Health Canada Santé Canada

Our Mandate:
To manage and deliver a national compliance and enforcement program for blood and donor semen; cells, tissues and organs; drugs (human and veterinary); medical devices and natural health products, collaborating with and across, all regions.

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.

Canada

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

Step 1: Read the Guidance on Medical Device Establishment Licensing and Medical Device Establishment Licence Fees (GUI-0016).

Guide 0016 can be found on the Health Canada website at http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/index-eng.php

Step 2: Determine if your product is a medical device. If yes, what class is it?

It is the responsibility of the applicant to determine 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. Fees for the review of the application are not refunded should it be later determined that the product(s) are not medical devices or of a different risk class.

1. Read the **DRAFT** *Guidance for the Risk-based Classification System* can be found on the Health Canada website at http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/risk5_risque5-eng.php#a32
2. If your product is a **licenced** class II, III or IV medical device, it will be listed found on www.mdall.ca.
3. If the class II, III or IV medical device cannot be found on www.mdall.ca, it is not licenced and cannot be imported or sold in Canada.
4. If further classification assistance is required, contact the Medical Device Bureau by email at device_licensing@hc-sc.gc.ca or by fax at (613) 957-6345.

Step 3: Determine your activities

Also read the Frequently Asked questions available on the Health Canada website at http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/index-eng.php and the common scenarios below.

Common scenarios & activities

Applicants in Canada	
I distribute medical devices from a supplier that is outside of Canada	Importer only
I distribute medical devices from a supplier in Canada	Distributor only
I distribute some medical devices from a supplier outside of Canada and some from a supplier in Canada	Importer and distributor (both)
Applicants outside of Canada	
I sell and/or send (distribute) medical devices to Canada and my name is **not** on the product label	Distribute only
I sell and/or send (distribute) medical devices to Canada and my name **is** on the product label	Manufacturer (see scenarios below)
Manufacturers (in & outside of Canada)	
I only distribute class I medical devices that has my	Manufacturer only

name on the label as the manufacturer	
I sell and/or distribute medical devices to Canada. I am the manufacturer listed on the label of some of the class I medical devices I sell but not all of them	Manufacturer & distributor (both)
I only distribute class II, III and/or IV medical devices that has my name on the label as the manufacturer	* Medical Device Licence (MDL) is required and NOT a MDEL. Contact Medical Device Bureau
I only distribute class I medical devices that has my name on the label as the manufacturer AND my client (importer) has an MDEL	Exempted. No need for an MDEL or MDL

Step 4: Complete the Application Form

Section 1
Company Name & Contact Information

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

- Applicant Name*: is the legal name of the person or company
- Trade Name is any other commercial company names(s) under the ownership of the Applicant Name
- Business Name Registration(s) is the Federal or Provincial Business Name Registration Numbers(s). If provincial, please specify which provinces.
- Contact Name* is the person that will be contacted by Health Canada about the licensing or licence
- Phone number and extension*
- Fax number*
- Email* is the primary form of correspondence for licensing and sharing information with stakeholders
- Language of preference

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

Section 2
Licence, Mailing and Billing Addresses

This page details the principle physical address where licensable activities occur. This is the address that will appear on the licence. This page also includes 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, Billing and Invoicing Unit (ELBIU), within 15 days of the changes.

Section 3
Classes and Activities Table

Put an X for each activity and class that applies. Use the scenarios in Step 2 and 3 to determine the activities.

Section 4
Site Address

Site: any additional building, of the same legal entity as the applicant (same corporation), 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.

Section 5
Manufacturer Information

This part of the form sees the highest amount of errors.
Errors lead to longer review times.
Please read the information below carefully.

Who is the manufacturer?

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

You are the Class I Manufacturer?

- Include your name and address in this section.

You are the distributor and/or importer of Class I medical devices?

- Provide the names and full addresses of **all** the manufacturers of the class I medical devices you will be importing or distributing as per the activities indicated on part 3.

You are an importer and/or distributor of class II, III, IV – Must do a MDALL Search

1. Visit www.mdall.ca - The MDALL (Medical Device Active Licences database) website allows you to search all licensed manufacturers of class II, III and IV medical device licences.
2. Search by device # (found on the label), product or company name as well as company ID.
3. **For each manufacturer** of class II, III and IV medical devices:
    a. Confirm that the manufacturer is licensed for all the risk classes of devices.
    b. Enter the address, as listed in MDALL.
    c. Enter the corresponding 6-digit company ID number, as listed in MDALL.

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

Section 6
Attestations

A Senior Official of the establishment applying for a licence must complete the attestations based on the activities conducted by this establishment.

- **Read each statement and annotate place an X, initial or for each applicable attestation statement. An MDEL will not be issued without completed attestations.**
- All attested to procedures must be in place.
- All establishments **must** have documented procedures pursuant to Section 45(g).
- All establishments that are Importers **must** have documented procedures pursuant to Section 45(h).

Section 7
Signature

This page is to be read carefully, signed and dated by a senior official of the establishment.

1. **The first signature is for the application.**

2. **The second signature section is only required if the establishment has not completed its first calendar year of activities under an MDEL.**

Class I Annexe

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 **amendments and annual review** applications, only provide changes to your product list in this section by indicating if it is a addition, removal or edit to an existing product.

Need help?

Establishment Licensing Questions
Email: MDEL_questions_LEPIM@hc-sc.gc.ca

Step 5: Fees

a. Fees are applicable for new and annual review applications. At this time, applications to amendment of the licence are not subject to fees.
b. Determine if you are eligible for fee deferral
c. Determine if you are eligible for fee remission. If yes, include a certified statement of revenue with this form when submitting your application to Health Canada.
d. Submit fees at the time of application**.**

Fee Deferral

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.

Fee remission

Applicants can also apply for 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

Need help?

Invoicing (Fees and Invoices) Questions
Email: ELIU_UFLE@hc-sc.gc.ca

Step 6: Submit your application, payment and fee documents

How?

- Send only one application. Chose email, fax **or** mail.
- Do not send duplicate applications.
- Always keep the records demonstrating that the application and information has been received by Health Canada before April 01, 2013. Save the email sent or cc. yourself; Keep the facsimile transaction confirmation with number of pages and our fax number; Keep all relevant shipping or mailing records.
- Always keep copies of the application and all information sent.
- To submit hard copy information such as fees related to an application previously sent by email or fax, simply print the email or fax cover page that was sent and enclose with the hard copy documents.

Where?

Email: **ELapplicationLE@hc-sc.gc.ca** (preferred)
Fax: (613) 957-6711 or (613) 957-4147

If hard-copy documents, such as cheques, must be submitted, you may submit them to the following address. If submitting hard-copy documents, please include as a cover letter a copy of the e-mail sent for reference.

Establishment Licensing, Billing and Invoicing Unit
Health Products and Food Branch Inspectorate
250 Lanark Avenue
Graham Spry Building – 2nd Floor
Address Locator 2002D
Ottawa, Ontario
K1A 0K9
Fax: 613-957-4147

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Submit the application form to: **ELapplicationLE@hc-sc.gc.ca** If hard-copy documents, such as cheques, must be submitted, you may submit them to the following address. If submitting hard-copy documents, please include a copy of the e-mail with the mailed information. This will serve as a reference. **Establishment Licensing, Billing and Invoicing 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 **Please retain a copy of the completed application in your file.**	**Envoyer le formulaire de demande a:** **ELapplicationLE@hc-sc.gc.ca** Les documents papier, comme des chèques, doivent être soumis à l'adresse ci-après accompagnés d'une copie du courriel envoyé à titre de référence en page couverture. **Unité des licences d'établissement et de facturation** Inspectorat de la Direction générale des produits de santé et des aliments 250, avenue Lanark Immeuble Graham Spry, 2e étage Indice de l'adresse 2002C Ottawa (Ontario) K1A 0K9 Téléc : 613-957-4147 **Veuillez garder une copie de l'application complétée pour vos dossiers.**

Reason for Application / Raison de la demande :
New/Nouvelle: ☐ **Amendment/Modification de la licence numéro:** ☐
Annual Review/Examen annuel ☐ **Reinstatement/Rétablissement** ☐ **Other / Autre:** ☐
_____
_____

SECTION 1 - APPLICANT INFORMATION / RENSEIGNEMENTS SUR LE DEMANDEUR

Applicant Name / Nom du demandeur:
_____
Trade Name(s)/ Dénomination(s) de commerce :
_____
Licence Number/ Numéro de l'établissement #:_____

Establishment Licence Contact Name / Nom du contact de la licence d'établissement :

Phone / téléphone : **Extension / poste :**

Fax / télécopieur :

Email / courriel :

Language / Langue : **English/Anglais** ☐ **French/Français** ☐

SECTION 2 - ADDRESSES

Establishment **Address / Adresse de l'établissement**

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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 :

SECTION 3 - ACTIVITIES / ACTIVITÉS

Read the instructions carefully and select those that apply / Lire les directives attentivement et selectioner la ou 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	☐	☐	☐

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Class / Classe II	☐	☐	
Class / Classe III	☐	☐	
Class / Classe IV	☐	☐	

SECTION 4 – SITES (buildings)

Please print this page off as many times as required / Vous pouvez imprimer cette page autant que de fois nécessaire.

Site Address List / Liste d'adresse des sites

Company ID #/ Numéro de l'établissement:_____
Company Name/Nom de l`établissement: _____
Street/Rue: _____

Suite/Bureau :_____

Post Office Box/Casier postal :_____

City/ Ville : _____

Province/State-Province/État: _____Postal/Zip Code postal/zip :_____

Site Status / Statut du site	
Active/Actif [ ]	Inactive/Inactif [ ]

Site Address / Adresse de site

Company ID #/ Numéro de l'établissement:_____

Company Name/Nom de l`établissement: _____

Street/Rue: _____

Suite/Bureau :_____

Post Office Box/Casier postal :_____

City/ Ville : _____

Province/State-Province/État: _____Postal/Zip Code postal/zip :_____

Site Status / Statut du site	
Active/Actif [ ]	Inactive/Inactif [ ]

Site Address / Adresse de site

Company ID #/ Numéro de l'établissement:_____

Company Name/Nom de l`établissement: _____

Street/Rue: _____

Suite/Bureau :_____

Post Office Box/Casier postal :_____

City/ Ville : _____

Province/State-Province/État: _____Postal/Zip Code postal/zip :_____

Site Status / Statut du site	
Active/Actif [ ]	Inactive/Inactif [ ]

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SECTION 5 - MANUFACTURERS / FABRICANTS

1. The manufacturer is who is listed on the label.
2. For all class II, III and IV medical device, verify that the manufacturer holds a valid medical device licence by searching www.MDALL.ca
3. To add manufacturers, please print as many manufacturer pages as required.

1. Le fabricant est l'établissement qui figure sur l'étiquette.
2. Pour les instruments médicaux de classe II, III et IV, effectuez une recherche sur www.mdall.ca pour vérifier que le fabricant détient une licence d'établissement valide.
3. Pour ajouter des fabricants, imprimez le nombre de pages nécessaire.

Manufacturers Address Form /Formulaire d'adresse des fabricants

Company ID # / Numéro de l'établissement :
Company name/ Nom de l`établissement :
_____
Street/Rue :
_____
Suite/Bureau :_____
Post Office Box/Casier postal : _____
City/ Ville : _____

Manufacturer Status / Statut du fabricant	
Active/Actif [ ]	Inactive/Inactif [ ]

Province/State-Province / État: _____ Country/Pays: _____ Postal/Zip Code postal/zip : _____

Risk Class / Classe de risque :

Class / Classe I ❑ Class / Classe II ❑ Class / Classe III ❑ Class / Classe IV ❑

Manufacturers Address Form / Formulaire d'adresse des fabricants

Company ID #/Numéro de l'établissement::
Company name/ Nom de l`établissement:
_____
Street/Rue:
_____
Suite/Bureau :_____
Post Office Box/Casier postal :_____
City/ Ville :

Manufacturer Status / Statut du fabricant	
Active/Actif [ ]	Inactive/Inactif [ ]

Province/State-Province/État: Country/Pays: Postal/Zip Code postal/zip :

Risk Class / Classe de risque :

Class / Classe I ❑ Class / Classe II ❑ Class / Classe III ❑ Class / Classe IV ❑

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SECTION 6 - 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.

SECTION 7 – SIGNATURE

I, the undersigned acknowledge that:

1. as a senior official of the establishment named in this application, that I have direct knowledge of the procedures in place, as confirmed by the annotation above. / En tant que dirigeant de l'établissement nommé dans la présente demande, j'atteste connaître de première main les procédures en place identifiées par les annotations ci-haut .

2. selling or importing medical devices without a valid establishment licence is in contravention of subsection 44.(1) of the Medical Devices Regulations and subject to compliance and enforcement actions/ Je reconnais que la vente ou l'importation des instruments médicaux sans licence d'établissement valide contrevient au paragraphe 44(1) du Règlement sur les instruments médicaux et est sujet aux mesures de conformité et d'application de la loi..

3. 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

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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.*

4. 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.

Signature : _____ Date : _____

Name / Nom : _____ Title / Titre : _____

Only for applicants who have not completed their first calendar year./Uniquement pour les demandeurs qui n'ont pas terminé leur première année civile :

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

« Je certifie ne pas avoir terminé ma première année civile de direction des activités en vertu d'une licence d'établissement**».**

Signature : _____ Date : _____

Name / Nom : _____ Title / Titre : _____

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Annex I: Class I Medical Devices/ Annexe I: Instruments médicaux de Classe I

Medical Device Name/ Nom de l'instrument médical	Type of Medical Device/ Type d'instrument médical	Description/ Description