



Our Mandate:

To promote good nutrition and informed use of drugs, food, medical devices and natural health products, and to maximize the safety and efficacy of drugs, food, natural health products, medical devices, biologics and related biotechnology products in the Canadian marketplace and health system.

Health Products and Food Branch Inspectorate

Medical Device Establishment Licence Application: Form and Instructions

FRM-0292

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Disclaimer:

This document does not constitute part of the Food and Drugs Act (Act) or its associated Regulations and in the event of any inconsistency or conflict between that Act or Regulations and this document, the Act or the Regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the Regulations and the applicable administrative policies. This document is not intended to provide legal advice regarding the interpretation of the Act or Regulations. If a regulated party has questions about their legal obligations or responsibilities under the Act or Regulations, they should seek the advice of legal counsel.

Medical Device Establishment Licence Application Instructions

Introduction:

The intent of the medical device establishment licensing requirements in the *Medical Devices Regulations* is:

1. To ensure that the Inspectorate is made aware of:
 - a. Who is importing and/or selling medical devices in Canada,
 - b. The identity of the manufacturers of the devices sold by the holder of the MDEL (licence holder), as well as the classification of those devices,
 - c. The identity of manufacturers of Class I devices.
2. To require licence holders to provide some assurance to the Inspectorate that they have met the regulatory requirements and have documented procedures in place, where applicable, related to distribution records, complaint handling, recalls, mandatory problem reporting and for handling, storage, delivery, installation, and servicing, with respect to the medical devices they sell.

For more information regarding medical device establishment licensing please see the Guidance on Medical Device Establishment Licensing located on the Establishment Licensing website:

<http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/index-eng.php>

A. Medical Device Establishment Licence Application Form

The following describes the documentation required to process for completing the Medical Device Establishment Licence (MDEL) application form.

Page 1 Company Name & Contact Information

This page is the contact information and the reason for the application (i.e. new, amendment, cancellation etc.).

- Company Name*
- Contact Name*
- Phone number and extension*
- Fax number
- Email
- Language of preference

*This information must be updated and correct at all times. If at any time this information changes notify the Establishment Licensing Unit (ELU) within 15 days.

Page 2 Classes and Activities

Please indicate the licensable activities that the establishment is performing.

Do not include the names of devices or manufacturers on this page. On page 7 of the application please ensure that there is supporting manufacturers for each activity and class of device indicated on page 2.

Definitions of Activities

Importer: a person other than the manufacturer of a device, whose establishment is in Canada, who causes the medical device to be brought into Canada from foreign manufacturers or distributors, for sale in Canada.

Note: the activity of import includes the activity of distributing the imported products.

Distributor: for the purposes of this guidance document, a distributor is a person, other than a manufacturer, an importer or a retailer, who sells a medical device in Canada for the purpose of resale or use, other than for personal use. A person outside of Canada selling.

Manufacturer: means a person, including an association or partnership, who under their own name, or under a trade-, design or word mark, trade name or other name, word or mark controlled by them, sells a food or drug; (FDR A.01.010)

Note: Manufacturers of Class I devices require an Establishment licence unless they are distributing their devices solely through a licenced distributor. Manufacturers of Class II, III, or IV devices do not require an establishment licence to distribute the devices they manufacture, so long as they hold the appropriate medical device licence

Classification of medical devices

It is the responsibility of the applicant to ascertain that the device(s) indicated on the application have been classified as a medical device and to obtain the correct classification of the medical device. Please provide a list of Class I medical device manufactured, distributed and /or imported by your company on the Class I device annexe attached to the application form. For information on medical device risk classification, please refer to:

DRAFT Guidance for the Risk-based Classification System

http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/risk5_risque5_main_principal-eng.php

For verification of the classification of a device please contact the Medical Devices Bureau:

Medical Devices Bureau

Email: device_licensing@hc-sc.gc.ca

Telephone: (613) 957-7285

Fax: (613) 957-6345

Page 3 Attestations

A Senior Officer of the establishment applying for a licence must complete the attestations based on the activities conducted by this establishment. All attested to procedures must be in place.

All establishments **must** have documented procedures pursuant to Section 45(g).

- distribution records
- complaint handling
- recalls

All establishments that are Importers **must** have documented procedures pursuant to Section 45(h).

- The establishment has documented procedures in place in respect of mandatory problem reporting.

Establishments that are importers or distributors Class II, III & IV medical devices are required to have documented procedures pursuant to Section 45(i), where applicable.

- handling, storage and delivery
- installation
- corrective action
- servicing

Note: We do not require the documentation of the procedures attested-to.

Page 4 **Signature**

This page is to be signed by a senior official of the establishment, acknowledging that all the information in the application is accurate and **all required procedures are in place**.

Page 5 **Licence, Mailing and Billing Addresses**

This page details the address where licensable activities occur, as well as the mailing and billing address, if different.

- Company Name*
- Full Company Address* (including postal code)

*This information must be updated and accurate at all times. If at any time this information changes notify the Establishment Licensing Unit (ELU), within 15 days of the changes.

Page 6 **Site Address**

Site: any building in Canada where the activities listed on the Medical Device Establishment Licence application are conducted, and where the attested to procedures are in place.

Please list all sites in the space provided and use additional pages if required.

Page 7 **Manufacturer Information**

Provide the names and full addresses of **all** the manufacturers of the medical devices you will be importing or distributing as per the activities indicated on page 2.

All manufacturers (with the exception of manufacturers of Class I) must hold a Medical Device Licence. To determine if a manufacturer holds a medical device licence please visit:

<http://webprod.hc-sc.gc.ca/mdll-limh/index-eng.jsp>

The MDALL (Medical Device Active Licences database) website allows you to search all licensed manufacturers of class II, III and IV medical device licences. When adding or amending manufacturers for your establishment licence, you must check MDALL for the following information for risk class II, III and IV:

- Ensure that the manufacturer is licensed for all the risk classes of devices at the address indicated on the application and
- There is a company ID number for each manufacturer you have listed on your application.

If you are adding manufacturers, you may include additional page 7 of the application form as required.

Class I Annexe

B. FEE AND FEE REMISSION:

The medical device establishment licence fee is payable at the time the applicant submits (1) an application for a MDEL or (2) an application for the annual review of a MDEL or (3) an application for the reinstatement of a MDEL. For applicants who have not completed their first full calendar year of conducting activities under an establishment licence, the payment of the applicable MDEL fee is deferred until the end of the first full calendar year. For example, if an applicant submits an application for a MDEL on any day in 2012, the payment of the fee is deferred until the final business day of December 2013. Please note that amendments do not require payment.

Applicants can also apply for a fee remission. If the fee payable is greater than 1% of the applicant's actual gross revenue generated from activities conducted under a MDEL during the previous calendar year, fee remission will be granted. The amount remitted will equal the difference between the fee which would normally be payable and the amount of 1% of gross revenue. If an applicant wishes to apply for fee remission, the request must be included with the application:

1. **Certified Statement** - which is a statement certified by the individual responsible for the applicant's financial affairs that sets out the actual gross revenue along with the application (1) for a MDEL or (2) for the annual review of a MDEL or (3) for the reinstatement of a MDEL. The statement can be a copy of the applicant's general ledger or sales logs from the general ledger. Where an applicant has audited financial records, this can be supplied to Health Canada in support of a request for fee remission. **Note: If an applicant does not submit a certified statement with their application The fee remission request will not be granted.**
2. **Medical Device Establishment Licence Calculation Chart** (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/directives/calcul-chart_md-im-eng.php) - which is used to calculate the total fee for an establishment licence. Applicants will **only** need to enter company name, MDEL

licence number, company code, and the gross revenue (box “A”) for the last completed calendar year to have the total value of an MDEL licence calculated.

3. **Medical Device Establishment Licence Fee Form**

For applicants who have not completed their first year of activities must ensure they submit payment, certified statement, MDEL Fee Form, and calculation chart before the final business day of December. MDEL Fee Form, calculation chart, and certified statements submitted after the final business day of December **will not** have their fee remission granted.

For more information regarding fees please see section 9 of the Guidance on Medical Device Establishment Licence or contact the **Establishment Licensing Invoicing Unit**:

Email: ELIU_UFLE@hc-sc.gc.ca

Telephone: 613-946-5141

Facsimile: 613-957-6711

C. CONTACT INFORMATION

Establishment Licensing	Tel: (613) 954-6790 Fax: (613) 957-4147 Email: MDEL_questions_LEPIM@hc-sc.gc.ca
Invoicing (Fees and Invoices)	Email: ELIU_UFLE@hc-sc.gc.ca Telephone: 613-946-5141 Facsimile: 613-957-6711
Medical Device Bureau (Classification of medical devices and Medical Device Licence information)	Email: device_licensing@hc-sc.gc.ca Telephone: (613) 957-7285 Fax: (613) 957-6345

D. SUBMISSION

Return the signed Summary Report and other applicable forms or information to ONE of the following:

Mail: Establishment Licence Unit
2nd Floor, Graham Spry Building
Address Locator 2002A
250 Lanark Avenue
Ottawa, Ontario
K1A 0K9
Fax: (613) 957-4147

E. CHECKLIST FOR RENEWAL

- Page 1:** Ensure that the Contact Information is accurate and up to date.
- Page 2:** Verify that the Classes and Activities are correct and that you have provided all required manufacturers information (page 7) for each class of device you are importing or distributing.
- Page 3:** Verify that you have made the appropriate Attestations.
- Page 4:** Ensure that page 4 has been signed and dated
- Page 5:** Ensure that the licence, mailing and billing addresses are accurate and up to date.
- Page 6:** Verify that all sites are appropriately and correctly identified. Add additional pages as needed.
- Page 7:** Ensure that the manufacturer information is complete including the Company ID (where applicable) and a full address including postal/zip codes. Add additional pages as needed.
- Fee Form:** Ensure that all applicable forms and documents are submitted with the MDEL application.



Medical Device Establishment Licence Application Form

Formulaire de demande de licence d’établissement pour les instruments médicaux

<p>Submit the application form to: Establishment Licensing Unit Health Products and Food Branch Inspectorate 250 Lanark Avenue Graham Spry Building – 2nd Floor Address Locator 2002C Ottawa, Ontario K1A 0K9 Fax: 613-957-4147</p>	<p>Envoyer le formulaire de demande a: Unité des licences d’établissement Inspectorat de la Direction générale des produits de santé et des aliments 250, avenue Lanark Immeuble Graham Spry, 2^e étage Indice de l’adresse 2002C Ottawa (Ontario) K1A 0K9 Téléc : 613-957-4147</p>
<p>Please retain a copy of the completed application in your file.</p>	<p>Veillez garder une copie de l'application complétée pour vos dossiers.</p>
<p>Year of Application (please circle): Current or Upcoming. / Année d’application (veuillez encercler): année en cours / année future Reason for Application / Raison de la demande : New/Nouvelle: <input type="checkbox"/> Amendment/Modification de la licence numéro: <input type="checkbox"/> Other / Autre: <input type="checkbox"/></p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>	
<p>COMPANY INFORMATION / RENSEIGNEMENTS SUR LA SOCIÉTÉ</p>	
<p>Company Name / Nom de l’établissement: _____</p>	
<p>Licence Number/ Numéro de l’établissement #: _____</p>	
<p>Establishment Licence Contact Name / Nom du contact de l’établissement : _____</p>	
<p>Phone / téléphone : _____</p>	
<p>Extension / poste : _____</p>	
<p>Fax / télécopieur : _____</p>	
<p>Email / courriel : _____</p>	
<p>Language / Langue : English/Anglais <input type="checkbox"/> French/Français <input type="checkbox"/></p>	



Medical Device Establishment Licence Application Form

Formulaire de demande de licence d'établissement pour les instruments médicaux

ACTIVITIES / ACTIVITÉS : Check all that apply - Cochez toutes les cases qui s'appliquent

	Distributor / Distributeur	Importer / Importateur	Manufacturers of Class I devices who distribute their own devices /Fabricants d'instruments médicaux de classe I qui vend ses instruments
Class / Classe I	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Class / Classe II	<input type="checkbox"/>	<input type="checkbox"/>	
Class / Classe III	<input type="checkbox"/>	<input type="checkbox"/>	
Class / Classe IV	<input type="checkbox"/>	<input type="checkbox"/>	

ATTESTATIONS

Pursuant to Part I, Section 45, paragraph (g), (h) and (i) of the *Medical Devices Regulations (MDR)*, a senior officer of establishment applying for an establishment licence shall submit an application to the Minister that contains attestations based on the activities conducted by this establishment. Please check all relevant attestations listed below.

Conformément à la partie I, article 45, paragraphe g), h) et i) du *Règlement sur les instruments médicaux (RIM)*, un dirigeant de l'établissement qui fait demande de licence d'établissement, doit présenter au Ministre une demande contenant les attestations nécessaires en fonction des activités réalisées par l'établissement et tous les sites énumérés. Veuillez cocher les attestations pertinentes indiquées ci-dessous.

Section 45(g) Required of all establishments

Article 45(g) Attestation exigée pour tous les établissements

The establishment has documented procedures in place in respect of / : L'établissement a mis en œuvre des procédures écrites pour :

distribution records, complaint handling , recalls / le traitement des plaintes, les rappels

Section 45(h) Required if the establishment is an importer

Article 45(h) Attestation exigée si l'établissement est un importateur

The establishment has documented procedures in place in respect of mandatory problem reporting. /

L'établissement a mis en oeuvre une procédure écrite concernant les rapports d'incident obligatoires.

Not applicable. Not an importer. / Sans objet. L'établissement n'est pas un importateur.

Section 45(i) Required if the establishment is an importer or distributor of Class II, III or IV devices (where applicable) / Article 45(i) Attestation exigée si l'établissement importe ou distribue des instruments de classe II, III ou IV (si applicable)

The establishment has documented procedures in place for: / L'établissement a mis en œuvre des procédures écrites pour :

handling, storage and delivery / la manutention, le stockage et la livraison

installation / l'installation

corrective action / les actions correctives

servicing / l'entretien

Not applicable. Not an importer or distributor of Class II, III or IV devices. / Sans objet. L'établissement n'est pas un importateur ou un distributeur d'instruments de classe II, III ou IV.



Health
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Medical Device Establishment Licence Application Form

Formulaire de demande de licence d'établissement pour les instruments médicaux

I hereby attest, as a senior official of the establishment named in this application, that I have direct knowledge of the procedures in place, as checked above, and that these statements are true as they apply to this establishment.

En tant que dirigeant de l'établissement nommé dans la présente demande, j'atteste connaître de première main les procédures en place susmentionnées et déclare qu'elles sont exactes, dans la mesure où elles s'appliquent à l'établissement visé.

- I acknowledge that it is a serious offence to knowingly make false attestations on this application.
- Je reconnais que le fait d'inclure sciemment de fausses attestations dans la demande est une infraction sérieuse.
- I acknowledge that knowingly making false attestations is grounds for refusal to issue an establishment licence, in accordance with subsection 47(1) of the *Medical Device Regulations*.
- Je reconnais que le fait d'inclure de fausses attestations est un motif de refus de la livraison licence d'établissement conformément à l'article 47(1) du *Règlement sur les instruments médicaux*.
- I acknowledge that the discovery, at some future time, that false attestations were knowingly made in this application is grounds for suspension of my establishment licence, in accordance with paragraph 49(1)(b) of the *Medical Device Regulations*.
- Je reconnais que si l'on découvre éventuellement que de fausses attestations ont été faites sciemment dans la demande, ma licence d'établissement pourrait être suspendue conformément à l'alinéa 49(1)b) du *Règlement sur les instruments médicaux*.
- I acknowledge that, for Class II, III, IV devices, this establishment shall only sell licenced devices, as per section 26 of the *Medical Devices Regulations*, unless authorized elsewhere in the *Medical Devices Regulations*.
- En ce qui concerne les instruments médicaux de classe II, III et IV, je reconnais que l'établissement visé peut seulement vendre des instruments homologués conformément à l'article 26 du *Règlement sur les instruments médicaux*, sauf si autorisé ailleurs dans le *Règlement*.

Signature : _____ Date : _____

Name / Nom : _____ Title / Titre : _____



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Medical Device Establishment Licence Application Form

Formulaire de demande de licence d'établissement pour les instruments médicaux

Enter the information below in the designated area(s) / **Entrer** l'information ci-dessous aux endroits désigné(s)

Licence Address / Adresse de la licence

Company Name/Nom de l'établissement:

Street/Rue :

Suite/Bureau :

Post Office Box/Case postal :

City/ Ville :

Province/State-Province/État:

Postal/Zip Code-Code postal:

Mailing Address / Adresse postale: same as licence address/ voir adresse de la licence

Company Name/Nom de l'établissement:

Street/Rue :

Suite/Bureau :

Post Office Box/Case postal :

City/Ville :

Province/State-Province/État:

Postal/Zip Code-Code postal :

Billing Address / Adresse de facturation:

same as licence address /voir adresse de la licence same as mailing address/ voir adresse postale

Company Name/Nom de l'établissement:

Street/Rue :	Suite/Bureau :	Post Office Box/Casier postal :
City/ Ville :	Province/State-Province/État:	Postal/Zip Code-Code postal :



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Medical Device Establishment Licence Application Form
Formulaire de demande de licence d'établissement pour les instruments médicaux

Site Address List / Liste d'adresse des sites			
Company ID #/ Numéro de l'établissement: _____			
Company Name/Nom de l'établissement: _____			
Street/Rue: _____			
Suite/Bureau : _____	<table border="1"> <tr> <th align="center">Site Status / Statut du site</th> </tr> <tr> <td align="center">Active/Actif [] Inactive/Inactif []</td> </tr> </table>	Site Status / Statut du site	Active/Actif [] Inactive/Inactif []
Site Status / Statut du site			
Active/Actif [] Inactive/Inactif []			
Post Office Box/Casier postal : _____			
City/ Ville : _____			
Province/State-Province/État: _____	Postal/Zip Code postal/zip : _____		
Site Address / Adresse de site			
Company ID #/ Numéro de l'établissement: _____			
Company Name/Nom de l'établissement: _____			
Street/Rue: _____			
Suite/Bureau : _____	<table border="1"> <tr> <th align="center">Site Status / Statut du site</th> </tr> <tr> <td align="center">Active/Actif [] Inactive/Inactif []</td> </tr> </table>	Site Status / Statut du site	Active/Actif [] Inactive/Inactif []
Site Status / Statut du site			
Active/Actif [] Inactive/Inactif []			
Post Office Box/Casier postal : _____			
City/ Ville : _____			
Province/State-Province/État: _____	Postal/Zip Code postal/zip : _____		
Site Address / Adresse de site			

Company ID #/ Numéro de l'établissement: _____	
Company Name/Nom de l'établissement: _____	
Street/Rue: _____	
Suite/Bureau : _____	Site Status / Statut du site
Post Office Box/Casier postal : _____	Active/Actif [<input type="checkbox"/>] Inactive/Inactif [<input type="checkbox"/>]
City/ Ville : _____	
Province/State-Province/État: _____ Postal/Zip Code postal/zip : _____	



Health Canada Santé Canada

Medical Device Establishment Licence Application Form

Formulaire de demande de licence d'établissement pour les instruments médicaux

Please print this page off as many times as required. For all class II, III and IV medical devices please use [MDALL](#) to ensure that the manufacturer holds a valid medical device licence. / Vous pouvez imprimer cette page autant que de fois nécessaire. Pour tout instrument de classe II, III et IV, veuillez consulter le site Web [MDALL](#) pour vous assurer que le fabricant détient une licence d'établissement pour les instruments médicaux.

Manufacturers Address Form / Formulaire d'adresse des fabricants			
Company ID # / Numéro de l'établissement :			
Company name/ Nom de l'établissement :			
Street/Rue :			
Suite/Bureau : _____		Manufacturer Status / Statut du fabricant	
Post Office Box/Casier postal : _____		Active/Actif [<input type="checkbox"/>] Inactive/Inactif [<input type="checkbox"/>]	
City/ Ville : _____			
Province/State-Province / État:	Country/Pays:	Postal/Zip Code postal/zip :	
_____	_____	_____	
Risk Class / Classe de risque :			
Class / Classe I <input type="checkbox"/>	Class / Classe II <input type="checkbox"/>	Class / Classe III <input type="checkbox"/>	Class / Classe IV <input type="checkbox"/>

Manufacturers Address Form / Formulaire d'adresse des fabricants
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Annex II: Medical Device Establishment Licence Fee Form

Company Name:		
Mailing Address		
Street:	Suite:	Post Office Box:
City:	Province:	Postal Code:
Attention:		Language: English French
Telephone:	Fax:	E-Mail:
Billing Address ____ same as mailing address		
Street:	Suite:	Post Office Box:
City:	Province:	Postal Code:
Attention:		Language: English French
Telephone:	Fax:	E-Mail:

Only for applicants who have not completed their first calendar year:

“I certify that I have not completed my first calendar year of conducting activities under an establishment licence”.

Name of Authorized Signing Official	Title	Signature	Date (yyyy-mm-dd)
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For all applicants:

“I certify that the information given on this form and in any documents attached is correct, complete, and fully discloses the total Canadian revenue from the sales of products covered by the establishment licence”.

Name of Authorized Signing Official	Title	Signature	Date (yyyy-mm-dd)