Health Canada Santé Canada

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New class IV medical device licence application form

(disponible en français)

Before completing this form, you must consult the document *Guidance for Industry – How to Complete the Application for a New Medical Device Licence* (available on the website).

1. Name of the device (as it appears on the label)

2. 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. 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:	P.O. Box:
City:	Province/State:	Country:	Postal/Zip Code:

Canada

4. 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:	P.O. Box:
City:	Province/State:	Country:	Postal/Zip Code:

5. Quality management system certificate (ensure that certificate is attached)

Quality Management System Certificate Number:	Name of Registrar:

6. Attestations

I, as a senior official of the manufacturer named in Item 2 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 2 of this application, hereby attest that I am 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 3 of this application, I hereby authorize that person to submit this application to the Minister on my behalf. I further authorize the Medical Devices Directorate to direct all correspondence relating to this application to the person named in Item 3 of this application.

Name:	
Title:	
Signature:	Date (yyyy/mm/dd):

7. Purpose/intended use of device: A description of the medical conditions, purposes and uses for which the device is manufactured, sold or represented. (*Note: failure to supply an appropriate level of detail may result in the application not being accepted for review*)

8. Licence application type (check one only)

O Single Device	O Test kit	O Medical device group
O System	O Medical device family	O Medical device group family

9. Place of use

Is this device sold for home use	O Yes O No	Is this device an IVDD?	O Yes O 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)	O Yes O No		

10. Medical devices containing drugs

10.1 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:	

10.2 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?	O Yes O 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.

11. Device history

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

12. Identifier of device: Include an identifier for each device or medical device group listed and indicate (by a check mark) if it contains ≥ 0.1% w/w of Di (2-Ethyl hexyl) Pthalate (DEHP) or is manufactured from raw materials containing or derived from Bisphenol A (BPA).

Name of device, components, parts and/or accessories as per product label	Identifier for device (bar code,catalogue, modelor part number)	DEHP	BPA	Preferred name code **(for Health Canada use only)**
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13. Compatibility of interdependent devices: For a Class IV 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

14. List of recognized standards complied with in the manufacture of the device:
Please answer "Yes" to one, and only one, of the following.

The medical devices subject to this application conform with Recognized Standards as set out in the *Guidance Document on Recognition and Use of Standards under the Medical Devices Regulations*, which is available on the website. O Yes O No

If yes, I am including with this application Declarations of Conformity that the medical devices comply with the following Recognized Standards:

The medical devices subject to this application DO NOT conform with recognized standards but meet an equivalent or better standard. O Yes O No

If yes, I am including detailed information proving that the devices meet the following equivalent or better standards:

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. O Yes O No

15. Priority review: The following section should be completed by manufacturers that wish to request priority review for their application in order to ensure a timely review of critical new medical devices for serious, life threatening, or severely debilitating diseases or conditions. Manufacturers will be notified at screening acceptance whether their application was accepted for priority review.

Is priority review requested for this application? ○ Yes ○ No

Priority review is being requested for the subject devices as it is intended for the diagnosis or treatment of a serious, life-threatening or severely debilitating disease or condition and there is substantial clinical evidence that the medical device:

- ☐ Provides effective treatment or diagnosis of a disease or condition for which no medical device is currently licensed in Canada.
- ☐ Provides significant risk-benefit improvement over existing therapeutic or diagnostic devices for a disease or condition that is not adequately managed by existing products marketed in Canada.
- ☐ Responds to an unmet urgent healthcare need.

If a priority review is requested, a rationale must be included with this application form. The rationale should be an executive summary (10 pages or less) consisting of the following information:

- A synopsis of the clinical evidence establishing that the device provides effective treatment or diagnosis of a disease or condition for which no medical device is currently licensed in Canada or for which existing devices are inadequate.
- A brief description of the disease or condition and the role of the device.
- A summary of the risk-analysis for the device and/or the improvements it represents over existing products.

16. Review documents: Indicate which documents listed below are included as attachments to this application. For details regarding content and format, you are requested to consult the *Guidance Document – Preparation of a Premarket Review Document for Class III and Class IV Device Licence Applications* (available on the website).

- ☐ Executive Summary
- ☐ Table of Contents
- ☐ Background, which includes Device Description, Design Philosophy, and Marketing History
- ☐ Risk Assessment
- ☐ Quality Plan
- ☐ Device Specific Detailed Information, which includes Material Specifications, Manufacturing Process Specifications, and List of Standards
- ☐ Safety and Effectiveness Studies
- ☐ Required information for any biological material (if applicable)
- ☐ Near Patient Diagnostic Device Testing Results (if applicable)
- ☐ Labelling Material

17. Device containing biological material

Does this device consist of recombinant material?	O Yes O No
Does this device contain, or is it produced using, any animal or human sourced material?	O Yes O No
If yes, please complete the information below for each material:	

Country of Origin (for animals only):
Species (for example [e.g.], human, bovine, ovine etc.):
Tissue Type (e.g., bone, heart valve, skin and hair):
Derivative (e.g., collagen, gelatin, hyaluronic acid, stearate):

Country of Origin (for animals only):
Species (for example [e.g.], human, bovine, ovine etc.):
Tissue Type (e.g., bone, heart valve, skin and hair):
Derivative (e.g., collagen, gelatin, hyaluronic acid, stearate):

Country of Origin (for animals only):
Species (for example [e.g.], human, bovine, ovine etc.):
Tissue Type (e.g., bone, heart valve, skin and hair):
Derivative (e.g., collagen, gelatin, hyaluronic acid, stearate):

Country of Origin (for animals only):
Species (for example [e.g.], human, bovine, ovine etc.):
Tissue Type (e.g., bone, heart valve, skin and hair):
Derivative (e.g., collagen, gelatin, hyaluronic acid, stearate):

18. Fees

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

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 Directorate (MDD).

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 MDD. 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 MDD 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 MDD, of the date when an application for the device entered above, has been received by the MDD.

☐ this certifies that (*enter the manufacturer's name*)_____ **objects** to the disclosure to the requester, by the MDD, of the date when an application for the device entered above, has been received by the MDD.

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:

Bureau of Licensing Services
Medical Devices Directorate
Health Canada
11 Holland Avenue
Address Locator : 3002A
Ottawa, Ontario
K1A 0K9

Phone: (613) 957-7285
Facsimile: (613) 957-6345
E-mail: devicelicensing-homologationinstruments@hc-sc.gc.ca