



COVID-19 medical device exceptional importation and sale notification form

Before completing this form, you must consult the *DRAFT - Guidance Document Exceptional Importation and Sale for Medical Devices under the Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in relation to COVID-19*

1. 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:
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. Device information				
Name of device, components, parts and/or accessories as per product label	Licensing (Medical Device License Number or Medical Device Establishment Number)	Identifier for device (bar code, catalogue, model or part number)	Purpose/Intended use of the device (a detailed description of the medical conditions, purposes and uses for which the device is manufactured, sold or represented, as well as the performance specifications of the device if those specifications are necessary for proper use)	Description of how the device is non-compliant? (i.e. non-bilingual labelling, expired product, different intended use)

6. Signature and label submission

I, **the Applicant**, attest that the information I have provided in regards to this Notification is true and that I 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 Exceptional Importation and Sale of Medical Devices**.

I have attached labels for all devices listed on this notification:

Name: _____

Title: _____

Signature: _____

Date: _____

Please send the completed and signed form along with labels for each device to:
medicaldevices.covid19.instrumentsmedicaux@canada.ca