Health Canada Santé Canada

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Medical device establishment licence application form (FRM-0292): Application checklist

Note: Your cover letter should identify all documents included with your application. If submitting a notification or amendment, clearly identify any changes from previous applications. You may include this checklist with your application to facilitate the processing of your request.

Do not modify this form.

Application type	Sections to be completed	Action
○ **New licence application** (applying for your first MDEL or applying for a new MDEL after a cancellation)	☐ Cover letter (recommended) ☐ Application checklist ☐ Entire application (Section 1-7)	
○ **Notification** (submit changes to name and address of the establishment or the contact information on your MDEL)	☐ Cover letter (recommended), include MDEL Number ☐ Application checklist ☐ Section 1 ☐ Section 2 ☐ Section 7	 ☐ Modify ☐ Modify
○ **Amendment of an existing MDEL** (submit any changes to your existing MDEL, for example, device class listed)	☐ Cover letter (recommended), include MDEL Number ☐ Application checklist ☐ Section 1 ☐ Section 2 ☐ Section 3 ☐ Section 4 ☐ Section 5 ☐ Section 6 ☐ Section 7	 ☐ Modify ☐ Modify ☐ Add ☐ Remove ☐ Modify ☐ Add ☐ Remove ☐ Modify ☐ Add ☐ Remove ☐ Modify ☐ Add ☐ Remove ☐ Modify ☐ Modify
○ **Reinstatement of an MDEL** (reinstate your licence after a suspension by Health Canada)	☐ Cover letter (recommended), include MDEL Number ☐ Application checklist ☐ Entire application (Section 1-7)	
○ **Cancellation of an MDEL** (request to cancel your MDEL)	☐ Cover letter (recommended), include MDEL Number ☐ Application checklist ☐ Section 1 ☐ Appendix A	

End of Checklist

Canada

Medical device establishment licence application form (FRM-0292)

* is a required field.

Section 1: Application Type	
1. *Application type ○ New ○ Notification (see section 48 of the *Medical Devices Regulations*) ○ Amendment ○ Reinstatement ○ Cancellation (see Appendix A below)	
2. Current MDEL number held by the establishment, if applicable:	3. Current or previous company ID held by the establishment, if applicable:
4. Any previous MDEL number(s) held by the establishment, if applicable:	
End of Section 1	

Section 2: Applicant Information

5. *Establishment name (this is the Medical Device Establishment Licence holder):

6. Operating, trade, or partnership name, if different from establishment name above:

7. Small Business Mitigation

Option 1 (both boxes must be selected)

- ☐ We certify that we meet the definition of small business at the time of this filing and have applied for small business status for our company with Health Canada and have received confirmation prior to submitting this submission/application.
- ☐ We understand that failure to hold a valid small business status with Health Canada at the time of submitting this submission/application will result in the full fee being charged.

Option 2

- ☐ I am not applying for the small business mitigation.

Note: If left blank, or if option 2 is selected, the full fee will be charged and you will not be considered for the small business mitigation.

See section 1 of the Fees in Respect of Drugs and Medical Devices Order for the definition of a small business.

8. Fee exemption

- ☐ I certify that I am a branch or agency of the Government of Canada or of a province or territory

See section 3 of the Fees in Respect of Drugs and Medical Devices Order for more details.

Section 2.1 Establishment address (where the licensable activities are conducted, this cannot be a P.O. Box)

9. *Building name or number:

10. *Street:	11. Suite:

12. *City:	13. *Province/State:	14. *Postal/ Zip code:	15. *Country:

16. *Business is located in a personal home/dwelling: ○ Yes ○ No	17. Business number (nine-digit number):

Section 2.2 Contact person for the establishment licence (Establishment representative)			
18. *Title:			19. *Preferred language: ○ English ○ French
20. *Surname:	21. *Given name(s):		
22. *Email:			
23. *Telephone:	24. Fax:		
Section 2.3 Mailing address 25. ☐ Same as Section 2.1 establishment address above			
26. Establishment name, if different:	27. Building name (if applicable):		
28. Street number:	29. Street name:		30. Suite:
31. City:	32. Province/State:	33. Postal/ Zip code:	34. Country:
Section 2.4 Billing address 35. ○ Same as Section 2.1 establishment address above 36. ○ Same as Section 2.3 mailing address above			
37. Establishment name, if different:	38. Building name (if applicable):		
39. Street number:	40. Street name:		41. Suite:
42. City:	43. Province/State:	44. Postal/ Zip code:	45. Country:
46. Billing contact person (if different) Title:			47. Preferred language: ○ English ○ French
48. Surname:	49. Given name(s):		
50. Email:			
51. Telephone:	52. Fax:		
End of Section 2			

Section 3: Activities

Important: Before filling out this section, you must carefully read *Guidance on Medical Device Establishment Licensing (GUI-0016)*. GUI-0016 provides definition of a distributor, importer and manufacturer.

		53. *Activity		
		Distributor	**Importer** (includes distribution)	**Manufacturer of Class I devices** (who imports/distributes their own devices)
54. *Class of device	Class I	☐	☐	☐
	Class II	☐	☐	n/a
	Class III	☐	☐	n/a
	Class IV	☐	☐	n/a

End of Section 3

Section 4: Site Information

Important: You must list one or more site(s) in section 4.

A **site** is any additional building that is used by the MDEL holder (establishment) for keeping the procedures attested to in paragraphs 45(g) to (i) of the *Medical Devices Regulations*. A site cannot be located at a P.O. Box address and must be in the same country as the establishment indicated in section 2.1.

If the site listed is not the same legal entity, then it is the responsibility of the licence holder to ensure that site(s) listed in section 4 of their MDEL application has the applicable procedures in place and that inspectors be able to verify compliance without any impediment.

If you list a site, you must indicate the procedure(s) in place at that site.

Site

55. ☐ Same as Section 2.1 establishment address above

56. *Documented procedure at this site (select all that apply):

- ☐ Distribution records procedure
- ☐ Complaint handling procedure
- ☐ Recall procedure
- ☐ Incident reporting procedure
- ☐ Serious risk of injury to human health procedure
- ☐ Handling procedure
- ☐ Storage procedure
- ☐ Delivery Procedure
- ☐ Installation procedure
- ☐ Corrective action procedure
- ☐ Servicing procedure

57. Establishment name:	58. Company ID number, if applicable:

59. Street number:	60. Street name:	61. Suite:

62. City:	63. Province/State:	64. Postal/ Zip code:	65. Country:

Site

66. Documented procedure at this site (select all that apply):

- ☐ Distribution records procedure
- ☐ Complaint handling procedure
- ☐ Recall procedure
- ☐ Incident reporting procedure
- ☐ Serious risk of injury to human health procedure
- ☐ Handling procedure
- ☐ Storage procedure
- ☐ Delivery Procedure
- ☐ Installation procedure
- ☐ Corrective action procedure
- ☐ Servicing procedure

67. Establishment name:	68. Company ID number, if applicable:

69. Street number:	70. Street name:	71. Suite:

72. City:	73. Province/State:	74. Postal/ Zip code:	75. Country:

Site			
76. Documented procedure at this site (select all that apply): ☐ Distribution records procedure ☐ Complaint handling procedure ☐ Recall procedure ☐ Incident reporting procedure ☐ Serious risk of injury to human health procedure ☐ Handling procedure ☐ Storage procedure ☐ Delivery Procedure ☐ Installation procedure ☐ Corrective action procedure ☐ Servicing procedure			
77. Establishment name:	78. Company ID number, if applicable:		
79. Street number:	80. Street name:		81. Suite:
82. City:	83. Province/State:	84. Postal/ Zip code:	85. Country:
End of Section 4			

Print more pages if needed.

Section 5: Manufacturer or Supplier information

Important:

The name of the manufacturer is on the label of each product.

A supplier is any person, other than the manufacturer, who distributes (sells) a medical device to an MDEL holder for the purpose of import or sale in Canada.

86. *

- ○ Manufacturer or
- ○ Supplier

87. *Name of the manufacturer or supplier:	88. *Company ID number:

89. *Street number:	90. *Street name:	91. Suite:

92. *City:	93. *Province/State:	94. *Postal/ Zip code:	95. *Country:

96. *Risk Class:

- ☐ Class I
- ☐ Class II
- ☐ Class III
- ☐ Class IV

97.

- ○ Manufacturer or
- ○ Supplier

98. Name of the manufacturer or supplier:	99. Company ID number:

100. Street number:	101. Street name:	102. Suite:

103. City:	104. Province/State:	105. Postal/ Zip code:	106. Country:

107. Risk Class:

- ☐ Class I
- ☐ Class II
- ☐ Class III
- ☐ Class IV

108. ○ Manufacturer or ○ Supplier				
109. Name of the manufacturer or supplier:		110. Company ID number:		
111. Street number:	112. Street name:			113. Suite:
114. City:	115. Province/State:	116. Postal/ Zip code:	117. Country:	
118. Risk Class: ☐ Class I ☐ Class II ☐ Class III ☐ Class IV				
End of Section 5				

Print more pages if needed.

Section 6: Attestations

Important:

Health Canada will inspect your establishment to verify your attestation in section 6 and your establishment's compliance with the *Medical Devices Regulations*.

Read each section below carefully and check all relevant attestations.

Pursuant to Part I, Section 45, paragraph (g), (h), (h.1) and (i) of the *Medical Devices Regulations*, a senior official of the establishment applying for an establishment licence shall submit an application to the Minister that contains attestations based on the activities conducted by this establishment, as applicable.

119. *Section 45(g): Required of all establishments

The establishment has documented procedures in place in respect of:

☐ distribution records, complaint handling, recalls.

120. *(**Note:** As per Section 59 of the *Medical Devices Regulations* there are incident reporting requirements for importers as well as manufacturers.)

Section 45(h): Required if you are an importer of Class I devices

☐ The establishment has documented procedures in place in respect of the making of reports under subsection 59(1) and (1.1);

Section 45(h.1): Required if you are an importer of Class II, III or IV devices

☐ The establishment has documented procedures in place in respect of the making of reports under subsection 59(1) and the provision of information under section 61.2;

or

☐ Not an importer.

121. *Section 45(i): Required if you are an importer or distributor of Class II, III or IV devices

The establishment has documented procedures in place for:

☐ handling, storage and delivery

☐ installation

☐ corrective action

☐ servicing

or

☐ Not an importer or distributor of Class II, III or IV devices.

End of Section 6

Section 7: Signature

This section must be read carefully, signed and dated by the Senior Official of the establishment acknowledging that all the information in this application is accurate and that all required regulatory procedures are in place. This section should only be signed by the senior official of the company.

Important: The name of the senior official associated with an MDEL is published in Health Canada's medical devices establishment licence listing along with other posted information about establishments.

I, the undersigned, acknowledge that:

1. It is a serious offence to knowingly make false attestations on this application and it could lead to establishment licence **refusal** or **suspension** (subsection 47(1) and paragraph 49(1)(b) of the *Medical Devices Regulations*, respectively).
2. As a senior official of the establishment named in this application, I have direct knowledge of the documented procedures in place, as confirmed by the attestations in section 6 of this document.
3. Selling or importing medical devices without a valid Medical Device Establishment Licence is contrary to subsection 44(1) of the *Medical Devices Regulations* and is subject to compliance and enforcement actions.
4. For Class II, III, or IV devices, this establishment shall only sell licensed devices, as per section 26 of the *Medical Devices Regulations* (unless authorized under the Medical Devices Regulations).

122. *Name:	123. *Title:
124. *Signature:	125. *Date (yyyy-mm-dd):

End of Section 7

Submit form

Annex 1 – Class I Medical Devices		
Medical Device Name	**Type of Medical Device**	**Description**
End of Annex 1		

Appendix A – Cancellation of Medical Device Establishment Licence

Important:

- Only the contact person or senior official for the MDEL may submit a cancellation request to Health Canada.
- Health Canada may inspect an establishment that had its MDEL cancelled, to verify that all licensable activities have ceased on the date indicated below.

126. *Company name:	127. *Medical Device Establishment Licence (MDEL) number:

128. *Street number:	129. *Street name:	130. Suite:

131. *City:	132. *Province/State:	133. *Postal/ Zip code:	134. *Country:

135. *

I (print name) _____,

(title) _____ , as an authorized representative of the above company, confirm that:

"I have ceased licensable activities for MDEL number _____ on (yyyy-mm-dd) _____ , and I do not plan to conduct licensable activities in Canada. I would like to request that my medical device establishment licence be cancelled."

136. *Name:	137. *Title:
138. *Signature:	139. *Date (yyyy-mm-dd):

End of Appendix A

Submit form

Privacy notice: The personal information you provide to Health Canada is governed in accordance with the *Privacy Act*. We only collect the information we need to administer Medical Device Establishment Licencing regime, authorized under the *Medical Devices Regulations*.

Purpose of collection: We require your personal information to process your request for a Medical Device Establishment Licence as per sections 44 to 51.1 of the *Medical Devices Regulations* to the *Food and Drugs Act*.

Other uses or disclosures: In limited and specific situations, your personal information may be disclosed without your consent in accordance with subsection 8(2) of the *Privacy Act*. The name of the senior official associated with a MDEL is published in Health Canada's medical devices establishment licence listing along with other posted information about establishments.

Refusal to provide the information: Failure to provide the requested information may prevent the processing your request for a Medical Device Establishment Licence.

For more information: This personal information collection is described in Info Source, available online at www.canada.ca/en/health-canada/corporate/about-health-canada/activitiesresponsibilities/access-information-privacy/info-source-federal-government-employeeinformation.html. Refer to the class of records HC HP 040.

Your rights under the *Privacy* Act: In addition to protecting your personal information, the *Privacy Act* gives you the right to request access to and correction of your personal information. For more information about these rights, or about our privacy practices, please contact mdel.questions.leim@hc-sc.gc.ca.

You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

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