



Application form for authorization of importation or sale of medical devices - COVID-19

Before completing this form, you must consult the *Guidance Document Applications for Medical Devices under the Interim Order for Use in Relation to COVID-19*.

1. Name of the device (as it appears on the label)			
2. Manufacturer information (as it appears on the label)			
Contact Name and Title:		Company ID (if known):	
Company Name:			
Telephone:	Fax:	E-mail:	
Street:		Suite:	P.O. Box:
City:	Province/State:	Country:	Postal/Zip Code:
3. Address of manufacturing site (If different from manufacturer)			
Same as Manufacturer		Other (specify below)	
Company name:		Company ID (if known):	
Street:		Suite:	P.O. Box:
City:	Province/State:	Country:	Postal/Zip Code:

4. Regulatory correspondent information

Same as Manufacturer		Other (specify below)	
Contact Name and Title:		Company ID (if known):	
Company Name:			
Telephone:	Fax:	E-mail:	
Street:		Suite:	P.O. Box:
City:	Province/State:	Country:	Postal/Zip Code:

5. Attestation

Under 4(1)(i) of the *Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19*, an applicant is required to attest to the availability of documented procedures for certain activities.

I, **the Applicant**, have objective evidence to establish that I have documented procedures in place with respect to distribution records, complaint handling, incident reporting and recalls. I submit this attestation in partial fulfillment of the application submission requirements of the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19.

I, **as a senior official** of the manufacturer of this application, hereby attest that I have direct knowledge of the item checked above and declare that these identified statements are true and that the information provided in this application and in any attached documentation is accurate and complete.

Where a person is named in Section 4 of this application, I hereby authorize that person to submit this application to the Minister on my behalf. I further authorize the Medical Devices Directorate to direct all correspondence relating to this application to the person named in Section 4 of this application.

Name: _____

Title: _____

Signature: _____

Date: _____

6. Purpose/Intended use of device

(a description of the medical conditions, purposes and uses for which the device is manufactured, sold or represented as per the device labelling.)

Empty text area for providing a description of the medical conditions, purposes and uses for which the device is manufactured, sold or represented as per the device labelling.

8. Availability of device

Quantity Available for Immediate Shipment:

Approximate Shipment Date:

Ongoing Availability:

9 . Disclosure request

As the COVID-19 pandemic situation is evolving, Health Canada would like to ensure that the most up-to-date information related to available technologies for use in the diagnosis, treatment, mitigation and prevention of COVID-19 is publically available. To that effect, Health Canada would like to make available on our website a statement indicating that your company has submitted a request for authorization under our Interim Order, and the expected device availability and timelines for Canadian acquisitions. Please select one of the following:

This certifies that **the manufacturer** (*listed in Section 2 above*) has **no objection** to the disclosure and/or publishing of the receipt of this application, for the device(s) listed above, by the Medical Devices Directorate.

This certifies that **the manufacturer** (*listed in Section 2 above*) **objects** to the disclosure and/or publishing of the receipt of this application, for the device(s) listed above, by the Medical Devices Directorate.

Name:

Title:

Signature:

Date: