Updates to the medical device establishment licence application (FRM-0292) and instructions

MDEL Bulletin December 4, 2023, from the Medical Devices Compliance Program

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Background

On December 4, 2023, Health Canada's Regulatory Operations and Enforcement Branch revised the medical device establishment licence (MDEL) application form. The form is used to:

- apply for an MDEL
- apply for an MDEL after a cancellation
- submit changes to your existing MDEL
- cancel your MDEL
- apply for a reinstatement of your MDEL after a suspension

The intent is to include a revised definition from the medical device establishment licensing guidance (GUI-0016) and updated instructions for amendments. We have added information related to medical device shortage reporting. We also incorporated some changes to the information on small business mitigation and fees, in addition to some clarifications throughout the document.

This bulletin also describes an earlier change we made to the form to include suppliers under the manufacturer information section.

View the revised form and instructions:

- Medical device establishment licence (MDEL) application: Instructions (FRM-0292)

Key changes in the application

We made the following key changes to the application:

- updated the small business option 1 to certify that you received confirmation your small business registration or renewal has been processed, and you hold valid small business status at the time of applying
- added the option to certify if you meet the definition of a publicly funded health care institution for fee exemption
- added a note under ‘Activities’ that only an establishment located in Canada can be an importer and a reminder that only importation and distribution are licensable activities under the MDEL
- revised the definition for a site as per paragraph 45 (j) of the *Medical Devices Regulations* and MDEL guidance (GUI-0016)
- added a checkbox for site and manufacturer/supplier information, to inform us if a site, manufacturer or supplier status has changed (for example, from active to inactive)

- added a recommendation under section 7 that manufacturers and importers develop internal written procedures for reporting medical device shortages and discontinuations, and that they acknowledge their shortage reporting obligations
- revised the instructions for timeline to submit amendments outside annual licence review period and clarified that establishments can make changes before the licence is updated

Previously, section 5 was for manufacturer information. We changed this to manufacturer/supplier information. We made this change so that we may be clear on the activity(ies) you as the applicant or licence holder are conducting, in order that you may be properly licensed.

Contact us

For questions about medical device establishment licences and the application process, email the Medical Device Establishment Licence Unit: mdel.questions.leim@hc-sc.gc.ca.

For questions about invoicing and fees for an MDEL, email the Cost Recovery Invoicing Unit: criu-ufrc@hc-sc.gc.ca.

For information about methods for payment of fees and questions about your account, email the accounts receivable staff: ar-cr@hc-sc.gc.ca.

For questions about medical device shortage and discontinuation reporting, email the Medical Device Shortages Unit: MD.shortages.penurie.de.IM@hc-sc.gc.ca.

For questions about medical devices (including classification, labelling, clinical trials and obtaining a medical device licence), email the Medical Devices Directorate: meddevices-instrumentsmed@hc-sc.gc.ca.

Related links

- *Medical Devices Regulations*
- How to pay your establishment licence fees
- Small business mitigation for drugs and medical devices: How to apply for small business status

Date modified:
2023-12-04