this application a *Declaration of Conformity* form (available on the Health Canada website) that the medical devices comply with Recognized Standards.	☐ Yes ☐ No
The medical devices subject to this application DO NOT conform with Recognized Standards but meet an equivalent or better standard. I am including with this application a *Declaration of Conformity* form (available on the Health Canada website) that the medical devices comply with equivalent or better standards.	☐ Yes ☐ No
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

14. FEES

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

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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
Facsimile: (613) 957-6345
E-mail: device_licensing@hc-sc.gc.ca