Guidance Document Applications for Medical Devices under the *Interim Order* for Use in Relation to COVID-19

Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

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Foreword

Guidance documents are meant to provide assistance to industry and health care professionals on how to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent, and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document ***may be*** acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant programme area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy, or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable Guidance documents.

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1. Introduction

1.1 Purpose/Overview

Health Canada has developed this guidance document in order to support the *Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19* pursuant to subsection 30.1(1) of the *Food and Drugs Act.* This *Interim Order* will allow the Department to issue expedited authorization for sale or import of medical devices to deal with the current significant risk of COVID-19 to the health and safety of Canadians.

1.2 Scope and application

This guidance document is intended to provide guidance to manufacturers and importers to organize and submit an application in a timely manner for the sale or importation of medical devices that are manufactured, sold or represented for use in relation to COVID-19. This includes a medical device that is part of a system, test kit, medical device group, medical device family or medical device group family as defined in the *Medical Devices Regulations*.

Devices that meet the defition of a COVID-19 medical device as defined in the *Interim Order*, must clearly indicate its direct use 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 guidance document also outlines manufacturers and importers responsibility to report incidents relating to COVID-19 medical devices to Health Canada, as soon as when they become aware of them. . It also provides information on what the responsibilities are of manufacturers and importers should they need to recall a device approved through this mechanism.

1.3 Policy objectives

To provide assistance to manufacturers and importers in preparing the documentation necessary to obtain authorization for the sale or importation of a COVID-19 medical device under *Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19.*

1.4 Policy statements

Manufacturers and importers are required to submit an application to Health Canada for the purpose of obtaining authorization to sell or import a COVID-19 medical device.

The *Interim Order* outlines Health Canada's expectation and the information that is required to obtain authorization to import and sell COVID-19 medical devices in Canada. Importantly, an authorization under this *Interim Order* will be granted only if Health Canada determines that there is a public health need for the importation or sale of the COVID-19 medical device submitted.

The *Interim Order* provides an expedited authorization pathway for

(i) new COVID-19-medical devices that are not yet licensed in Canada or other jurisdictions,

(ii) for COVID-19-related uses for existing devices licensed under the *Medical Device Regulations*, or under this *Interim Order*, and

(iii) for COVID-19 medical devices that leverage an authorization of a device from a trusted foreign regulatory authority, whereby the Minister would maintain the ability to request additional information on a case-by-case basis.

This expedited authorization for sale or import is not intended to apply to devices which are currently licensed, or which were previously licensed in Canada, but the licence was suspended on the grounds of safety or effectiveness concerns.

Note: The authorization for importation and sale is only valid for as long as the *Interim Order* is in effect, for a period of up to one year, unless it is renewed.

1.5 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 Wuhan, China, in December 2019. 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 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 a global pandemic related to COVID-19. Most people recover from the disease without needing special treatment, however, it appears that around 1 out of every 6 people who gets COVID-19 becomes seriously ill and develop difficulty breathing.

The *Interim Order* and this guidance document have been developed to ensure that medical devices that are integral to the diagnosis, treatment, mitigation or prevention of COVID-19 can be quickly authorized for sale or importation in order to to address the urgent public health need.

2. Guidance for implementation

Definitions

COVID-19 medical device
Means a medical device that is manufactured, sold or represented for use in relation to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Control number
A unique series of letters, numbers or symbols, or any combination of these, that is assigned to a medical device by the manufacturer and from which a history of the manufacture, packaging, labelling and distribution of a unit, lot or batch of the device can be determined.

Foreign regulatory authority
A government agency or other entity outside Canada that has a legal right to control the manufacturing, use or sale of medical devices within its jurisdiction and that may take enforcement action to ensure that medical devices marketed within its jurisdiction comply with the applicable legal requirements.

Incident
Any incident involving a COVID-19 medical device 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 patient, user or other person, or could do so were it to recur.

In Vitro Diagnostic Device (IVDD)
A medical device that is intended to be used *in vitro* for the examination of specimens taken from the body.

List of Medical Devices for Expanded Use
The List of Medical Devices for Expanded Use in Relation to the COVID-19 Pandemic that is published by the Government of Canada on its website, as amended from time to time.

Manufacturer
A person who sells a medical device under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.

Medical device
A device within the meaning of the Act, but does not include any device that is intended for use in relation to animals.

Medical device family
A group of medical devices that are made by the same manufacturer, that differ only in shape, colour, flavour or size, that have the same design and manufacturing process and that have the same intended use.

Medical device group
A medical device comprising a collection of medical devices, such as a procedure pack or tray, that is sold under a single name.

Medical device group family
A collection of medical device groups that are made by the same manufacturer, that have the same generic name specifying their intended use, and that differ only in the number and combination of products that comprise each group.

Name of the device
In respect of a medical device, includes any information necessary for the user to identify the device and to distinguish it from similar devices.

Recall
In respect of a 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

System
A medical device comprising a number of components or parts intended to be used together to fufil some or all of the device's intended functions, and that is sold under a single name.

Test kit
An *in vitro* diagnostic device that consists of reagents or articles, or any combination of these, and that is intended to be used to conduct a specific test.

Regulations
Refers to the *Medical Devices Regulations*.

Authorization for Importation or Sale

The *Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19* provides COVID-19 medical device manufacturers an exemption from the requirements under Part 1 of the *Medical Devices Regulations*, provided they have received an authorization for the importation or sale from Health Canada.

When Health Canada determines that there is an urgent public health need for the importation or sale of a COVID-19 medical device, the manufacturer may submit an application for authorization under the *Interim Order*. If an authorization is granted, the manufacturer may import or sell their COVID-19 device in Canada. The Minister may also decide to issue an expanded indication for use to a device that has either been approved through this *Interim Order*, or a device that was granted a Medical Device Licence. The authorization for importation or sale is only valid for so long as the *Interim Order* is in effect. The *Interim Order* will expire after a one year period, but may be subject to renewal based on the ongoing public health need.

Fees related to the submission of an application for a COVID-19 medical device

To remove impediments for manufacturers in this time of public health need, Health Canada will waive all application fees for COVID-19 medical devices subject to the *Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19.*

Quality Management System requirements related to the submission of an application for a COVID-19 medical device

To remove impediments for manufacturers in this time of public health need, Health Canada does not require an MDSAP certificate prior to submitting an application for COVID-19 medical devices subject to the *Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19.* Manufacturers will be required to share information to demonstrate that their products are of quality; this information is further specified below.

Submitting an application for a COVID-19 medical device

An application for medical devices manufactured, sold or represented for use in relation to COVID-19 shall contain sufficient information and material for the Minister to render a decision whether or not to issue a COVID-19 medical device authorization, on the basis of the issuance criteria in s.5 of the *Interim*

Order. This information is highlighted in section 4 of the *Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19.*

This information can be submitted electronically, in whatever manner the applicant chooses. Applicants are welcome to use standard document submission guidelines (ie: the ToC format), orto provide a "question and answer" style of application, using the criteria specified below as headers. Applications should be submitted to the following email address:

hc.devicelicensing-homologationinstruments.sc@canada.ca

Clarification on the specifics of the information required in an application filed in accordance with the *Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19* is provided below.

Name of the Device

4(1)(a) of the *Interim Order* requires including the name of the device. This is the name that appears on the labelling proper and for which the authorization shall be issued under the Order. It includes any information necessary for the user to identify the device and to distinguish it from similar devices.

Class of the Device

4(1)(b) of the *Interim Order* must specify the class of the device. This is the classification that is attributed to the device according to the rules set out in Schedule 1 of the *Medical Devices Regulations*. According to the classification scheme, Class I represents the lowest risk and Class IV represents the highest risk. For this purposes of submitting an application under the *Interim Order*, a COVID-19 medical device can be classified into more than one class, the class representing the higher risk applies.

Identifier of the Device

4(1)(c) of the *Interim Order* requires 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 be provided. For greater certainty, the definitions of each of these instances have been included above (see "Definitions").

Manufacturer information

4(1)(d) and 4(1)(e) of the *Interim Order* requires the submission of 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

4(1)(f) of the *Interim Order* requires the submission include information related to the diagnosis, treatment, mitigation, or prevention for which the COVID-19 medical device be provided. This information is crucial in establishing an understanding of the device and the device classification. 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.

Quality, Safety and Effectiveness information

4(1)(g) of the *Interim Order* requests that the applicant provide the known information in relation to the quality, safety and effectiveness of the device. To clarify the type of information that should be submitted, the following non-exhaustive list is provided as a guide to inform a submission. The Minister, under section 9 of the *Interim Order*, may request any additional information, if the information provided is deemed insufficient to render a decision whether to grant an authorization under this *Interim Order*.

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 Manufacturing 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 applicants 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 applicant has questions specific to the type of quality, safety and effectiveness information, they are urged to contact the Medical Devices Directorate, using the following email address:

hc.devicelicensing-homologationinstruments.sc@canada.ca

Directions for Use

4(1)(h) of the *Interim Order* requests that the applicant provide the directions for use, unless directions are not required for the device to be used safely and effectively. This is the information supplied to the lay person and/or the health care professional enabling them to use the device without causing unnecessary harm to themselves or another person and to achieve the desired result. The Directions for Use should be written at a level commensurate with the training of the expected users.

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

4(1)(i) of the *Interim Order* requires the applicant to provide an that documented procedures are in place in respect of distribution records, complaint handling, incident reporting and recalls. Appendix A provides an example of what Health Canada would look for in an attestation from an applicant.

Device Label

4(1)(j) of the *Interim Order* requires that the applicant provides a copy of the label of the COVID-19 medical device. This label should be expressed in a legible, permanent and prominent manner, in terms that are easily understood by the intended user. Additionally, where a package that contains a COVID-19 medical device is too small to display all the information required according to section 10 of the *Interim Order*, 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.

Materials

4(2)(a) of the *Interim Order* requires that, for Class III and IV COVID-19 medical devices, the applicant provides a description of the materials used in the manufacture and packaging of the device. Additionally, if there are any materials that are patient contacting for any period of time, biocompatibility testing of those materials may be required in order to render a decision on whether the Minister may issue an authorization.

Marketing History

4(2)(b) of the *Interim Order* requires that, for Class III and IV COVID-19 medical devices, the applicant provides a list of countries other than Canada where the device has been sold, the total number of units sold in those countries, and a summary of any reported problems with the device and any recalls of the device in those countries. This information can be provided in any format, however, summary tables are preferred.

Foreign Regulatory Approval

4(3) of the *Interim Order* stipulates that an applicant may omit the information required to be submitted in their initial application, specifically, items 4(1)(g), 4(2)(a) and 4(2)(b), if they provide evidence that their COVID-19 medical device has gained market approval by a foreign regulatory authority. This approval need not be at the National level, as Health Canada may accept approval at the State level. This evidence should include a copy of the formal approval letter issued by the authority, as well as any review summaries authored by the authority. For absolute certainty, if the Minister deems that the evidence of approval by a foreign authority is insufficient to ensure that section 5 of the *Interim Order* is met, the Minister may request additional information under section 9 of the *Interim Order*, and may also decide to issue an authorization with terms and conditions under section 7.

If a foreign jurisdiction waives all pre-market submission and evaluation requirements, this would not be considered a foreign regulatory approval for the purposes of the *Interim Order*.

Issuance of Authorization

For Health Canada to grant authorization for importation or sale of the COVID-19 medical device, all of the following conditions must be met:

a) An application is submitted to Health Canada in accordance with subsection 4(1) and if applicable subsection 4(2) of the *Interim Order*;
b) All additional requested information and material (including samples) is submitted to Health Canada upon request;
c) Health Canada has assessed the submitted information and has concluded that the applicant provided sufficient evidence to support the benefits of the COVID-19 medical device and that the benefits of the COVID-19 medical device outweighs the risks associated with it. This takes into consideration the uncertainties related to the device in the context of an urgent public health need; and
d) Health Canada determines that the health or safety of patients, users or any other person will not be unduly affected.

Submitting an amendment to a COVID-19 approval

Section 6 of the *Interim Order* states that no person can import or sell a COVID-19 if there are significant differences in the device from that which was initially submitted to Health Canada for approval under the *Interim Order*, unless the Minister has issued an amended authorization. These changes apply to any information submitted to the Minister under section 4 of this *Interim Order*, or as a response to a request for additional information under section 9.

The onus is on the authorization holder to identify and communicate these significant differences to Health Canada. It is recommended that a summary of the changes, compared to that which was initially approved, is submitted to Health Canada in electronic format using the following email address:

hc.devicelicensing-homologationinstruments.sc@canada.ca

Terms and Conditions

Due to the nature of the application and issuance of expedited authorization to deal with the significant public health risk of COVID-19, Health Canada may, at any time, impose terms and conditions on the authorization for importation or sale of COVID-19 medical devices, or amend them.

Cancellation

As per above, Health Canada may cancel the authorization for importation or sale under the following conditions if:

a) Health Canada determines that the benefits no longer outweigh the risks of the device and that the health or safety of Canadian patients, users or any other person may be unduly affected;
b) Health Canada determines that the terms and conditions imposed are not met;
c) A medical device licence is issued for the COVID-19 medical device under section 36 of the Regulations; **or**
d) The authorization for sale of a COVID-19 medical device that has been issued by a foreign regulatory authority is suspended or cancelled.

An authorization for importation or sale under the *Interim Order* is subject to compliance and enforcement should Health Canada be made aware of issues of noncompliance.

Additional Information and Material

Health Canada may, at any time, request additional information or material (including samples) from the applicant in order to ensure that the provisions under section 5 of the *Interim Order* continue to be met. This information will be used to determine whether Health Canada will move forward with the issuance, amendment or cancellation of the COVID-19 medical device authorization.

Labelling

For the express purpose of expediting access to COVID-19 medical devices to the Canadian market, Health Canada will accept labelling in either English or French at the time of application.

The following information will be required on the label:

(a) The name of the device;

Each device including a system, medical device group, medical device family, or medical device group family must have a name. The device licence is issued for (a) the device name on the label which may describe one device, (b) an administrative grouping of devices sold for convenience under a single name or (c) a grouping of devices that carry the same generic name specifying the intended use of the devices. This name permits the user to identify it and distinguish it from other devices or device types.

(b) The name and address of the manufacturer;

If more than one name appears on the label, the relationship of each name to the device must be made clear, such as in the case of private labelling agreements between the manufacturer and the distributor or importer. The device licence is issued to the manufacturer named on the label.

(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 medical device group family;

The identifier is a unique number assigned to the device by the manufacturer, which along with the name of the device, will permit a device to be distinguished from all other devices. It may be a catalogue

number, model number, or a barcode and will permit, in combination with the name, a certain level of control and traceability in the market place.

(d) In the case of a Class III or IV device, the control number;

The control number means a unique series of letters, numbers or symbols, or any combination of these, that is assigned to a COVID-19 medical device by the manufacturer and, from which the history of the manufacturing, packaging, labelling or distribution of a unit, lot or batch of finished devices can be determined. The control number allows the device to be traced from manufacture to the end user, including an individual in whom the device may have been implanted. Along with the name of the device and the identifier, it provides the highest degree of traceability.

This is a requirement for Class III and Class IV devices only. Although not mandatory for Class I and Class II devices, the control number enhances postmarket traceability.

(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;

The intent of this requirement is to provide specific information describing the package contents to the user and to enable the user to make an informed choice when comparing similar devices. The information will also allow the user to select a size suitable for his/her purposes. Units should be expressed in metric or SI units (International System of Units). When applicable, the material used in the device should be specified.

(f) If the device is sterilized by the manufacter and the manufacturer intends for it to be sold in a sterile condition, then this must be indicated on the label.

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

The life of the least stable component determines the expiration date. The expiration date must be based on the results of studies which demonstrate that the device will perform as intended and will meet its specifications until that date. The date should be expressed in the internationally accepted format (ISO 8601 Data Elements and Interchange Formats-Information Exchange-Representation of Dates and Times): year (in four digits), month (in two digits), and day (in two digits). The separator for the three portions of the date should be a hyphen (-).

(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;

This section requires the manufacturer to state succinctly what the device is intended to do and on which population subgroup the device is intended to be used, for example, "For use in adults over 18 years of age." The purposes and uses refer to the function of the device as well as to the objective intent of the manufacturer. This intent may be communicated by the labelling claims, advertising, or written or oral statements made by the manufacturer or representatives.

There are some devices for which the indications for use are commonly understood, and such labelling may not be necessary.

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

This is the information supplied to the lay person and/or the health care professional enabling them to use the device without causing unnecessary harm to themselves or another person and to achieve the desired result. The Directions for use should be written at a level commensurate with the training of the expected users.

For some complex, diagnostic, active or powered devices, the Directions for use may require a special Surgeon's Instruction Manual, Operator's Manual, and a User's Manual.

(j) any special storage conditions applicable to the device.

Some devices may deteriorate rapidly under certain environmental conditions as they relate to temperature, humidity, or light, and may need to be stored in a specified manner to prevent this deterioration. The user must be provided with this information in order to decide if such storage conditions are accessible or within their means. Storage temperatures should be provided in degrees Celsius.

Importation

Each shipment of a COVID-19 medical device imported into Canada must be accompanied by a copy of an authoritization to import. This document will be issued to the applicant upon and will facilitate transport of the COVID-19 medical device(s) across the border, as it will be used as a signal that the device has been authorized under this *Interim Order*.

Incident Reporting

The holder of the COVID-19 medical device authorization for the importation or sale of the device is to report to Health Canada within 10 days of becoming aware, all Canadian incidents 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.

A description, the frequency and the circumstances surrounding the incident is also to be provided as part of the report. The description of each type of problem should be clear and any remedial or corrective actions undertaken should be explained. The submission should clearly state that the device was approved under the *Interim Order*, and provide the *Inteirm Order* authorization number in lieu of a medical device license number.

The incident report can be submitted according to the procedure outlined in the following website:

https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/mandatory-medical-device-problem-reporting-form-industry-adverse-reaction-reporting.html

It is expected that the authorization holder submit a preliminary report to Health Canada within 10 days, followed by a final report once investigation is completed.

Expanded Use

Sections 13-15 of the *Interim Order* allow the Minister to grant an expanded indication for use or intended use, to include COVID-19 related diagnostic, treatment, mitigation or prevention claims based on known evidence. This expansion may be applied to COVID-19 medical devices authorized under this *Interim Order*, or to medical devices licensed under the *Medical Devices Regulations*.

When the Minister decides to issue an expanded use indication, it will make information publically available, related to the device approved and the new indication. This will then be published to **the List of Medical Devices for Expanded Use in Relation to COVID-19 Pandemic** that is published by the Government of Canada on its website. Additionally, if the Minister believes that a medical device authorization holder has any information in relation to the proposed expanded use of the licensed medical device or the COVID-19 medical device, the Minister may request that information and the authorization holder must provide it.

Recall

While the *Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19* does not have unique requirements related to recall, it is important to clarify that any device authorized under this *Interim Order* is subject to Mandatory Recall provisions under *The Food and Drugs Act*. In addition, while the ability for the Minister to order a mandatory recall is still available, manufacturers should proactively notify Health Canada if they become aware of the need to recall their COVID-19 medical device in Canada. The following link provides guidance to how to conduct a recall in Canada: https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/drugs/recall-policy-0016/policy.html#aa

Appendices

Appendix A – Attestation Form (Example)

ATTESTATION

Under 4(1)(i) of the *Interim Order 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. **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 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 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: _____