Health Canada Santé Canada

Protected B when completed

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

Before completing this form, you must consult the Guidance Documents - interim order no. 2 Respecting the importation and sale of medical devices for use in relation to COVID-19 as well as 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)

O Same as manufacturer O Other (specify below)

Company name:			Company ID (if known):
Telephone:	Fax:		
E-mail:			
Street:		Suite:	P.O. Box:
City:	Province/State:	Country:	Postal/Zip code:

Canada

4. Regulatory correspondent information

O Same as manufacturer O 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, **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 indicated 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.)

7. Identifier of device
(include an identifier for each device or medical device group listed, adding additional rows as necessary)

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)

8. Availability of device

Quantity Available for Immediate Shipment:

Approximate Shipment Date:

Ongoing Availability:

9. Quality management system

To remove impediments for manufacturers in this time of urgent public health need, Health Canada does not require manufacturers to provide a Medical Device Single Audit Program (MDSAP) certificate with their application for a COVID-19 medical device subject to Interim Order No. 2. Manufacturers will be required to share information to demonstrate that their products are of consistent quality and effectiveness. This can be demonstrated by either providing a copy of the manufacturer's Quality Management System certificate to ISO 13485:2016, or by submitting evidence of Good Manufacturing Practices and its proper implementation. Select one of the following:

ISO Certificate

- ○ I have submitted a valid ISO 13485:2016 QMS Certificate with this application form.

Document/File name of submitted QMS Certificate (e.g. ISO13485Cert.pdf):

Or

Quality checklist – Other evidence of quality

- ○ In lieu of a valid ISO 13485:2016 QMS Certificate, I have completed *Appendix 1: Quality Management System: Application for a COVID-19 Medical Device Screening Checklist* below as evidence of Good Manufacturing Practices and its proper implementation.

10. 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:

Appendix 1: Quality management system: Requirements for the submission of an application for a COVID-19 medical device screening checklist

Purpose: In the absence of a valid ISO 13485:2016 certificate, an application for a COVID-19 medical device should meet at the very least the following five categories and their criteria. This checklist is for manufacturers preparing supporting QMS documentation for an application for a COVID-19 medical device in the absence of a valid ISO 13485:2016 certificate.

The manufacturer should provide a documented process for each category. Ideally cross-linking how and where in the provided documentation they meet each criteria specific to the device subject to the IO application.

If the manufacturer does not provide enough objective evidence to meet one or more of the criteria below, the missing information will be requested before the application can move forward.

Exception for Class I and II devices: Under the first category Design Control, we can generally overlook weak design controls. Not all items under this category need to be provided for Class I and II devices. Emphasis will be put on design transfer and whether it is done properly so that conforming product can be produced. The Medical Device Regulations do not require design controls for Class II (and ergo Class I), but design controls are required for Class III and IV.

Under the other four categories (Quality Systems Planning, Purchasing Controls, Manufacturing and Production, and Corrective Actions and Post-Market Activities), **ALL** of the criteria need to be substantiated with some form of objective evidence for all classes of devices.

Under the list "explanation and supporting evidence": You must explain how the company conforms to the criterion and give supporting objective evidence. This documentation should be specific to the device subject to the IO application and not just generic procedures.

Quality management system: Application for a COVID-19 medical device screening checklist

Category 1: Design control This is a documented process for controlling design and development. The process should include the following criteria.	
Criteria	**Explanation and supporting evidence**
Relevant planning stages	
Identification of design inputs and product performance requirements	
Risk management activities associated with the device and its use	
Identification, review, and approval of design outputs	
Validation of design	
Control of design changes (incl. review and approval)	
Design transfer into production. Relevant records of approved design outputs, risk management, and design validation should be included where available (e.g. Design History File (DHF)).	

Category 2: Quality system planning Evidence of adequate quality planning, including but not limited to the following criteria.	
Criteria	**Explanation and supporting evidence**
Final approved specification for the product and all components, including labelling, Instructions for Use (IFU), packaging, etc. (e.g. Device Master File (DMF))	
Complete manufacturing/production process	
Implementation of risk mitigation measures in manufacturing/production	
Complete test and acceptance activities, including pass/fail criteria, for product and all components	
Validation of test and inspection methods, including statistical rationale as appropriate	
Specifications for infrastructure (e.g. controlled environments, water for injection (WFI)/deionized water (DIW), refrigerated storage, biocontrol hoods, material flow, etc.)	
Identification of retained samples required to assist stability studies and post-market investigations	
Competence/training requirements, as necessary	
Process validation requirements (e.g. master validation plan)	

Category 3: Purchasing controls Evidence of adequate purchasing controls, including but not limited to the following criteria.	
Criteria	**Explanation and supporting evidence**
Approved specifications for purchased components, products, and services	
Acceptance criteria and planned verification of purchased components, products, and services	
Documented process and procedures for evaluation and qualification of suppliers;	
Evidence of supplier evaluation and qualification	

Category 4: Manufacturing/production Documented procedures and work instructions for the following criteria	
Criteria	**Explanation and supporting evidence**
All manufacturing activities	
All in-process inspections and tests	
Maintaining traceability, including results of tests and inspections and environmental conditions as necessary (e.g. preparation of Device Master Record (DMR))	
Identification of product status (e.g. in-process, under review, nonconforming, released, etc.)	
Final review of production records and final product release	
Identification and calibration of test equipment, fixtures, jigs, etc.	
Inventory control	
Service and installation activities (as required)	
Handling, storage, and distribution including record keeping	

Category 5: Corrective actions and post-market activities Documented procedures and work instructions (as appropriate) for the following criteria	
Criteria	**Explanation and supporting evidence**
Identification, analysis, and monitoring or data sources to identify nonconformities or potential nonconformities	
Handling/disposition of in-process nonconformities (e.g. Material Review Board (MRB), Out of Spec (OOS) procedure, etc.)	
Receiving, evaluating, and investigating feedback (i.e., complaints handling)	
Detecting, evaluating, and investigating nonconformities	
Corrections and actions to prevent the recurrence of nonconformities including verification of effectiveness	
Reporting adverse events to Health Canada (i.e., mandatory problem reporting);	
Conducting and reporting advisory notices, corrections, and removals to Health Canada (i.e. recall procedures)	

The following is for MDD use only

Screened by: _____

Date: _____

O Accepted O Deficiencies