Health Canada Santé Canada

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COVID-19 medical device application form: Application for 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* (MDR) and the Medical devices for use in relation to COVID-19 guidance document. A new application for authorization under Part 1.1 of the MDR can only be submitted by a manufacturer of a COVID-19 medical device or a medical device that belongs to a category of medical devices that is on the *List of Medical Devices for an Urgent Public Health Need 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:		
Email:			
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:		
Email:			
Street:		Suite:	P.O. Box:
City:	Province/state:	Country:	Postal/zip code:

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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

Under paragraph 68.11(2)(j) of the *Medical Devices Regulations*, a manufacturer is required to attest to the availability of documented procedures for certain activities.

I, **the Manufacturer**, 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 Part 1.1 of the *Medical Devices Regulations*.

I, **as a senior official** of the manufacturer named in Section 2 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. UPHN medical device (check one only to clearly identify if your COVID-19 medical device appears under Part 1 or belongs to a category of medical devices that is set out in Part 2 of the UPHN list)

- ○ The COVID-19 medical device is set out in Part 1 of the UPHN list.
- ○ The COVID-19 medical device belongs in the following category of medical devices that is set out in Part 2 of the UPHN list.

7. 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. (Note: Failure to supply an appropriate level of detail may result in the application not being accepted for review.)

8. Licence application type (check one only)

- ○ Single device
- ○ Test kit
- ○ Medical device group
- ○ System
- ○ Medical device family
- ○ Medical device group family

9. Place of use

Is this device sold for home use? ○ Yes ○ No	Is this device an IVDD? ○ Yes ○ No

Is this device used at a point of care, such as a pharmacy, bedside or health care professional's office?
(In vitro diagnostic devices [IVDD] ONLY) ○ Yes ○ No

10. Medical devices containing drugs

10.1 Non-IVD devices containing drugs If the device contains a drug and is not an IVDD, indicate the drug identification number (DIN) or the natural product number (NPN) and complete the information listed below. If the drug does not have a DIN or NPN, please provide the drug establishment licence (DEL) number of the company from where the drug is sourced.

Brand/trade name of drug:
DIN/NPN:
Active ingredient(s):
Drug manufacturer:
DEL number:

10.2 IVDD test kits containing controlled substances If this device is an IVDD test kit containing a substance listed in Schedule I, II, III or IV of the *Controlled Drugs and Substances Act*, complete the section below.

Is this an IVDD test kit containing a controlled substance? ○ Yes ○ No
Test kit number (T.K. number):

Please note: The manufacturer will need to contact the Office of Controlled Substances to obtain a T.K. number if one has not yet been issued

11. Device history

Has this device been previously authorized for sale in Canada under the investigational testing or special access provisions of the *Medical Devices Regulations*? ○ Yes ○ No

If yes, provide the authorization number or device identification number

12. Identifier of device

(Include an identifier for each device or medical device group listed, adding additional rows as necessary. Indicate [by a check mark] if it contains ≥ 0.1% w/w of Di (2- Ethyl hexyl] Pthalate (DEHP) or is manufactured from raw materials containing or derived from bisphenol A (BPA). If the device contains material of a particle size of 1000 nanometers or less, please specify the type and size range)

Name of device, components, parts and/or accessories as per product label	Identifier for device (bar code, catalogue, model or part number)	DEHP	BPA	Device risk class (if known)	GMDN (if known)	Preferred name code (for Health Canada use only)

13. Availability of device

Quantity available for immediate shipment:

Approximate shipment date:

Ongoing availability:

14. Quality management system

To remove impediments for manufacturers of devices that are on the *List of Medical Devices for an Urgent Public Health Need in Relation to COVID-19* (UPHN list), Health Canada does not require manufacturers of devices that are on the UPHN list to provide a Medical Device Single Audit Program (MDSAP) certificate with their application for a COVID-19 medical device. To comply with paragraph 68.11(2)(h) of the MDR, 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 an MDSAP-issued QMS certificate, a copy of the manufacturer's accredited QMS certificate that demonstrates conformity to ISO 13485:2016 or by submitting evidence of good manufacturing practices and its proper implementation. Select one of the following:

MDSAP-issued QMS certificate

○ I have submitted a valid MDSAP issued QMS certificate with this application form.

Document/file name of submitted QMS Certificate (for example, ISO13485Cert.pdf):

Or

ISO certificate

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

Document/file name of submitted QMS certificate for example, 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.

15. 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 diagnosing, treating, mitigating and preventing COVID-19 is publicly available. To that effect, Health Canada may indicate on our website that this application has been received by Health Canada and is under evaluation under Part 1.1 of the MDR. 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 submitting an application for the authorization of a COVID-19 medical device screening checklist

Purpose: In the absence of a valid ISO 13485:2016 certificate, an application for the authorization of a COVID-19 medical device should meet at the very least the following 5 categories and their criteria. This checklist is for manufacturers preparing supporting QMS documentation for an application for the authorization of 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 4 categories (Quality Systems Planning, Purchasing Controls, Manufacturing and Production, and Corrective Actions and Post-Market Activities), **ALL** 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 the authorization of 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 (for example, Design History File (DHF)).	

Category 2: Quality system planning Evidence of adequate quality planning, including 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. (for example, 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 (for example, controlled environments, water for injection (WFI)/deionized water (DIW), refrigerated storage, biocontrol hoods, material flow)	
Identification of retained samples required to assist stability studies and post-market investigations	
Competence/training requirements, as necessary	
Process validation requirements (for example, master validation plan)	

Category 3: Purchasing controls Evidence of adequate purchasing controls, including 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 for example, preparation of Device Master Record (DMR))	
Identification of product status (for example, in- process, under review, nonconforming, released)	
Final review of production records and final product release	
Identification and calibration of test equipment, fixtures, jigs and so on	
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 (for example, Material Review Board (MRB), Out of Spec (OOS) procedure)	
Receiving, evaluating and investigating feedback (for instance, 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 (for instance, mandatory problem reporting)	
Conducting and reporting advisory notices, corrections and removals to Health Canada for instance, recall procedures)	

The following is for MDD use only

Screened by: _____

Date: _____

O Accepted O Deficiencies