Health Canada Santé Canada

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COVID-19 medical device interim order authorization amendment form

Before completing this form, you must consult the Guidance Document - Interim Order No. 2 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19.

1. Name of interim order (IO) authorization being amended (as it appears on the IO authorization)

2. IO authorization number being amended (as it appears on the IO authorization)

3. Manufacturer information (as it appears on the IO authorization)

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:

Canada

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 No. 2 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, as a senior official of the manufacturer named in Item 3 of this application, hereby attest that I have direct knowledge of the items indicated above. I declare that these identified statements are true and that the information provided in this application and in any attached documentation is accurate and complete.

I, as a senior official of the manufacturer named in Item 3 of this application, hereby attest that I also providing the information and documents set out in Part 1, Section 32(4) of the Medical Devices Regulations.

Where a person is named in Item 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 Bureau to direct all correspondence relating to this application to the person named in Item 4 of this application.

Name:	Title:
Signature:	Date:

6. Proposed change(s)

Please provide safety and effectiveness evidence to support any significant changes (Refer to the *Guidance for the interpretation of significant change of a medical device* for more information on significant changes). Responses to conditions to your authorization should not be submitted as

Check if applicable	Briefly describe change(s)
☐ A change in the device name Please ensure to indicate the Device ID for any device name change.	
☐ A significant change in the labelling of the device including indication for use	
☐ A significant change in the manufacturing process, facility or equipment	

Check if applicable	Briefly describe change(s)
☐ A significant change in the manufacturing quality control procedures	
☐ A significant change in the design or performance specifications	
☐ A significant change in the materials	
☐ A change in the manufacturer name and/or address	
☐ To address a post market quality, safety, or effectiveness issue	
☐ An addition, deletion or change in device components or associated model, part or catalogue numbers	Complete Section 8 below
☐ Other Change(s)	

7. Reasons for change(s)

Please specify the nature of and reason for the proposed change(s). Indicate the Health Canada Assigned ID number(s) that are impacted by the change where applicable. A complete rationale should be included; a lack of detail may result in a deficiency letter. If there are previously submitted amendments related to this authorization that have yet to be actioned by Health Canada, briefly outline the differences between these submissions.

8. Identifier of device

(Include an identifier for each device or medical device group listed, adding additional rows as necessary)

Additions (New devices to be added to the Authorization)

Name of device, components, parts and/or accessories as per product label	identifier for device (bar code, catalogue, model or part number)	Device Risk Class (if known)	GMDN (if known)	Preferred Name Code (if known)

Deletions (Devices being removed from Authorization)

Name of device, components, parts and/or accessories as per product label	Device ID (as per the Authorization)	identifier for device (bar code, catalogue, model or part number)

Changes (This section should only be used for changes to identifiers, no physical changes to devices should be reported in this section)

Name of device, components, parts and/or accessories as per product label	Old identifier for device	New identifier for device	Device Risk Class (if known)	GMDN (if known)	Preferred Name Code (if known)