



APPLICATION FOR A MEDICAL DEVICE LICENCE AMENDMENT FOR A PRIVATE LABEL MEDICAL DEVICE

(disponible en français)

1. NATURE OF AMENDMENT (check one only)

<input type="checkbox"/> A change in the name and/or address of the private label manufacturer (complete Item 3 below)	<input type="checkbox"/> A change in the name of the private label medical device (complete Item 4 below)	<input type="checkbox"/> Addition/change/deletion of identifier(s) of the private label medical device (complete Item 5 below)
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2. INFORMATION ON THE CURRENTLY LICENSED PRIVATE LABEL MEDICAL DEVICE

Name of Device (as it appears on the current medical device licence):		
Device Class (II, III or IV):	Licence Number:	Original Manufacturer's Licence Number:

3. 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:	E-mail:	
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.):

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

Proposed New Name of the Private Label Medical Device:
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REASON FOR CHANGE (provide the reason for the change in name of device):

5. 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 not 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 Licence



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6. 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-note medical device licence 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 licensed by Health Canada under Licence Number _____ (*licence 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: