GETTING COVID-19 MEDICAL DEVICES INTO CANADA

There are currently five regulatory pathways, as outlined in the table and described in more detail below. Please note that in an effort to facilitate earlier access to medical devices related to COVID-19, Health Canada is expediting the review of COVID-19 medical device submissions through any of these pathways.

Please note that a COVID-19 Medical Device is defined as a medical device that is manufactured, sold or represented for use in relation to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

	Interim Order Authorization	Device Licensing	Establishment Licensing	Special Access	Investigational Testing
Why do I choose this option for my COVID-19 medical device?	I do not currently have the Medical Device Licence / Medical Device Establishment Licence that is required to sell this device in Canada. I do not have an MDSAP certificate for my ISO 13485 quality system. There is an urgent public health need for the importation or sale of the device.	My device is not a COVID-19 medical device. I intend on marketing my Class II, III or IV device in Canada following the urgent public health need. There is no urgent public health need for this device.	I wish to import or sell a Class I COVID-19 medical device but there is **not** an imminent shortage situation for this device.	My device is intended for use on one patient in an emergency, and a suitable licensed device is not available in Canada.	I wish to sell my medical device to a qualified investigator for the purpose of conducting investigational testing.
Why should I not choose this option?	My device is not a COVID-19 medical device. There is no urgent public health need for this device.	I cannot get my COVID-19 medical device licence in time to address the urgent public health need. I do not wish to market my COVID-19 medical device in Canada beyond the urgent public health need.	There is an imminent shortage situation for my device.	I wish to sell my COVID-19 medical device in Canada commercially.	I wish to sell my COVID-19 medical device in Canada commercially.
Timeline	**Health Canada will be expediting all regulatory submissions related to COVID-19 medical devices.**				
Fees	No fee	As of April 1, 2020: Class II - $450 Class III - $7,477 Class IV - $12,851	$8,438, but the MDEL holder can qualify for a fee remission.	No fee	No fee

	Interim Order Authorization	Device Licensing	Establishment Licensing	Special Access	Investigational Testing
What do I submit?	There is no required format, but you may use the attached request form and follow the guidance provided below for submitting all supporting documentation.	A Class II, III or IV Medical Device Licence application form. Please follow the guidance below for submitting all supporting documentation.	An MDEL application form.	Application Form for Custom-Made Devices and Medical Devices for Special Access. Please follow the guidance below for submitting all supporting documentation.	Application for New Investigational Testing Authorization (ITA). Please follow the guidance below for submitting all supporting documentation.
Where do I submit?	hc.devicelicensing-homologationinstruments.sc@canada.ca Please indicate the following in the subject line of your email: COVID-19 IO Submission [name of company]	hc.devicelicensing-homologationinstruments.sc@canada.ca Please indicate the following in the subject line of your email: COVID-19 Licence Application [name of company]	Dan Donovan (dan.donovan2@canada.ca) and cc Rezaul Hoque (rezaul.hoque@canada.ca) Please indicate the following in the subject line of your email: *URGENT – COVID-19 – MDEL application for ¬ [name of company]*	hc.sapd-pasm.sc@canada.ca	hc.it-ee.sc@canada.ca
Additional information	See attached Guidance Document Applications for Medical Devices under the Interim Order for Use in Relation to COVID-19. Link to be provided by Health Canada	Guidance Document - How to Complete the Application for a New Medical Device Licence	Guidance on Medical Device Establishment Licensing and Medical Device Establishment Licence Fees)	Medical Devices – Special Access Programme	Applications for Medical Device Investigational Testing Authorizations Guidance Document - Summary

Interim Order

The *Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19* (Interim Order) provides COVID-19 medical device manufacturers an exemption from certain provisions under Part 1 of the *Medical Devices Regulations*, provided they have received an authorization for the importation or sale from Health Canada.

When Health Canada determines that there is an urgent public health need for the importation or sale of a COVID-19 medical device, the manufacturer may submit an application for authorization under the Interim Order. If an authorization is granted, the manufacturer may import or sell their COVID-19 device in Canada. The Minister may also decide to issue an expanded indication for use either to a device that has been approved through this Interim Order, or to a device that was granted a medical device licence. The authorization for importation or sale is only valid for so long as the Interim Order is in effect; Orders typically expire after a one-year period, but may be subject to renewal based on the ongoing public health need.

An application for medical devices manufactured, sold or represented for use in relation to COVID-19 shall contain sufficient information and material for the Minister to render a decision whether or not to authorize on the basis of the issuance criteria in section 5 of the Interim Order. The information required to be submitted is highlighted in section 2 (Submitting an application for a COVID-19 device) of the "Guidance Document: Applications for Medical Devices under the Interim Order for Use in Relation to COVID-19".

Although Health Canada will accept all submission formats, it would be optimal if the attached Interim Order Request Form is completed and submitted electronically with all other supporting documentation and information. Applicants are welcome to use standard document submission guidelines (i.e., the ToC format), or provide a "question and answer" style of application. Applications should be submitted to the following email address: hc.devicelicensing-homologationinstruments.sc@canada.ca.

Medical Device Licensing

Manufacturers who wish to commercialize their devices in Canada need to hold evidence that their devices are both safe and effective for the intended use under which they are represented. For Class II, III and IV medical devices, manufacturers need to register individual devices, or appropriate groupings of devices, with Health Canada in order to obtain a medical device licence, which grants them authorization to sell in Canada. Please note that a valid Medical Device Single Audit Program (MDSAP) certificate is required to support a medical device licence submission.

For more information on this regulatory pathway, please refer to Health Canada's website on medical device licensing.

Note: Medical device licensing is covered under Part 1 (General) of the *Medical Devices Regulations.*

Medical Device Establishment Licensing

For Class I medical devices, manufacturers need to register their company with Health Canada to obtain a Medical Device Establishment Licence (MDEL), which grants them authorization to manufacture, and import or distribute (sell) their Class I medical devices in Canada. Class I medical device manufacturers, however, are exempt from this requirement if they import or sell **solely** through a company who holds a MDEL.

Distributors and importers of Class I, II, III or IV medical devices are also required to obtain a MDEL prior to importing or selling a medical device in Canada. Retailers and health care facilities, however, are exempt from this requirement.

For more information, please refer to Health Canada's "Guidance on Medical Device Establishment Licensing and Medical Device Establishment Licence Fees (GUI-0016)".

Note: Medical device establishment licensing is covered under Part 1 (General) of the *Medical Devices Regulations.*

Helpful Links:

- Listing of all Medical Device Establishment Licence Holders
- Link to General information on Medical Device Establishment Licensing
- Frequently Asked Questions

Special Access

Health care professionals (HCP) may be permitted to have special access to unlicensed devices for emergency use or for unique patient circumstances (e.g., when conventional therapies have failed, are unavailable or are unsuitable to treat a patient). Only HCPs can apply for Special Access Authorization which requires the submission of a valid medical rationale. For more information, please visit the Special Access Programme website.

Note: Special access is covered under Part 2 (Custom-Made Devices and Medical Devices to Be Imported or Sold for Special Access) of the *Medical Devices Regulations.*

Investigational Testing

Investigators may be permitted to have access to unproven medical devices so that they can perform testing involving human subjects. Manufacturers that can demonstrate that their device will not seriously endanger the life, health or safety of the human subjects or users will be issued an Investigational Testing Authorization that will allow them to sell the device to an investigator to test the safety and/or effectiveness of that device in Canada. For further guidance, please refer to the "Applications for Medical Device Investigational Testing Authorizations Guidance Document".

Note: Investigational testing is covered under Part 3 (Medical Devices for Investigational Testing Involving Human Subjects) of the *Medical Devices Regulations*.

For questions regarding the regulatory pathways outlined above, please feel free to contact the Medical Devices Directorate at hc.meddevices-instrumentsmed.sc@canada.ca. Thank you.