Health Canada Santé Canada

New Class II Medical Device Licence Application Form

(disponible en français)

Before completing this form, you must consult the document Guidance Document – 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 and the quality management system certificate)

Contact Name and Title:		Company ID (if known):	
Company Name:			
Telephone:	Facsimile:	E-mail:	
Telephone (international):		Facsimile (international):	
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:	Facsimile:	E-mail:	
Telephone (international):		Facsimile (international):	
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:	Facsimile:	E-mail:
Telephone (international):		Facsimile (international):
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

Specific to Part 1, section 32(2), item (c), (d), and (e) of the Medical Devices Regulations 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: **Check (✓) the relevant attestations**.

☐ I, **the Manufacturer** of this device (other than a decorative contact lens), have objective evidence to establish that it is compliant with section 10, subsections 11(1) and 12(1) and sections 13 to 20 of the Medical Devices Regulations.

☐ I, **the Manufacturer** 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 Medical Devices Regulations.

☐ The device IS a near patient IVDD (In Vitro Diagnostic Device). I, **the Manufacturer** of this device, have evidence of investigational testing of this device using human subjects representative of the intended users and under conditions similar to the intended conditions of use of the device.

☐ The device IS NOT a near patient IVDD.

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.

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 Bureau 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: Provide a description of medical devices covered by this application and their intended use. The intented use statement should be verbatim as it appears on the device labelling. Please indicate the document, document date and version number where the formal intended use appears, if applicable.

8. Licence Application Type (check one only)

Single device	◯	Test kit	◯	Medical device group	◯
System	◯	Medical device family	◯	Medical device group family	◯

9. 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		

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), if applicable. Otherwise, for combination products, please complete the information listed below with respect to the drug or drug substance

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

10.2 IVDD Test Kits containing Controlled Substances

If this device is an IVDD test kit (T.K.) 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.

11. Radiation Emitting Medical Devices

Do any of the devices contained in this application emit radiation?	◯ Yes ◯ No

12. 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?	◯ Yes ◯ No
If yes, provide the authorization number or the device identification number:	

13. Identifier of Device

[Include a device 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)]. If the device contains material of a particle size of 1000 nanometers or less, please specify the type and size range.

Name of device, components, parts and/or accessories as per product label	Identifier for device (bar code, catalogue, model or part number)	DEHP ✓	BPA ✓	If device contain nano- scale material enter YES and specify Type. If not, enter NONE.	Size range of nano-scale material particles	Preferred Name Code **(Health Canada Use Only)**
		☐	☐			
		☐	☐			
		☐	☐			
		☐	☐			
		☐	☐			
		☐	☐			
		☐	☐			
		☐	☐			
		☐	☐			
		☐	☐			
		☐	☐			
		☐	☐			

14. 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

15. List of Recognized Standards Compiled with in the Manufacturer of the Device

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.	◯ 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 -

A) Indicate that labelling material is included as an attachment to this application. Manufacturers of 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 is included as an attachment:	☐ Yes

B) For high-level disinfectants and sterilants and/or contact lens disinfectants: Manufacturers must submit safety and effectiveness information, as per the Safety and Effectiveness Requirements for Contact Lens Disinfectants (2018), or the Safety and Effectiveness Requirements for High-Level Disinfectants and Sterilants for use on Reusable Semi-Critical and Critical Medical Devices (2018) guidance documents

Safety and Effectiveness Information for High-level Disinfectants and Sterilants and/or Contact Lens disinfectants is included as an attachment	☐ Yes
is confirmed by an existing Drug Information Number (DIN)	☐ Yes Din#

17. Fees

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

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 _____ 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 _____ **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
11 Holland Avenue
Address Locator: 3002A
OTTAWA, Ontario K1A 0K9

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

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