Applications for medical device clinical trials under the Interim Order: Guidance document

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This guidance document is intended to support applicants who wish to sell or import a COVID-19 medical device for the purposes of a clinical trial (also known as investigational testing), or to conduct a clinical trial in respect of a COVID-19 medical device, as authorized under the *Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19* ("Interim Order").

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Introduction

Scope and application

This document outlines the requirements when applying for a clinical trial authorization involving a COVID-19 medical device, as defined in the Interim Order, and when conducting such a trial.

A COVID-19 medical device clinical trial may be authorized under the Interim Order or under Part 3 of the *Medical Device Regulations* (MDR). Those applying and authorized under the Interim Order would be exempt from Part 3 of the MDR and subject to certain modified requirements, including:

- Authorization of the clinical trial across its entire life-cycle;
- An expanded range of applicants who are able to apply for a medical device clinical trial authorization, which includes clinicians, academic researchers, and contract research organizations, in addition to manufacturers and importers; and
- An enhanced means to obtain informed consent, and the ability to conduct more decentralized (or virtual) trials.

The Interim Order applies to COVID-19 drugs and medical device clinical trials, which

are expected to be the predominant therapies used with respect to COVID-19. For information on COVID-19 trials involving drugs, please see Health Canada's guidance document on Applications for Drug Clinical Trials under the *Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19*.

Policy objectives

The Interim Order is intended to facilitate COVID-19 clinical trials to investigate and offer patients potential medical devices for the diagnosis, treatment, mitigation, or prevention of COVID-19, while upholding patient protections and ensuring the validity of results.

Policy statements

Health Canada is committed to prioritizing the review of clinical trial applications designed to investigate the diagnosis, treatment, mitigation and/or prevention of COVID-19.

The Interim Order provides an expedited authorization pathway:

- for new COVID-19-medical devices that are not yet licensed in Canada or other jurisdictions; and
- for COVID-19-related uses for existing devices licensed under the *Medical Device Regulations*, or under the *Interim Order Respecting the Importation and Sale of Medical Devices for use in Relation to COVID-19*.

Such measures respond to the urgent need to identify potential diagnostic, treatment, mitigation or prevention options in the context of Canada's response to the COVID-19 pandemic. However, clinical trials involving COVID-19 medical devices must still be conducted according to high ethical standards of research, and the safety of patients must be safeguarded throughout. As such, many requirements from Part 3 of the *Medical Devices Regulations* that protect those involved in the trials and those that help ensure reliability of results are duplicated in the Interim Order.

Where possible and where proper procedures are in place to monitor such activities remotely from the site, trial activities may include virtual recruitment, informed consent, monitoring and/or visits.

An authorization for importation or sale for the purposes a clinical trial under this Interim Order is subject to compliance and enforcement should Health Canada be made aware of issues of non-compliance.

Background

COVID-19 is the infectious disease caused by the most recently discovered coronavirus, SARS-CoV-2. This new virus and disease were unknown before the outbreak began, in December 2019 and have since spread around the world. COVID-19 has been known to cause respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In more severe cases, COVID-19 infection can cause pneumonia, severe acute respiratory distress syndrome, kidney failure and even death. Older people, and those with underlying medical problems like high blood pressure, heart problems or diabetes, are more likely to develop serious illness.

On March 11, 2020, the World Health Organization (WHO) declared COVID-19 a global pandemic. As there are currently no specific authorized therapies or vaccines to effectively treat or prevent COVID-19, there is an urgent need to get such therapeutic products into clinical trials. Clinical trials represent an important step in finding safe and effective treatment options for patients. The Interim Order and this guidance document have been developed to ensure that drugs that are integral to the diagnosis, treatment, mitigation or prevention of COVID-19 can be investigated efficiently within a clinical trial.

Definitions

Unless explicitly listed below or in the Interim Order, all expressions in this guidance document have the same meaning as under the MDR. A full list of applicable definitions

is available in Section 2.1.2 of the Applications for Medical Device Investigational Testing Authorizations Guidance Document.

Clinical trial	Means a study, involving human subjects (participants) for the purpose of discovering or verifying the effects of a drug, a device or a food for special dietary purpose.
Clinical trial site	Means the location where a qualified investigator conducts or monitors clinical trial activities.
COVID-19	Means the coronavirus disease 2019.
COVID-19 medical device	Means a medical device that is manufactured, sold or represented for use in relation to COVID-19.
COVID-19 medical device authorization	Means an authorization to do any of the following activities: (a) import or sell a COVID-19 medical device that is to be tested in a clinical trial; and (b) conduct a clinical trial in respect of such a device.
Incident	Means any incident involving a COVID-19 medical device that is tested in a clinical trial that (a) is related to a failure of the device or a deterioration in its quality or effectiveness, or any inadequacy in its labelling or in its directions for use; or (b) has led to the death or a serious deterioration in the state of health of a clinical trial subject, user or other person, or could do so were it to recur.
Qualified Investigator	Means a person who is a member in good standing of a professional association of persons entitled under the laws of a province to provide health care under their licence in that province and who (a) conducts a clinical trial; or (b) in the case of a clinical trial conducted by a team, is the responsible leader of that team.
Recall	In respect of a COVID-19 medical device that has been sold, means any action taken by the manufacturer, importer or distributor of the device to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness, after becoming

	aware that the device: (a) may be hazardous to health, or (b) may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety.
Research Ethics Board	Means a body that is not affiliated with an applicant for a COVID-19 medical device authorization, or a holder of such an authorization, and whose principal mandate is to approve the initiation of, and conduct periodic reviews of, biomedical research involving human subjects in order to ensure the protection of their rights, safety and well-being.

Pre-clinical trial application interactions with Health Canada

For general enquiries regarding the conduct of a COVID-19 medical device clinical trial, please contact the Investigational Testing Division of the Medical Devices Directorate by email at hc.it-ee.sc@canada.ca or by telephone at 613-941-4308.

For more involved questions regarding a COVID-19 medical device clinical trial application, particularly for those involving novel Class III and IV devices, applicants are encouraged to contact Health Canada to request a pre-clinical trial application meeting via teleconference. Health Canada will prioritize requests for advice related to COVID-19 clinical trials. Requesting a pre-clinical trial application meeting for a consultation should be submitted in writing by the applicant to the Investigational Testing Division of the Medical Devices Directorate at: hc.it-ee.sc@canada.ca.

Submitting an application for a COVID-19 medical device clinical trial

Under this Interim Order, an application may be submitted for an authorization to import and sell medical devices for use in a COVID-19 clinical trial by not only manufacturers and importers but also others such as clinicians, academia, contract research organization,

etc. For all applications, the applicant's senior official must complete, sign and date the submission.

The information can be submitted electronically, in whatever format the applicant chooses. Applicants are welcome to use standard document submission guidelines (that is: the IMDRF Table of Contents format), or to provide a "question and answer" style of application, using the criteria specified below as headers. Applications should be submitted to: hc.devicelicensing-homologationinstruments.sc@canada.ca.

The cover letter accompanying an application for a clinical trial authorization involving a COVID-19 medical device must clearly indicate the direct use of the device in relation to the SARS-CoV-2 virus, including the active role the device plays in the diagnosis, treatment, mitigation or prevention of COVID-19, the disease caused by the virus. The application must contain sufficient information to enable Health Canada to determine whether or not to issue a clinical trial authorization.

The following subsections provide greater detail about the information required in an application filed in accordance with the Interim Order. Please note that the information to be submitted for a clinical trial authorization is dependent on the risk class of the device. For the purposes of this Interim Order, all information is required to be submitted for Class II to IV COVID-19 medical devices unless otherwise stated. The applicant and qualified investigator must possess records that contain all of the information and documents required under the Interim Order and this must be kept for the duration of the Interim Order being in force.

Name and contact information of the applicant and if applicable, the importer

The name and the contact information of the applicant and importer (if different from the applicant) should include the formal mailing address, as well as telephone number(s) and email address.

Name and class of the device

The device name is the name that appears on the labelling and for which the authorization is issued under the Interim Order. It includes any information necessary for the user to identify the device and to distinguish it from similar devices. The classification is that which is attributed to the device according to the rules set out in Schedule 1 of the *Medical Devices Regulations*. When a COVID-19 medical device can be classified into more than one class, the class representing the higher risk applies.

Description of device and materials used

(Applies to Class III and IV COVID-19 medical devices)

The description of the device should always include the physical parameters and photos/diagrams (if available). If the device subject of the application is a version based on a previously authorized device, a summary of the differences in the specifications between the current device and the previous version should be provided. Specific to the requirement related to materials used in the device manufacture and packaging, a line list of the materials used in the manufacturing and packaging of the device, as well as an assessment of whether the material is patient/user contacting for any period of time, should be required. Biocompatibility testing of those materials may be required in order to render a decision on whether the Minister may issue an authorization.

Description of features of the device

(Applies to Class III and IV COVID-19 medical devices)

This section should include a description of the features of the device that permit it to be used for the medical conditions and purposes for which it will be sold by the manufacturer. A brief description of the device's design philosophy and performance specifications should be provided and linked to the objectives of the proposed clinical trial.

Identifier of the device

The identifier of the device, including 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, should be provided.

Manufacturer information

The applicant must provide the name and address of the manufacturer as it appears on the device label, including the address where the device is manufactured (if different). For greater certainty, this should be listed as the legal manufacturer of the device.

Intended use of the device

(Applies to Class III and IV COVID-19 medical devices)

The following information should be included in this section:

- intended purpose, mechanism of action, indications for use, conditions for which the device is used (the intended use statement should be *verbatim* as it appears on the device labelling);
- patient population for which the device is intended including age range, if applicable, and specific diagnoses;
- anatomical and physiological particulars related to the patient using the device, if applicable;
- whether or not the device uses an energy source and whether energy is transferred to the patient;
- the document version number and the date where the formal intended use appears.

Marketing history

(Applies to Class III and IV COVID-19 medical devices)

The applicant must provide a list of countries other than Canada where the device has been sold, the total number of units sold in those countries, a summary of any reported

problems with the device and any recalls of the device in those countries.

Quality, safety and effectiveness information

(Applies to Class III and IV COVID-19 medical devices)

The applicant must provide the known information in relation to the quality, safety and effectiveness of the device. The following non-exhaustive list is provided as a guide to inform an application. Additional information may be requested, if the information provided is deemed insufficient to grant an authorization.

a. A clear description of the device, including how it works, any accessories to be used with it, and diagrams/photos of the device;

b. A copy of the manufacturer's Quality Management System Certificate, evidence of Good Manufacturing Practices, or other;

c. A discussion of whether any components are manufactured using additive manufacturing (3D printing, laser sintering, bioprinting, etc.);

d. If this device is manufactured from or incorporates animal or human tissue or their derivative, evidence of biological safety of the device;

e. A summary of any mechanical/bench testing data performed for the device;

f. A summary of any animal testing and clinical investigations carried out with the device;

g. A summary of any biocompatibility testing performed with the device (if applicable);

h. A summary of the evidence of shelf-life and packaging validation testing (if applicable);

i. A summary of electrical safety and electromagnetic compatibility (EMC) testing (if applicable);

j. If the device is intended to be used at point of care or sold directly to a consumer,

marketing materials for the device;

k. If the device is intended to be sold in a sterile condition, a description of the sterilization method and a summary of sterilization validation testing performed;

l. A list of applicable standards used in the design/manufacture of the device;

m. Incidents with a discussion of each event and response from the manufacturer;

n. A comparison table outlining technological differences between this device and predecessors that are or were licensed in Canada (if applicable);

o. A comparison table outlining technological differences between the proposed COVID-19 medical device and any available (authorized) comparators, to the applicant's knowledge

p. If the COVID-19 medical device is, or includes software, a discussion of the software validation testing performed;

q. If the COVID-19 medical device is, or includes an *in-vitro* diagnostic device, analytical validation studies including but not limited to, specimen validation testing, sample preparation validation, the limit of detection, when applicable, inclusivity, cross reactivity (in silico analysis and cross reactivity testing), preliminary precision results (if applicable), stability of samples, preliminary reagent stability and clinical validity studies. If the in-vitro diagnostic device involves a serological test, refer also to information provided in the Guidance: Requirements for Serological Antibody Tests Submitted under the COVID-19 Interim Order.

Directions for use

The applicant must provide the directions for use, unless directions are not required for the device to be used safely and effectively. For some complex, active or powered devices, the Directions for Use may require a special Surgeon's Instruction Manual, Operator's Manual, and a User's Manual. All documents should have a control or version number clearly indicated in the document.

Attestation for post-market oversight

The applicant must provide an attestation that documented procedures are in place in respect of distribution records, complaint handling, incident reporting and recalls. Annex 1 provides a template for an attestation by an applicant.

Device label

The device label should be expressed in a legible, permanent and prominent manner, in terms that are easily understood by the intended user. If a package is too small to display all of the required information, the directions for use shall accompany the device but need not be on the outside of the package or be visible under normal conditions for sale.

Qualified investigator

(Applies to Class III and IV COVID-19 medical devices)

The applicant must provide the name of the qualified investigator and their qualifications, including training and experience. Inclusion of an academic and/or clinical *Curriculum Vitae* for the qualified investigator, as well as evidence of membership in good standing with a health care professionals' regulatory body, would be suitable.

Where a clinical trial is conducted by a team, the applicant must provide the name of the responsible leader (qualified investigator) of that team. The applicant is not required to provide Health Canada with the names and credentials of the other qualified investigators at other trial sites. However, the applicant is required to maintain this information in their records, and to make this information available to Health Canada upon request, in the event that there is a safety issue that requires traceability of the medical device.

Institution information

The applicant must provide the name and contact information of the institution at which the qualified investigator is conducting the clinical trial. The contact information should include the formal mailing address, as well as telephone number(s) and email address.

Protocol

The applicant must provide the protocol of the proposed clinical trial, indicating the number of human subjects, the number of units of the device proposed to be used for the clinical trial, the hypothesis for and objective of the clinical trial, the period of time during which the clinical trial will be carried out and a copy of the informed consent form.

Written undertaking

(Applies to Class III and IV COVID-19 medical devices)

The applicant must provide a written agreement from the lead qualified investigator to:

a. conduct the clinical trial in accordance with the protocol provided by the applicant,
b. inform a clinical trial subject of any risks and benefits associated with the use of the device, and obtain the subject's informed consent for its use, and
c. not permit the device to be used by any other person except under the direction of the qualified investigator.

The applicant and the lead QI should possess the information described in the above paragraphs but the applicant does not need to submit it in the application.

Research Ethics Board contact information

(Applies to Class III and IV COVID-19 medical devices)

For each trial site, the applicant must provide the name and contact information of the research ethics board that approved the protocol and the informed consent form. The contact information should include the formal mailing address, as well as telephone number(s) and email address.

Other pertinent information

Applicants should follow the principles of the Declaration of Helsinki and the Tri-Council Policy Statement (2nd Edition): Ethical Conduct for Research Involving Humans (2014), and conform to Good Clinical Practices as set out by ISO 14155 - *Clinical investigation of medical devices for human subjects*. This standard is generally consistent with the definitions and requirements of the Regulations; however, where inconsistencies exist, the Interim Order takes precedence.

Applications for devices that were previously authorized for investigation under a different study protocol can be cross-referenced for device specific information. The results of the previously authorized study should be provided, if available at the time the application is submitted.

For Class II, III and IV devices, the applicant and qualified investigator must possess records that contain all of the information and documents required under the Interim Order and this must be kept for the duration of the Interim Order being in force.

Issuance of authorization

Health Canada is committed to reviewing clinical trial applications and clinical trial application amendments for COVID-19 medical devices within 14 days. All additional requested information and material (including samples) is submitted to Health Canada upon request within 2 calendar days.

For further information on the review/authorization process, please consult the Applications for Medical Device Investigational Testing Authorizations Guidance Document.

The holder of the authorization cannot import or sell a COVID-19 medical devices or conduct a clinical trial with that device unless they have obtained the approval of a research ethics board at each clinical trial site.

Terms and conditions

Health Canada may, at any time, impose or amend terms and conditions on the authorization for importation or sale of COVID-19 medical devices for the purposes of clinical trials. This authority allows for flexibility in allowing a trial to proceed while attaching additional conditions or limitations on the authorization. Terms and conditions would be applied on a case-by-case basis and only to ensure appropriate oversight or to manage uncertainties or risks.

Examples could include requiring additional reporting or safety measures such as limiting the population tested based on emerging information; monitoring specific populations because of potential increased risk (for example, children); or requiring new information to characterize and mitigate new risk.

Information regarding the fulfilment of Terms and Conditions that fall outside the amendment process should be submitted in the form of a notification and include a cover letter and any supporting documentation. The notification and documentation will be reviewed to determine whether the conditions have been met. Once an authorization holder provides Health Canada with satisfactory evidence that all the terms and conditions of the original authorization have been met, Health Canada will issue a letter indicating that the terms and conditions have been fulfilled.

Post-authorization requirements

Submitting an amendment to a COVID-19 medical device clinical trial authorization

An amendment to a clinical trial authorization is required if there are any significant changes to be made to any information submitted to the Minister under section 4(2) of the Interim Order, or as a response to a request for additional information under section 10 of the Interim Order. Please refer to section 2.5 of the Applications for Medical Device Investigational Testing Authorizations Guidance Document for examples of significant changes. Note that under the Interim Order, the addition or removal of an institution where the trial is being conducted, or a change to the list of qualified investigators, would

not require an amendment to an authorization. These two changes, as well as all other changes can be implemented immediately, do not need to be submitted to Health Canada. Applicants must keep records of such changes on file.

Suspension of a clinical trial

At any time, Health Canada may suspend, in whole or in part, the authorization under the Interim Order.

For example, Health Canada will have the ability to suspend one arm, or treatment group, of a multi-arm trial, if needed, allowing the rest of the trial to proceed so that other patients can continue to receive a promising therapy. Health Canada may take this action if it has reasonable grounds to believe that any of the requirements of the original authorization are no longer met, if requested information was not submitted in the time, form and manner requested, or if the authorization holder has contravened the Interim Order or *Food and Drugs Act*.

Additional information and material

The authorization holder must supply Health Canada with additional information, materials or samples that are requested by Health Canada to enable it to issue, amend or suspend a COVID-19 medical device clinical trial authorization.

Discontinuance of a clinical trial

The authorization holder is required to notify Health Canada as soon as possible, but no later than 15 calendar days if a COVID-19 clinical trial, in its entirety, or at a clinical trial site, has been discontinued. The Applications for Medical Device Investigational Testing Authorizations Guidance Document provides greater detail on the information to be included in the notification.

A new application would be required if the authorization holder subsequently wishes to resume the trial.

Revocation of a clinical trial authorization

Mandatory revocation

Following the receipt of a notice of discontinuance by the authorization holder of a COVID-19 trial, Health Canada must cancel, in whole or in part, the authorization for importation or sale of COVID-19 medical devices for the purposes of clinical trials.

Discretionary revocation

Health Canada may, at any time, cancel in whole or in part, the authorization for importation or sale of COVID-19 medical devices for the purposes of clinical trials, if the holder of the authorization fails to provide satisfactory information following a suspension. Failure to provide satisfactory information includes not providing the requested information under section 9(2) of the Interim Order in the specified time frame or if Health Canada determines the information provided does not demonstrate that the situation giving rise to the suspension did not exist or has not been corrected.

Revocation: Notice/transparency

Following a mandatory or discretionary cancellation, Health Canada will issue a cancellation letter to the authorization holder either confirming the receipt of notice of discontinuation (mandatory cancellation) or giving reasons for the cancellation (discretionary cancellation). Information published on the authorized COVID-19 Clinical Trial database will also be updated.

Incident reporting

The holder of the COVID-19 medical device clinical trial authorization must report to Health Canada within 10 days of becoming aware, all incidents (within and outside of Canada) that:

a. are related to a failure of device or a deterioration in its quality or effectiveness, or any inadequacy in its labelling or in its directions for use; **or**

b. have led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so were it to recur.

The incident report can be submitted according to the procedure outlined for the Mandatory Medical Device Problem Reporting Form for Industry. The report should clearly state that the device was approved under this Interim Order.

The authorization holder should submit a report of the incident to Health Canada even if the clinical trial was terminated prematurely.

Record keeping

Records to confirm that the clinical trial has been conducted in accordance with the Interim Order, including the information referred to in section 4(1) of the Interim Order, must be maintained by the authorization holder for the period that this Interim Order is in force, following which further requirements will extend that retention period. This information should also be kept by the qualified investigator, to allow Health Canada to obtain the necessary information if an issue arises.

Distribution records

Distribution records are to be maintained by the holder of the authorization with respect to COVID-19 medical devices that are imported, sold or used in a clinical trial. All necessary information should be kept while the Interim Order is in force to ensure timely retrieval and rapid withdrawal of the COVID-19 medical device from the market should an issue arise.

Complaint handling

Records must be kept by the authorization holder with respect to complaint handling. Furthermore, the holder of the authorization is required to develop, maintain and implement procedures to:

a. Investigate problems in a timely manner related to the performance characteristics or

safety of the device, including any consumer complaints; and

b. Ensure effective and timely recall of the device.

Recall

Manufacturers should proactively notify Health Canada if they become aware of the need to recall a COVID-19 medical device in Canada. The procedure for recalling a COVID-19 medical device used in a clinical trial follows the same instructions that are outlined in the Guide to Recall of Medical Devices (GUI-0054) .

Following completion of the recall, the holder of the authorization should notify Health Canada of the results of the recall and all action taken to prevent the recurrence of the issue. The importer of the COVID-19 medical device may submit the above required information on behalf of the authorization holder if the information that the holder and importer submit are identical. However, the holder is required to advise Health Canada that they have permitted the importer to provide all information on the holder's behalf.

Labelling

The label must include the following information:

a. the name of the device;

b. the name and contact information of the manufacturer;

c. the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or device group family;

d. in the case of a Class III or IV device, the control number;

e. if the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the device, such as the size, net weight, length, volume or number of units;

f. an indication that the device is sterile, if the manufacturer intends the device to be

sold in a sterile condition;

g. the expiry date of the device, if the device has one, to be determined by the manufacturer on the basis of the component that has the shortest projected useful life;

h. unless self-evident to the intended user, 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;

i. the directions for use, unless directions are not required, for the device to be used safely and effectively;

j. any special storage conditions applicable to the device;

k. an indication that the device is an investigational device;

l. an indication that the device is to be used by qualified investigators only; and

m. in the case of an in vitro diagnostic device, an indication that the performance specifications of the device have not been established.

The label should be provided in both English and French. For further explanation of the labelling requirements for COVID-19 medical devices to be imported or sold for use in a clinical trial, please refer to the Applications for Medical Device Investigational Testing Authorizations Guidance Document.

Importation

Each shipment of a COVID-19 medical device imported into Canada must be accompanied by a copy of an authorization to import. This document will be issued to the applicant upon authorization under this Interim Order.

General requirements applicable to drugs and devices

Informed consent

In the context of the COVID-19 pandemic, the Interim Order enables the qualified investigator two alternate means of obtaining informed consent when clinical trial subjects are unable to consent in person and in writing:

- remote written informed consent of an individual who will participate in a clinical trial in respect of a COVID-19 medical device; or
- if written informed consent cannot be obtained, non-written informed consent through reading the contents of the informed consent form to the trial participant and receiving the individual's non-written informed consent before a witness, and subsequent attestation.

Registration

In line with existing Health Canada policy recommendations and international best practices, clinical trial authorization holders are encouraged to register their clinical trial in publically accessible registries such as Clinical Trials.gov and ISRCTN. Authorization holders are recommended to use the World Health Organization's preferred term (COVID-19) in the public or scientific title in order to make these studies easy to search. The authorization holder should notify Health Canada at hc.it-ee.sc@canada.ca within 5 days of their registration and provide the following information:

- Clinical trial registry name
- Link to clinical trial posting
- Registration number (for example, Clinicaltrials.gov Identifier – NCT#)

Health Canada maintains a list of authorized clinical trials involving COVID-19 medical devices .

Annex 1: Attestation form

Attestation

Under 4(2)(l) of the *Interim Order Respecting Clinical Trials for Medical Devices and Drugs Relating to COVID-19*, an applicant is required to attest to the availability of documented procedures for certain activities. **Check (□) the relevant attestation.**

[ ] 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 Clinical Trials for Medical Devices and Drugs Relating to COVID-19***.

I, as a senior official, hereby attest that I have direct knowledge of the item checked 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 *Item X* 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 X* of this application.

Name:

Title:

Signature:

Date:

Date modified: 2020-05-27