

Health Products & Food Branch Inspectorate

MEDICAL DEVICE ESTABLISHMENT LICENSING

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Establishment Licensing Unit
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Establishment Licensing Overview

- f* Regulatory Basis
- f* Who Requires an Establishment Licence (EL)?
- f* Who is Exempt?
- f* What is the Process?
- f* What Are the Attestations?
- f* What is the Renewal Process?
- f* Where to Find More Information

Purpose of Medical Device Establishment Licence (MDEL)

- f* To ensure that Health Canada is aware of:
 - f* who is importing and/or selling medical devices in Canada,
 - f* 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,
 - f* the identity of manufacturers of Class I devices.

Establishment Licensing Regulatory Basis

f Medical Devices Regulations

- Sections
- 44 - Prohibition
 - 45 - Application
 - 46 - Issuance
 - 47 - Refusal
 - 48 - Notification
 - 49, 50 - Suspension
 - 51 - Reinstatement of Licence

Who Requires an EL?

f (1) No person shall import or sell a medical device unless the person holds an establishment licence.

f Unless exempted or excluded by the regulations

Who is Exempt from EL?

- f* (2) Subsection (1) does not apply to the importation or sale of a medical device by:
- f* (a) a retailer
 - f* (b) a healthcare facility,
 - f* (c) in the case of a Class II, III or IV medical device, the manufacturer of the medical device; or
 - f* (d) in the case of a Class 1 device, the manufacturer of the medical device, if the manufacturer imports or distributes solely through a person who holds a establishment licence

Exclusions

f Establishments who import or sell only:

f Custom-made devices

f Medical Devices for Special Access

f Devices for investigational testing or clinical trials

Establishment Licensing

What is the Process?

- f* Complete an application form including:
 - f* Names & addresses of
 - f* the establishment
 - f* additional sites
 - f* manufacturers (suppliers)
 - f* Attestations
 - f* Regulatory affairs contact officer (person responsible for completing the application)
 - f* Risk classes of the devices
 - f* Medical specialty associated with the devices for each supplier represented.

Company & Contact Information

Reason for application:

New/Nouvelle Amendment/Modification de la licence numéro Renewal/Renouvellement

COMPANY INFORMATION / RENSEIGNEMENTS SUR LA SOCIÉTÉ :

Company Name / Nom de l'établissement

Cole's Medical Marketing Inc.

Establishment Licence Contact Name / Nom du contact de l'établissement

Jane Smith.

Phone / téléphone: **613-888-2233**

Extension / poste: **23**

Fax / télécopieur: **613-888-2234**

E Mail / courriel: **jsmith@Colemedical.ca**

Language / Langue : **English** **Français**

Activities and Classes

	Distributor / Distributeur	Importer / Importateur	Manufacturer/ Fabricant d'instruments
Class / Classe I	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/> <input type="checkbox"/>
Class / Classe II	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Class / Classe III	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Class / Classe IV	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Attestation

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 oeuvre des procédures écrites pour :

- distribution records / les registres de distribution
- complaint handling / la manutention des plaintes
- recalls / les rappels

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 oeuvre 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 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.

Licence/ Mailing/ Billing Address



Santé Health
Canada Canada

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).

Address Information / Renseignements sur l'adresse

Company Name / Nom de l'établissement

Cole's Medical Marketing Inc.

123456

Licence Address / Adresse de la licence Address

Street/Rue :

16 Long Winding Road.

Suite/Bureau :

88

Post Office Box/Casier postal :

City/ Ville :

Toronto

Province:

ON

Postal Code postal :

A1B 2B3

Attention/ Aux soins de :

John Smith

Langue: English
Français

Telephone/ Téléphone :

613-999-2233 ext:23

Fax :

613-999-2234

E-Mail/ Adr. électr.:

jsmith@Colemedical.ca

Health Products and Food Branch Inspectorate

Inspectorat de la Direction générale des produits de santé et des
aliments



Health Canada
Santé Canada

Site Address

Site Address List / Liste d'adresse des sites

Company Name	Cole's Medical Marketing Inc.	Company ID #	123456		
Street/Rue:	22 Winding Road.	<table border="1"><tr><td>Site Status / Statut du site</td></tr><tr><td>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 []					
Suite/Bureau	88				
Post Office Box/Casier postal :					
City/ Ville :	Ottawa				
Province:	Ontario, Canada	Postal Code postal:	A1B 2B3		

Manufacturers: The Application

Manufacturers Address Form / Formulaire d'adresse des fabricants		
Company Name <u>Medovations Inc.</u>		Company ID No. <u>106874</u>
Street/Rue: <u>102 East Keefe Avenue</u>		
Suite/Bureau : _____ Post Office Box/Casier postal : _____		Manufacturer Status / Statut du fabricant Active/Actif [<input checked="" type="checkbox"/>] Inactive/Inactif [<input type="checkbox"/>]
City/Ville : <u>Milwaukee</u>		
Province: <u>WI</u>		
Country <u>United States</u>		Postal Code postal: <u>53212</u>
Risk Class / Classe de risque : (Please indicate any changes / S.V.P. identifiez les changements)		
Class / Classe I <input type="checkbox"/> Class / Classe II <input checked="" type="checkbox"/> Class / Classe III <input type="checkbox"/> Class / Classe IV <input type="checkbox"/>		
Add code numbers, here / Ajoutez les numéros de code, ici:		
Medical Specialty / Spécialités médicales Code	English Description (please see Annex A for the codes)	Description française (veuillez vous référer à l'annexe A pour des codes)
<u>80</u>	<u>General hospital</u>	

MDALL



Medical Devices Active Licence Listing

Therapeutic Products Directorate
Medical Devices Bureau

Manufacturer
MEDOVATIONS INC.

Company ID: 106874

102 EAST KEEFE AVENUE MILWAUKEE 53212 WI US

Licence Section			Device Section		Identifier Section		
Lic #	Device Class	First Issue Date	Licence Name	First Issue Date	Device Name	First Issue Date	Device Identifier
1887	2	1999 - 03 - 01	ESOPHAGEAL DILATORS	1999 - 03 - 01	DILATION SYSTEM 1214 SERIES	1999 - 03 - 01	1214-00
						1999 - 03 - 01	1214-01
						1999 - 03 - 01	1214-02
						1999 - 03 - 01	1214-03
						1999 - 03 - 01	1214-04
						1999 - 03 - 01	1214-10
				1999 - 03 - 01	ESOPHAGEAL DILATOR, MERCURY FILLED HURST STYLE	1999 - 03 - 01	1210-01
						2001 - 10 - 22	1212-10
						2001 - 10 - 22	1212-16
						2001 - 10 - 22	1212-18
						2001 - 10 - 22	1212-20
						2001 - 10 - 22	1212-22
						2001 - 10 - 22	1212-24
						2001 - 10 - 22	1212-26
						2001 - 10 - 22	1212-28
						2001 - 10 - 22	1212-30
						2001 - 10 - 22	1212-32
						2001 - 10 - 22	1212-34
						2001 - 10 - 22	1212-36

The classes of devices that this manufacturer holds a Device Licence for.

The Devices that the manufacturer holds a Device Licence for.

How to Apply for an EL

f Establishment Licensing:

http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/index_e.html

f Links to

f MDEL Guide

f Application Form

f Fee Form

f Renewal Documents

f Medical Devices Regulations:

laws.justice.gc.ca/en/f-27/sor-98-282/text.html

f MDALL: www.MDALL.ca

f Questions about the application can be sent to:

mdel_questions_lepim@hc-sc.gc.ca
Health Products and Food Branch Inspectorate

Inspectorat de la Direction générale des produits de santé et des aliments

Where to Send Your Application

- f* Establishment Licensing Unit
- f* Health Products and Food Branch Inspectorate
- f* 250 Lanark Avenue
- f* Graham Spry Building - Second Floor
- f* Address Locator 2002C
- f* Ottawa, ON K1A 0K9

f Or Fax it to: (613) 957-4147

What is the Renewal Process for an EL?

- f* All licences expire on **December 31st**
- f* If you require an EL for the upcoming year you must apply
- f* Prior to the expiry date, a summary package and a renewal request will be sent to each licence holder

What is the Renewal Process for an EL? (cont'd)

- f* The intent of the renewal process is:
 - f* to confirm the activities and suppliers
 - f* to renew the attestations that the required procedures are in place, and
 - f* to capture any changes that occurred since the previous year
- f* Fees are charged for each year a licence is issued

Establishment Licensing

What is an Amendment?

- f* Amendments are submitted for changes to an existing EL
- f* The Establishment Licensing Unit should be notified within **15** days of changes to:
 - f* name and/or address of the establishment
 - f* name, title and/or telephone number of the regulatory affairs contact person identified on the application

Establishment Licensing

Device Classification

f Review Schedule 1 of the *Medical Devices Regulations* (classification rules for medical devices)

f Call the Manufacturer

f Contact the Medical Devices Bureau

Telephone: (613) 957-1909

Fax: (613) 957-7318

E-mail: MDB_Enquiries@hc-sc.gc.ca

MDB Clients

- f* Companies that are manufacturers of Class II, III and IV devices are clients of the Medical Devices Bureau, MDB.
- f* The Establishment Licence Unit is unable to make name or address changes for companies that are MDB clients.
- f* To make changes to, or apply for a Medical Device Licence contact MDB.

Establishment Licensing

Fee Information

f Fee reduction forms are required to be completed even if a fee reduction is not being requested.

f To contact the Establishment Licence Invoicing Unit:

f

Tel: (613) 946-5141

f

Fax: (613) 957-6711

f

E-Mail: ELIU_UFLE@hc-sc.gc.ca

f The fee reduction form can be found on our website:

http://www.hc-sc.gc.ca/dnp-mps/compli-conform/licences/index_e.html
Health Products and Food Branch Inspectorate
Inspectorat de la Direction g n rale des produits de sant  et des aliments

Thank you

f Questions can be sent to:

mdel_questions_lepim@hc-sc.gc.ca

Establishment Licence Invoicing Unit:

E-Mail: ELIU_UFLE@hc-sc.gc.ca

Medical Devices Bureau

E-mail: MDB_Enquiries@hc-sc.gc.ca

Establishment Licensing on the web

http://www.hc-sc.gc.ca/dhp-mps/compli-conform/licences/index_e.html