Health Canada Santé Canada

Protected B when Completed

COVID-19 medical device authorization amendment form: Application to amend an authorization for importing or selling a COVID-19 medical device

Before completing this form, you should consult Part 1.1 of the *Medical Devices Regulations* and the Medical devices for use in relation to COVID-19 guidance document.

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

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

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

Contact name and title:			Company ID (if known):
Company name:			
Telephone:		Fax:	
Email:			
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:		
Email:			
Street:		Suite:	P.O. Box:
City:	Province/state:	Country:	Postal/zip code:

5. Attestation

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.

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 Directorate 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) – reason for amendment

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 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 to the classification of the device	From Class: To Class:
☐ A change in the name of the manufacturer and/or address	Ensure that item 1 is completed
☐ A change in the name of the device (that is, previous device name no longer available for sale) Please ensure to indicate the device ID for any device name change.	New device name: (add attachment if more space is needed)
☐ A change in the identifier of the device (this includes the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family)	
☐ A change in the medical conditions, purposes or uses	
☐ A change 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 item 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 is(are) impacted by the change where applicable. A complete rationale should be included, as 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 the 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)