Health Canada – COVID-19 Submissions Frequently Asked Questions (FAQs)

Q. Can importers or distributors be issued Interim Order (IO) Authorizations for importation and sale of COVID-19 medical devices?

A. No. For traceability reasons, Health Canada is striving to issue IO Authorizations to manufacturers of COVID-19 medical devices which will allow the manufacturer's information and device information on the device label to be cross-matched against the IO Authorization.

Q. Do importers and distributors require Medical Device Establishment Licences (MDELs) to import and sell COVID-19 medical devices that have been granted IO Authorization?

No. MDEL licensing requirements to not apply to the importation or sale of a COVID-19 medical device. Each shipment of a COVID-19 medical device that is imported into Canada must be accompanied by a copy of the IO Authorization. Importers should rely on this mechanism to demonstrate to Health Canada how a given shipment should be allowed access into Canada.

Q. Can an importer or distributor act as a regulatory contact or regulatory representative on behalf of a manufacturer of a COVID-19 medical device?

A. Yes. Importers and distributors can send complete IO Submissions to Health Canada and facilitate communication between Health Canada and COVID-19 manufacturers by supplying additional information and materials that are requested when processing a submission. Health Canada's expectation is that authorized regulatory representatives will be listed in the IO Request Form (Section 4).

Q. Who should sign the attestation section on the IO Request From (Section 5)?

A. A senior official from the manufacturer must sign the attestation to indicate that procedures are in place with respect to maintaining distribution records, complaint handling, incident reporting and recalls.

Q. What is the expected turnaround time for HC to review an application for a ventilator or a COVID test kit (i.e. Class III device)?

A. Processing applications for authorization of the sale of COVID-19 medical devices under the IO is our highest priority, and we are doing so as fast as possible. With the current number of applications, issuing an authorization can take anywhere from **5 to 20** days. We do strongly recommend that consultants and manufacturers review our guidance document on the IO application to assist in a smooth review of their application.

Q. Are Class 1 devices (i.e. PPE) still be required to obtain an MDEL?

A. Class I medical devices specific to the COVID-19 pandemic may be authorized for sale via the IO pathway or an MDEL. Therefore, an MDEL is not mandatory should a manufacturer obtain an IO for their Class I medical device (i.e. PPE).

Refer to the table on page 5 that outlines the differences between the two pathways.

Q. How do I get a diagnostic test, a ventilator, a PPE or other COVID-19 related medical device authorized for sale in Canada?

A. As an emergency public health measure, the Minister of Health has signed an Interim Order (IO) to allow expedited access to COVID-19-related medical devices.

You may apply for an authorization to sell medical devices related to COVID-19 through the Interim Order pathway, which applies to manufacturers of Class I to IV medical devices.
Under the IO, manufacturers will be required to submit an abbreviated application to support the safety, effectiveness and quality of their medical device. The fees associated with an application through the IO pathway will be waived. In addition, manufacturers applying through this pathway will not be required to hold a Medical Device Single Audit Programme (MDSAP) certification. This is the most effective pathway manufacturers should be following in order to apply for authorization.

Q. How do I start the application process using the Interim Order pathway?

A. If you wish to submit an application for authorization under the Interim Order, please contact the Medical Devices Directorate via email hc.devicelicensing-homologationinstruments.sc@canada.ca or call 613-324-7842.

Q. What are my obligations after I receive an Interim Order authorization for a medical device?

A. As with all drugs and medical devices, Health Canada will assess and monitor the safety and effectiveness of all products authorized under the Interim Order, and will take immediate action if required to protect the health and safety of Canadians.
Manufacturers will still be required to follow strict post-market safety requirements such as mandatory problem reporting, recall procedures and complaint handling.

Q. How does a healthcare provider get access to a diagnostic test or a medical device that is not approved in Canada?

A. Healthcare professionals can request access to COVID-19 related medical devices not yet licensed in Canada, or authorized for sale under the Interim Order pathway, through Health Canada's Special Access Program (SAP). Applications are considered on a case-by-case basis. Information on the SAP for medical devices can be found here.
For questions related to the SAP programme for medical devices, please contact the programme via email hc.sap.devices.mdb.sc@canada.ca or call 613- 946-8711. For urgent requests, please call 613-410-9186.
Health Canada published a list of diagnostic devices for use against coronavirus (COVID-19), including both authorized tests under the Minister's Interim Order and the submissions under review. The list is updated daily: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19.html.

FUNDING SUPPORT /RE-TOOLING

Q. My company has manufacturing capability to produce medical supplies to fight COVID-19, who do I talk to in the government to get help with my idea?

A. Industry, Science and Economic Development Canada (ISED) has launched a "call to action" to Canadian manufacturers to help fight COVID-19. They have created a new web page as well as an intake for manufacturers that make needed supplies, have the potential to rapidly re-tool existing facilities or equipment, or who have skilled workers that could be available to work elsewhere in Canada.

Web page:
https://www.canada.ca/en/services/business/maintaingrowimprovebusiness/manufacturers-needed.html

Generic email address: ic.mid-dim.ic@canada.ca

Q. My company has near to market solution(s)/product(s) to help fight COVID-19 and we need financial support, who do we talk to in the government?

A. National Research Council (NRC) has issued a COVID-19 "Challenge Program" to bring together a national network of researchers and scientific facilities to address the pressing needs for supplies, medical counter measures, and disease-tracking technology. Additionally, through the Industrial Research Assistance Program (IRAP), the NRC has issued a call out, leveraging its existing relationships with Canada's innovative SMEs, seeking innovative solutions and candidate for funding through Innovative Solutions Canada.
Web page: https://nrc.canada.ca/en/research-development/research-collaboration/nrc-covid-19-response
Intake form for Challenge Program: https://nrc.canada.ca/en/research-development/research-collaboration/programs/expression-interest-challenge-program-collaboration
Intake form for the IRAP: https://nrc.canada.ca/en/support-technology-innovation/covid-19-national-research-council-industrial-research-assistance-program

PROCUREMENT

Q. Once I have my COVID-19 related product authorized for sale by Health Canada, how do I get in touch with people who want to buy my health products?

A. Once your product has been authorized by Health Canada, you can complete a submission form for Coronavirus disease (COVID-19) products and services found here: https://buyandsell.gc.ca/calling-all-suppliers-help-canada-combat-covid-19. This form is for suppliers with authorization to sell in Canada that are able to provide specific products (i.e. N95 masks, gowns, gloves and other PPE) or services (i.e. nursing, food, security).
If you have questions about this form please send an email to: TPSGC.PABPMEClient-APOSMEClient.PWGSC@tpsgc-pwgsc.gc.ca.

Comparison of IO and MDEL Submission Pathways

	IO Submission	MDEL Submission
Who can apply?	Class I, II, III and IV manufacturers can apply.	Importers/distributors (of any class of device) and Class I manufacturers can apply.
Who signs the application?	Application requires manufacturer's signature.	If the applicant is the importer/distributor, the application does not require manufacturer's signature.
Who is the authorization issued to?	The IO authorization is issued to the manufacturer.	The MDEL is issued to the importer/distributor or Class I manufacturer.
What needs to be submitted?	There is no required format, but please use the attached IO Request Form and submit it along with all supporting documentation as outlined in the IO guidance.	An MDEL application form.
Is device labelling required?	Yes, must submit a copy of the device label.	No device label required.
What are the fees?	No fee.	$4,590, but the MDEL holder can qualify for a fee remission.
What are the timelines?	Aiming for expedited issuance but could take several days depending on quality of information.	Aiming to process within 24 hours.

NOTE: In light of the unprecedented demand for Personal Protective Equipment (PPE) and other medical devices to help combat COVID-19 and the extraordinary number of companies making efforts to supply these products in Canada, HC has encountered an unanticipated increase in applications for MDELs. In order to facilitate rapid access to needed supplies, HC is implementing a temporary discretionary measure by assigning MDEL applicants an interim submission number while MDEL applications continue to be processed. A submission number is not an MDEL. It is a temporary number that is being assigned to applicants that have submitted the critical information required to ensure effective oversight of the activity being licensed and will facilitate quicker access to needed products to help combat COVID-19, including at the border. Once applications are fully processed, Health Canada will contact applicants to issue or to refuse to issue an MDEL, at which time, the temporary submission number will no longer be valid.