Manufacturing Healthcare Items for the COVID-19 Response (Information Sheet)

If you are designing and/or manufacturing a medical device (as defined by Health Canada) in response to the COVID-19 pandemic, there are two requirements that must be met before you provide your design or manufactured device to a third party:

- Health Canada approval through a license or approval under the interim order
- A waiver of liability

Health Canada Approval

Types of Classes and Approvals

Class I medical devices are those devices that represent the lowest risk, such as personal protective equipment including N95 masks and face shields. An MDEL is required for Class I manufacturers.

Class II devices are items such as medical exam gloves and ventilators. Class III devices are items such as orthopedic implants. Class IV devices are items such as cardiac pacemakers. An MDL is required to all manufactures who want to provide Class II, III and IV medical devices.

In response to the COVID-19 pandemic, Health Canada has established a process under an interim order to fast track approval of all COVID-19 related medical devices that fall under any class. The approval granted under the interim order is in lieu of obtaining an MDEL or MDL, as applicable.

When a License Will Not Be Required

- Manufacturers of Class I medical devices who provide their devices directly to end users (i.e. not providing the device to an institution or business);
- If you are partnering with an institution, and the partnered institution is the deemed manufacturer and currently holds a valid Health Canada license or will apply for a valid Health Canada license;

Health Canada Approval Processes

	Expedited MDEL	Interim Order
Application	Applies to Class I medical device in relation to COVID-19	Applies to all COVID-19 medical devices
Licensing	• Step 1: Contact the ORS. • Step 2: Provide related information to the ORS and complete the MDEL application form. • Step 3: The ORS will screen for the completeness of the application.	• Step 1: Contact the ORS. • Step 2: Provide related information to the ORS. • Step 3: The ORS will screen for the completeness of the information provided.

	• Step 4: The ORS will email the completed application form to the Health Canada email account with a request to expedited review. • Step 5: Health Canada will review the application immediately, and the license will normally be issued within 24 hours.	• Step 4: The ORS will email the information to Health Canada. • Step 5: Health Canada will review the information within 24 hours.
Information	• the name and address of the establishment; • the name, title and telephone number of the representative; • a statement as to whether the activity of the establishment is importation or distribution, or both; • the names and addresses of the manufacturers of the devices; • the medical specialties; • the classes; • an attestation by a senior official of the establishment; and • the address of each building where the procedures of establishment are in place.	• the name of the device; • the class of the device; • the identifier of the device; • the name of address of the manufacturer as it appears on the device label; • the address where the device is manufactured; • the diagnosis, treatment, mitigation or prevention; • the known information in relation to the quality, safety and effectiveness of the device; • the directions for use; • an attestation by the applicant that documented procedures are in place; • a copy of the label of the device; • a description of the materials used (Class III or Class IV only); and • a list of counties, other than Canada, where the device has been sold (Class III or Class IV only).

Liability Disclaimer

What is a disclaimer of liability? What is the purpose of requiring a disclaimer?

Ontario Tech ("**University**") requires a disclaimer of liability to be entered for any medical devices manufactured and/or provided by University members in response to COVID-19.

A disclaimer of liability is any statement intended to limit the scope of rights and obligations that may be exercised and enforced by the other party. By using a disclaimer of liability, University makes no warranties and guarantees with respect to the medical devices manufactured and/or provided related to COVID-19, which can limit its exposure to damages if a harm or injury happens and represent as a voluntary waiver of right or obligation that may be owed to the other party.