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# Health Canada launches electronic manufacturer's certificate to export

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**MDEL Bulletin, January 4, 2022, from the Medical Devices Compliance Program**

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## Piloting an electronic manufacturer's certificate to export

Due to the impacts of the COVID-19 pandemic on the way we work, Health Canada stopped processing requests for a manufacturer's certificate to export (MCE) in March 2020. This is a paper-based process that requires a wet-ink signature from a departmental official. MCEs confirm information on valid medical device establishment licences (MDELs) and medical device licences (MDLs). This information is available online.

However, Health Canada recognizes that some manufacturers may still require an MCE to export their medical devices.

On January 5, 2022, we launched a pilot project to implement an electronic version of the MCE. Once the pilot is over, we will be replacing the paper-based process.

## Why we're launching this pilot

Due to remote working conditions implemented at the outset of the COVID-19 pandemic, Health Canada was unable to process paper-based requests for an MCE. The pandemic presented both challenges as well as opportunities for us to "build back better."

We have modernized and streamlined the MCE process to better adapt to the demand for doing business online.

Issuing an electronic MCE (eMCE) with a secure e-signature will offer the following benefits:

- continued support for Canadian manufacturers that export medical devices
- a more environmentally friendly way of doing business
- a more efficient process

## What's new

Health Canada will be posting a notice on the [MCE guidance page](#) to redirect applicants to this bulletin and eMCE process.

The eMCE application form will not be initially available online.

Applicants may request the form by emailing us at [mce.questions-cfe@hc-sc.gc.ca](mailto:mce.questions-cfe@hc-sc.gc.ca). Manufacturers may only submit completed application forms by email.

The eMCEs will be digitally signed via a secure application, which authenticates the signer's identity and proof of signing. The secure application will also prevent modifications to the certificate and forgery. Health Canada will email signed certificates back to the applicant.

The eMCE will be expanded to include medical devices that have been approved by Health Canada under the [interim order](#).

Other changes include the following:

- additional documentation, such as a cover letter and a copy of all listed licences will not be required
- a notarized form will no longer be needed
- the new eMCE application form will produce a certificate entitled "MCE/Certificate of Free Sale"

To obtain a copy of the fillable eMCE application form and instructions on how to fill it out, please contact us by email at [mce.questions-cfe@hc-sc.gc.ca](mailto:mce.questions-cfe@hc-sc.gc.ca).

## How long this pilot project will last

The eMCE pilot began on January 5, 2022, and will last for 6 months. Health Canada will be monitoring the effectiveness of the pilot and will communicate any updates through a bulletin.

We are inviting MDEL holders to share your feedback on the pilot, including the acceptability of eMCEs by foreign jurisdictions. You may email us at any time at [mce.questions-cfe@hc-sc.gc.ca](mailto:mce.questions-cfe@hc-sc.gc.ca).

We understand that there may be exceptional circumstances where an eMCE is not accepted by a foreign jurisdiction. In these cases, with a refusal document, you may contact us for an assessment of what can be done to facilitate your export objectives.

# Contact us

If you have questions about an eMCE or the application process, please contact the Medical Device Establishment Licensing Unit at [mce.questions-cfe@hc-sc.gc.ca](mailto:mce.questions-cfe@hc-sc.gc.ca).

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