Regulatory Operations and Enforcement Branch

Guidance to apply for a Manufacturer's Certificate to Export licenced medical devices from Canada (GUI-0097)

GUI-0097

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Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health.

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Document d'orientation pour présenter une demande de certificat du fabricant relatif à l'exportation d'instruments médicaux homologues au Canada (GUI-0097)

For more information, please contact:

Health Canada
Address Locator 0900C2, Ottawa, ON K1A 0K9
Tel.: 613-957-299
Toll free: 1-866-225-0709
Fax: 613-941-5366
TTY: 1-800-465-7735
Email: publications@hc-sc.gc.ca

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Disclaimer

This document does not constitute part of the *Food and Drugs Act* (the Act) or its regulations and in the event of any inconsistency or conflict between the 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.

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1. Purpose

This document is a guide for companies in Canada who want to obtain a Manufacturer's Certificate to Export licensed medical devices from Canada (MCE).

Issuing MCEs is **not** a regulatory requirement. It is a voluntary service provided to manufacturers by the Regulatory Operations and Enforcement Branch (ROEB) of Health Canada.

2. Scope

This guide is for anyone located in Canada who plans to get an MCE in order to export medical devices from Canada to a foreign country.

MCEs will only be issued if you are located in Canada and hold one of the following licences:

- Medical device establishment license (MDEL) – a licence for the establishment that imports or sells medical devices in Canada (for manufacturers of Class I only)

- Medical device licence (MDL) – a licence to manufacture Class II, III and IV devices (Class I devices do not require an MDL, and are instead monitored through MDELs)

MCEs cannot be issued for medical devices exported from Canada if you have invoked section 37 of the *Food and Drugs Act*, because those devices will not have the required Canadian licensing.

3. Background

Companies exporting medical devices from Canada may be asked by foreign governments or customers to supply a certificate proving that their medical devices meet Canadian regulations and can be marketed in Canada.

Health Canada's Regulatory Operations and Enforcement Branch issues these certificates as a voluntary service to the Canadian medical device industry, to make it easier to export licensed medical devices. An MCE includes an attestation by both the manufacturer and by Health Canada.

It is important to note that industry, foreign regulators, and the public can also validate an establishment licence or device licence by using the following online tools:

- For **establishment licenses**, see the Medical devices establishment licence listing (MDEL)
- For **device licences**, see the Medical Devices Active Licence Listing (MDALL)

It is the medical device licence holder's responsibility to market a safe and effective product. Issuing an MCE does not preclude Health Canada from taking regulatory action against the manufacturer of a medical device, if such action is needed.

4. How to apply for a certificate

Who can apply

An MCE can only be requested by someone who is located in Canada and who is:

- the **medical device licence** (MDL) holder for Class II, III, IV devices, or
- the manufacturer with a **medical device establishment licence** (MDEL) for Class I devices

Requirements you must meet

The Regulatory Operations and Enforcement Branch (ROEB) of Health Canada will only issue a certificate if the following requirements are met:

- the medical device has an active Canadian medical device licence (MDL) for Class II, III and IV devices, or
- the manufacturer of a Class I device has an active medical device establishment licence (MDEL)

If you do not have the necessary licence and would like to apply for one, please see:

- Medical device establishment licence application form
- Medical device licence application form (for each Class II, III and IV device)

How to apply

To apply to Health Canada for certification, you must:

1. Complete the "Manufacturer's Certificate to Export licenced medical devices from Canada (MCE)" form (see Appendix A).
2. Make a formal declaration before an authorized official (public notary or commissioner of oaths), who will notarize the form under Section (iv).
3. Send the notarized form with a copy of the necessary documentation (see below) to Health Canada.

Please print legibly on your application form. **Do not modify the form**. Do not staple the application and supporting documents together.

A single form can be filled out for exporting multiple medical devices. Include device licences for each specified Class II, III and IV medical device with your completed MCE form.

Documents you must provide with your request

- ☐ Cover letter with contact information / person
- ☐ A completed MCE application form (see Appendix A)
- ☐ A copy of all listed licences in the MCE application form (MDEL and MDL)
- ☐ If you want Health Canada to return your certificate to you by courier, include the completed bill of lading or waybill from the courier of your choice with the courier's packaging/envelope (you must complete the bill of lading before you send it to Health Canada—do not send a blank waybill)

How to complete the MCE form

You must provide the following information and declarative statement in your MCE form (Appendix A):

Section of Appendix A	Instructions
i) Devices	In this section, you must list all medical devices you wish to export from Canada under this certificate.

	For class II, III and IV – provide the device name and ID, licence name and number of **all the devices** that are listed in this section.
ii) Name and address of manufacturer	Provide the name and address of the manufacturer of the devices listed in section (i).
iii) Name and title of authorized person	Provide the name and title of the authorized official—a public notary or commissioner of oaths—who will notarize the completed MCE form.
iv) Notary acknowledgement	The form must be signed by a notary public.
v) Health Canada authorization	Office use only: An authorized Government of Canada representative must sign the form, providing approval of the Manufacturer's Certificate.

Health Canada will complete Section (v) and affix a seal for attestation.

Where to submit your application

Send your completed and notarized MCE form and supporting documentation to:

Medical Devices Compliance and Licensing Unit
Regulatory Operations and Enforcement Branch
Jeanne Mance Building, 13th floor
200 Eglantine Driveway
Address Locator #1913D
Ottawa, Ontario
K1A 0K9

Completed certificates are returned via regular mail. To speed up this process, you may include a **completed** waybill or bill of lading (from Purolator, FedEx, Loomis, UPS, Dicom, etc.) with each request.

5. Certificate approval or rejection

What happens once you apply

Once your application is received, Health Canada will review your form to ensure it is complete and meets all the requirements described in these guidelines.

Service standards for certificate approval

This is a voluntary service. We will strive to issue an MCE within 10 business days from the date on which complete information is received.

We will affix a seal on each page of the MCE issued. Each seal indicates – in large font – the year the MCE was issued.

You are responsible for making and selling a safe and effective product and providing clear instructions on how to use it properly. If Health Canada issues a certificate and your device becomes non-compliant, Health Canada will take action as required.

Refusal to issue a certificate

Heath Canada will not certify or issue an MCE if:

- Your application is incomplete.
- You do not have an active medical device licence (MDL) or a medical device establishment licence (MDEL).
- The MCE form was modified. The form must be printed and filled out as one page
- Your form is not legally notarized.
- Your medical device cannot be legally sold in Canada.
- You are not the medical device manufacturer.
- The company holding the MDL and the manufacturer are located in a country other than Canada. Documents can only be returned to a Canadian mailing address.
- The medical device is imported into Canada for packaging or labelling but is manufactured in a foreign country by a foreign manufacturer, who retains ownership of the device.

- The device was made for export only and not for use or sale in Canada under section 37 of the *Food and Drugs Act*.

If your application is rejected

You may reapply if your request is rejected for one of these reasons:

- It was incomplete. You can complete it and resend it.
- You did not have the necessary medical device licence (MDL) or medical device establishment licence (MDEL). You must first obtain the necessary licence before you can reapply.

For more information

Contact the Medical Devices Compliance and Establishment Licensing Unit:

- Phone: 613-954-6790
- Email: hc.mce.questions-cfe.sc@canada.ca

Appendix A – Form: Manufacturer's Certificate to Export licenced Medical Devices from Canada

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 the *Medical Devices Regulations* authorized under the *Food and Drugs Act*. The information you provide will help you meet the requirement of a foreign regulatory authority regarding the medical device you wish to export in accordance with section 89 of the *Medical Devices Regulations*.

In limited and specific situations, your personal information may be disclosed without your consent in accordance with subsection 8(2) of the *Privacy Act*.

This personal information collection is described in Info Source, available online at infosource.gc.ca. Refer to the personal information bank *(PIB)*.

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 the Privacy Coordinator, Privacy Management Division, at 613-355-1458 or privacy-vie.privee@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.

Please do not modify the form. If you modify the form, your application may be rejected.

Manufacturer's Certificate to Export (MCE) Licenced Medical Devices from Canada

We, the undersigned manufacturer of the following devices:

i) Devices (include the MDEL information for your class l medical device and the MDL information for Class II, III, IV medical devices)			
Device Name	Medical Device Establishment Licence # (For Class I Medical Devices)		
	Medical Device Licence (MDL) # (For Class II, III, IV Medical Device)	MDL Name	Device ID

Do hereby certify that:

a) each device is manufactured, produced and sold in Canada in accordance with the requirements of Canada's *Food and Drugs Act* and Regulations thereunder; and

b) tests have been conducted in respect of each device and that the tests indicate that the nature of the benefits claimed to be obtained through the use of each device and the performance characteristics of each device are justified.

ii) Name and address of manufacturer	
Name:	Address:

iii)

Date (YY/MM/DD) Print Name and Title of Authorized Person Signature of Authorized Person

iv) Declared before me at _____

this _____ day of _____ 20_____.

_____

A Commissioner, Notary, etc.

Place the seal of the notary here

For Office Use Only

Health Canada
Regulatory Operations and Enforcement Branch

It is hereby certified that

a) devices manufactured, produced and sold in the manner above described would not, by reason of the method of manufacture thereof, be in violation of the *Food and Drugs Act* of Canada and the Regulations thereunder; and

b) devices manufactured and sold in compliance with said *Act* and *Regulations* may be exported without restriction.

v)

Date (YY/MM/DD) Title of Authorized Health Canada Representative Name and Signature of Authorized Health Canada Representative

Appendix B – Glossary

Acronyms

MCE: Manufacturer's Certificate to Export

MDB: Medical Devices Bureau

MDEL: Medical Device Establishment Licence

MDL: Medical Device Licence

ROEB: Regulatory Operations and Enforcement Branch

Terms

These definitions explain how terms are used in this document. If there is a conflict with a definition in the *Food and Drugs Act* or associated regulations, the definition in the Act or regulations prevails.

Device: Any article, instrument, apparatus or contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in:

> (*a*) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
>
> (*b*) restoring, correcting or modifying a body function or the body structure of human beings or animals,
>
> (*c*) the diagnosis of pregnancy in human beings or animals, or
>
> (*d*) the care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring, and includes a contraceptive device but does not include a drug

Medical Device Establishment Licence (MDEL): A Medical Device Establishment Licence is separate from a Medical Device Licence and is issued for the activities of importing and selling medical devices for human use in Canada. An MDEL is issued by the Regulatory Operations and

Enforcement Branch (ROEB) of Health Canada after an establishment certifies that it meets certain requirements and Health Canada inspects it for compliance.

Medical Device Licence (MDL): An MDL is issued to the manufacturer of class II, III, or IV devices by the Medical Devices Bureau (MDB) of the Therapeutic Products Directorate based on review of scientific evidence for quality, safety and efficacy. For information on medical device licences, please contact the MDB:

E-mail: hc.devicelicensing-homologationinstruments.sc@canada.ca
Telephone: (613) 957-7285
Fax: (613) 957-6345

Appendix C – References

Food and Drugs Act

https://laws-lois.justice.gc.ca/eng/acts/f-27/

Guidance on Medical Device Establishment Licensing and Medical Device Establishment Licence Fees (GUI-0016)

https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/directives-guidance-documents-policies/guidance-medical-device-establishment-licensing-medical-device-establishment-licence-fees-guide-0016.html

Guidance on Medical Device Compliance and Enforcement (GUI-0073)

https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/medical-devices/guidance-medical-device-compliance-enforcement-0073.html

Medical Devices Regulations

https://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/

Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce

http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en