Health Canada Santé Canada

APPLICATION FOR A MEDICAL DEVICE AUTHORIZATION AMENDMENT FOR A PRIVATE LABEL MEDICAL DEVICE (UPHN/NON-UPHN)

(disponible en français)

1. APPLICATION FOR:

☐ COVID-19 Private Label Medical Device Authorization Amendment (**UPHN**)	☐ COVID-19 Private Label Medical Device Authorization Amendment (**non-UPHN**)

2. NATURE OF AMENDMENT (check one only)

☐ A change in the name and/or address of the private label manufacturer **(complete Item 3 below)**	☐ A change in the name of the private label medical device **(complete Item 4 below)**	☐ Addition/change/deletion of identifier(s) of the private label medical device **(complete Item 5 below)**

3. INFORMATION ON THE CURRENTLY AUTHORIZED PRIVATE LABEL MEDICAL DEVICE

Name of device (as it appears on the current medical device authorization):		
Device Class (II, III or IV):	Authorization number:	Original manufacturer's authorization number:

4. CHANGE IN THE NAME AND/OR ADDRESS OF THE PRIVATE LABEL MANUFACTURER (complete only the information that is changing)

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:

REASON FOR CHANGE (specify the nature of the proposed change, for example, acquisition, moving, etc.):

For Medical Devices Directorate Use
Device Authorization Application Number

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5. CHANGE IN THE NAME OF THE PRIVATE LABEL MEDICAL DEVICE

Proposed new name of the private label medical device:

REASON FOR CHANGE (provide the reason for the change in name of device):

6. ADDITION / CHANGE / DELETION OF IDENTIFIER(S) OF THE PRIVATE LABEL MEDICAL DEVICE (include an identifier for each device or medical device group listed)
NOTE: Use additional pages if necessary using this same format. Catalogue pages, computer printouts, etc. will <u>not</u> be accepted.

Name of device, components, parts and/or accessories as per product label	Add = A Change = C Delete = D	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

7. FEES (for non-UPHN applications only)

☐ Please indicate that the Medical Device Application Fee Form has been included with this application form

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8. ATTESTATIONS

I, the private label manufacturer, hereby attest that: (indicate the relevant attestations)

☐ in accordance with the *Medical Devices Regulations*, the amendment described above represents a legal change in the ownership of the above-noted medical device authorization and/or a change in the private label manufacturer's address

☐ in accordance with the *Medical Devices Regulations*, the amendment described above represent a legal change in the name of the private label medical device only

I, the private label manufacturer, also 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 number _____ *(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 device identifier.

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