Health Canada Santé Canada

COVID-19 PRIVATE LABEL MEDICAL DEVICE APPLICATION FORM:
APPLICATION FOR AN AUTHORIZATION FOR THE IMPORTATION OR SALE OF A PRIVATE LABEL COVID-19 MEDICAL DEVICE

(disponible en français)

Before completing this form, you must consult the UPHN List and Medical devices for use in relation to COVID-19 guidance document (available on the website) to confirm that your device meets the requirements of a UPHN device.

1. NAME OF THE PRIVATE LABEL MEDICAL DEVICE (as it appears on the label)

2. PRIVATE LABEL 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. PRIVATE LABEL REGULATORY CORRESPONDENT INFORMATION (if applicable)

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:

4. ORIGINAL MANUFACTURER INFORMATION

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

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5. INFORMATION ON MEDICAL DEVICE MANUFACTURED BY THE ORIGINAL MANUFACTURER

Name of device:	
Device class (II, III or IV):	Authorization No.:

☐ ISO13485:2016 Certificate Number (if applicable): _____
Name of auditing organization (if applicable: _____

OR

☐ In lieu of a valid ISO 13485:2016 QMS certificate, the original manufacturer of the cross-linked medical device submitted *Appendix 1: Quality Management System: Application for a COVID-19 Medical Device Screening Checklist* as evidence of good manufacturing practices and its proper implementation in its initial application for authorization.

FOR HC USE ONLY	Near patient (Y/N):	Home use (Y/N):	Point of care (Y/N):

6. LICENCE APPLICATION TYPE (check one only)

< Single device	☐	< Test kit	☐	< Medical device group	☐
< System	☐	< Medical device family	☐	< Medical device group family	☐

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7. IDENTIFIER OF PRIVATE LABEL MEDICAL DEVICE
(include an identifier for each device or medical device group listed)

Name of device, components, parts and/or accessories as per product label	Identifier for private label medical device (bar code, catalogue, model or part number)	Corresponding identifier for medical device manufactured by original manufacturer (bar code, catalogue, model or part number)	Corresponding **device ID** as it appears on the original manufacturer's medical device authorization	GMDN (if known)

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8. ATTESTATIONS

I, the private label manufacturer, hereby attest that:

(1) I have included in this application a Declaration of Compliance (Section 9, below) with the *Medical Devices Regulations* signed by a senior official of the private label manufacturer

(2) I have included in this application a Letter of Authorization (Section 10, below) signed by a senior official of the original manufacturer

(3) I have included in this application a copy of the device label and

(4) I understand that all of the provisions of the *Food and Drugs Act* and *Medical Devices Regulations* apply to a private label medical device and private label manufacturer and are the responsibility of the private label manufacturer.

I, the private label manufacturer, also certify that the information and material included in this medical device authorization application is accurate and complete.

Name of private label manufacturer's authorized signing official:	Signature:
Title:	Date:

LABELLING: ***The private label manufacturer must include in this application a copy of the device label*****. The application should include copies of all labelling, package inserts, product brochures and file cards to be used in connection with the private label medical device, as well as copies of information and instructions for use given to practitioners and/or patients.**

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9. DECLARATION OF COMPLIANCE WITH THE *MEDICAL DEVICES REGULATIONS*

To be completed by an authorized senior official of the private label manufacturer.

DECLARATION OF COMPLIANCE
with the
MEDICAL DEVICES REGULATIONS

Name of the private label medical device: (as it appears on the label)
Name of the private label manufacturer:
Address of the private label manufacturer:

I, the private label manufacturer, hereby declare that the medical device named above is a private label medical device, as defined in the *Guidance for Industry - Private Label Medical Devices*, in that it is identical in every respect to the medical device *(name of medical device manufactured by original manufacturer)*, manufactured by *(name of the original manufacturer)* and authorized by Health Canada under Authorization No. *(authorization number for medical device manufactured by original manufacturer)*, except that the medical device named above is labelled with the private label manufacturer=s name, address and product name and identifier.

I, the private label manufacturer, hereby declare that procedures have been established and documented and will be maintained for the private label medical device named above to ensure that activities described in sections 57 to 65.1 inclusive of the *Medical Devices Regulations* regarding complaint handling, mandatory problem reporting and product recalls can be undertaken. These procedures include two-way communication links with the original manufacturer of the identical medical device. I also declare that the private label manufacturer will notify Health Canada of any recalls of the private label medical device named above.

As a senior official of the private label manufacturer, having responsibility for this Declaration of Compliance and the regulatory compliance of the medical device with the requirements of the *Medical Devices Regulations*, I hereby declare that the information I have provided in support of this application to be accurate and complete.

I, the private label manufacturer, also acknowledge that any false statement made with respect to the procedures in place, or a determination by Health Canada that the procedures are not in *place, could result in the cancellation of any medical device authorization which has been issued for the medical device subject of this Declaration of Compliance.*

Name of private label manufacturer's authorized senior official:	*Signature:*
Title:	*Date:*

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10. TEMPLATE FOR LETTER OF AUTHORIZATION

The private label device authorization application must include a letter signed by an authorized senior official of the original manufacturer on the original manufacturer letterhead in the format below.

(Original Manufacturer Letterhead)

Manager, Licensing Services Division
Medical Devices Directorate
Health Products and Food Branch
11 Holland Avenue
Address Locator: 3002A
Ottawa ON K1A 0K9

(Date)

Dear Madam or Sir,

RE:

(Name of medical device manufactured by original manufacturer):
Authorization No.:

Quality Systems (select and complete one of these sections below):

☐ Quality Systems (QS) Certificate No. (if applicable):
Name of QS Auditing Organization (if applicable):

☐ In lieu of a valid ISO 13485:2016 QMS Certificate, *Appendix 1: Quality Management System: Application for a COVID-19 Medical Device Screening Checklist* was submitted in the initial application for authorization as evidence of Good Manufacturing Practices and its proper implementation.

Please accept this letter as authorization for (*name of private label manufacturer*) and Health Canada to cross-reference the original medical device authorization application and amendment(s) and the supporting safety, effectiveness and quality systems information, held by the original manufacturer or by Health Canada, for (*name of medical device manufactured by original manufacturer*), authorized by Health Canada under Authorization No. (*authorization number for medical device manufactured by original manufacturer*), in support of medical device authorization application for (*name of private label medical device*) to be filed with the Medical Devices Directorate by (*name of private label manufacturer*). This authorization is, however, subject to all applicable regulations regarding confidentiality of such information.

I, as a senior official of the original manufacturer, attest that (*name of private label medical device*) is a private label medical device, as defined in the Guidance for Industry - Private Label Medical Devices, in that it is identical in every respect to the medical device (*name of medical device manufactured by original manufacturer*) manufactured by (*name of original manufacturer*) and authorized by Health Canada under Authorization No. (*authorization number for medical device manufactured by original manufacturer*), except that the device is labelled with the private label manufacturer's name, address and product name and identifier.

I also agree to provide, upon request from Health Canada, any additional information respecting the safety, effectiveness and quality of the aforementioned private label medical device.

Yours sincerely,

(*Signature of authorized senior official*)

(*Name and title of authorized senior official*)