Health Canada Santé Canada

GUIDANCE DOCUMENT

How to Complete the Application for a New Medical Device Licence/Medical Device Licence Amendment for a Private Label Medical Device

Published by authority of the
Minister of Health

Date Adopted	2005/06/01
Revised Date	2011/02/28
Effective Date	2011/04/01

Health Products and Food Branch

Canada

Our mission is to help the people of Canada maintain and improve their health. *Health Canada*	The Health Products and Food Branch's mandate is to take an integrated approach to the management of the risks and benefits to health related products and food by: • Minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, • Promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. *Health Products and Food Branch*

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Également disponible en français sous le titre : Ligne directrice - Comment compléter une nouvelle demande d'homologation et une demande de modification d'homologation pour les instruments médicaux de marque privée

FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with the policies and governing statutes and regulations. They also serve to provide review and compliance guidance to staff, thereby ensuring that mandates are implemented in a fair, consistent and effective manner.

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 scientific justification. Alternate approaches should be discussed in advance with the relevant program 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 guidance, 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 guidances.

Document Change Log			
File Name	Guidance Document - How to Complete the Application for a New Medical Device Licence/Medical Device Licence Amendment for a Private Label Medical Device	**Replaces**	Guidance for Industry - How to Complete the Application for a New Medical Device Licence/Medical Device Licence Amendment for a Private Label Medical Device
Date	2011/04/01	**Date**	2005/06/01

Change
This document was updated to reflect the new cost recovery regulations entitled *Fees in Respect of Drugs and Medical Devices Regulations*. The new regulations exempt Private Label medical devices from review fees associated with licence applications and licence amendment applications.

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1. PURPOSE

This guidance describes how to complete an application for a new medical device licence or a medical device licence amendment for a Class II, III or IV private label medical device.

2. SCOPE

This guidance applies to applications submitted by private label manufacturers for new device licences and amendments to existing device licences for Class II, III and IV medical devices.

3. BACKGROUND

Health Canada recognizes that certain businesses, typically those who retail products to the general public, sell medical devices under their own name or trade-mark while having limited or no control over the activities covered in the definition of manufacturer (see Section 4 below). These manufacturers are commonly referred to as private label manufacturers. Although private label manufacturers may not undertake any of the activities outlined in the definition, they do fall within the definition of "manufacturer" since they sell medical devices under their own name and the tasks listed in the definition are being performed "**on their behalf**"; that is (i.e.), on behalf of the private label manufacturer. Therefore, private label manufacturers and the devices that they market must comply with the requirements of the *Medical Devices Regulations*.

This guidance is to be used in conjunction with the *Guidance for Industry - Private Label Medical Devices*, which outlines the conditions under which private label manufacturers will be able to obtain a Class II, III or IV medical device licence, utilizing safety, effectiveness and quality systems information held by the original manufacturer or in the possession of Health Canada.

4. DEFINITIONS

"Device ID" refers to the device identification number assigned by Health Canada.

"identifier" means a unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the manufacturer and that identifies it and distinguishes it from similar devices. Examples of an identifier for a device are a catalogue, model or part number.

"licence application type" means the device can be submitted either as a single device, a system, a test kit, a device group, a device family or a device group family. The term “test kit” applies only to *in vitro* diagnostic devices. For more information on licence application types, refer to the guidance document *Guidance for the Interpretation of Sections 28 to 31: Licence Application Type*.

"manufacturer" means a person who sells a medical device under their own name, or under a trade-mark, 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. “Person” includes a partnership, firm or association.

"original manufacturer" has the same meaning as “manufacturer” in the *Medical Devices Regulations*.

"private label manufacturer" means a person who sells a private label medical device under their own name or trade mark.

"private label medical device" means a medical device that is identical in every respect to a medical device manufactured by an original manufacturer and licensed by Health Canada, except that the device is labelled with the private label manufacturer’s name, address and product name and identifier.

5. TIMING OF APPLICATIONS

The private label manufacturer may submit an application for a new medical device licence for a private label medical device only **after** a medical device licence has been issued to the original manufacturer. In the case of an amendment to an existing private label medical device licence for the addition of new identifiers (for example [e.g.], catalogue numbers), the amendment application may be submitted by the private label manufacturer only **after** the corresponding identifiers (e.g., catalogue numbers) for the original manufacturer’s medical device have been licensed by Health Canada.

6. APPLICATION FORMS

To apply for a new device licence, the private label manufacturer must complete the form *Application for a New Medical Device Licence for a Private Label Medical Device*. The private label manufacturer must also ensure that Appendix 1 and Appendix 2 of this guidance are completed and signed.

To apply for a medical device licence amendment, the private label manufacturer must complete the form *Application for a Medical Device Licence Amendment for a Private Label Medical Device*.

The application forms are available on the Therapeutic Products Directorate website (http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_devices_information_e.html#forms).

The private label manufacturer must submit the application to:

Information Dissemination Unit
Licensing Services Division
Medical Devices Bureau
Health Canada
Therapeutic Products Directorate
Room 1605, Main Stats Building
Address Locator 0301H1, Tunney's Pasture
Ottawa, Ontario
K1A 0K9
Canada

7. FEES

Private label medical devices are currently exempt from Division 2 - Fees for the Examination of Medical Devices Licence Applications contained in Part 3 - Medical Devices Fees of the *Fees in Respect of Drugs and Medical Devices Regulations*. Therefore, there are no fees associated with the review of private label medical device applications or private label licence amendment applications. Health Canada will review the costs associated with service delivery every three years and will propose new or amended fees to reflect the results of that review.

Application for a New Medical Device Licence for a Private Label Medical Device

Item 1: NAME OF THE PRIVATE LABEL MEDICAL DEVICE

This is the name of the device as it appears on the product label. The device name indicated for a System, Medical device family or a Medical device group family must appear, at least in part, on the label of each of the member devices. Only one name is to be entered in Item 1.

Item 2: PRIVATE LABEL MANUFACTURER INFORMATION

This is the name and address of the private label manufacturer. A complete address would include: name and title of a contact person; Company ID (if known); telephone number, FAX number and e-mail address of the contact person; street name and number or Post Office Box; city, province or state; postal or zip code; and country. This information will be used for licensing, correspondence and financial purposes.

Item 3: PRIVATE LABEL REGULATORY CORRESPONDENT INFORMATION

All regulatory correspondence will be sent to this address (if different from Item 2), but the licence will be issued to the Private Label Manufacturer. A medical device licence application for a private label medical device can be submitted by a third party; the mailing address and name of this authorized Regulatory Correspondent will be entered here.

Item 4: ORIGINAL MANUFACTURER INFORMATION

This is the name and address of the original manufacturer. A complete address would include: name and title of a contact person; Company ID (if known); telephone number, FAX number and e-mail address of the contact person; street name and number or Post Office Box; city, province or state; postal or zip code; and country.

Item 5: INFORMATION ON MEDICAL DEVICE MANUFACTURED BY THE ORIGINAL MANUFACTURER

This is the information on the medical device manufactured by the original manufacturer. Indicate the name of the device, device risk class (II, III or IV), medical device licence number (issued by Health Canada), quality systems certificate number, and name of the quality systems registrar.

Item 6: LICENCE APPLICATION TYPE

The following represent the device licence application "types" a manufacturer may apply for:

A single medical device:
A medical device that is identified by a unique device name, is sold as a distinct packaged entity and does not meet the criteria for a medical device group, a medical device family, a medical device group family, a system, or a test kit. It may be offered in a range of package sizes, and is represented by a unique device name. Examples might include: an acupuncture needle, an aneurysm clip, a larynx prosthesis or dental cement.

A medical device family:
Means 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. Examples might include: intra vascular catheters, insulin syringes, feeding tubes or vascular access grafts.

A medical device group:
Means a medical device comprising a collection of medical devices, such as a procedure pack or tray, that is sold under a single name. Examples might include: a denture repair kit, a declotting tray, a parenteral administration kit or disposable circumcision tray.

A medical device group family:
Means 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. Examples might include: IV administration sets, dressing trays, contact lens care kits or irrigation trays.

System:
Means a medical device comprising a number of components or parts intended to be used together to fulfil some or all of the device's intended functions, and that is sold under a single name and are manufactured by the same manufacturer. Examples might include hip prostheses, knee prostheses or an ultrasonic imaging system.

Test Kit:
Means 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.

For further assistance in ascertaining the appropriate licence application type for your product, consult the *Guidance for the Interpretation of Sections 28 to 31: Licence Application Type*.

Item 7: IDENTIFIER OF PRIVATE LABEL MEDICAL DEVICE

Only devices, components, parts and accessories listed on the application will be considered for licensing. If additional room is required, photocopy the Item 7 page and attach it to the application.

All columns must be completed (with the exception of the Preferred Name Code column, which is for Health Canada use only).

For a **single device**, enter the name of the device in the first column and enter the identifier for the device (bar code, catalogue, model or part number) in the second column.

For a **medical device group**, a **medical device family**, or a **medical device group family**, the names of the constituent members must be listed in the first column. Associated identifiers must be entered in the second column.

For **systems** and **test kits**, every component name must be listed in the first column. Associated identifiers must be entered in the second column.

Refer to the definitions of "Device ID" and "identifier" in Section 4 of this guidance.

Item 8: ATTESTATIONS

This item must be completed and signed by an authorized senior official of the private label manufacturer.

The private label manufacturer must include in the 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.

Appendix 1: Template for the Declaration of Compliance with the *Medical Devices Regulations*

This template must be completed by an authorized senior official of the private label manufacturer in respect of each device licence application. The completed template must be included in the application.

Appendix 2: Template for Letter of Authorization

The private label device licence application must include a letter signed by an authorized senior official of the original manufacturer on the ***original manufacturer's letterhead*** in the format prescribed in Appendix 2.

Application for a Medical Device Licence Amendment for a Private Label Medical Device

Item 1: NATURE OF AMENDMENT

The applicable type of amendment must be indicated on the form: a change in the name and/or address of the private label manufacturer; a change in the name of the private label medical device; **or** addition/change/deletion of identifier(s) of the private label medical device.

The private label manufacturer must submit a **separate** application for **each** amendment.

Item 2: INFORMATION ON THE CURRENTLY LICENSED PRIVATE LABEL MEDICAL DEVICE

This is the information on the currently licensed private label medical device. Indicate the name of the device, device risk class (II, III or IV) and medical device licence number (issued by Health Canada) for the private label medical device.

Item 3: CHANGE IN THE NAME AND/OR ADDRESS OF THE PRIVATE LABEL MANUFACTURER

Only the new information is to be provided (i.e., new name and/or address of the private label manufacturer). A reason for the change must also be provided (e.g., acquisition, merger, buy-out, moving, etc.).

Item 4: CHANGE IN THE NAME OF THE PRIVATE LABEL MEDICAL DEVICE

The new name of the private label medical device must be provided with a reason for the change.

Item 5: ADDITION/CHANGE/DELETION OF IDENTIFIER(S) OF THE PRIVATE LABEL MEDICAL DEVICE

Only devices, components, parts and accessories listed on the application will be considered for amendment. Use additional pages if necessary using the same format as shown in Item 5. Catalogue pages, computer printouts, etc. will **not** be accepted.

Indicate whether an identifier of a device is being added, changed or deleted, by using an A, C or D, respectively.

All columns must be completed.

Refer to the definitions of "Device ID" and "identifier" in Section 4 of this guidance.

Item 6: ATTESTATIONS

This item must be completed and signed by an authorized senior official of the private label manufacturer.

APPENDIX 1 Template for the 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 licensed by Health Canada under Licence No. _____ *(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 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 suspension of any medical device licence 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:*

APPENDIX 2 *Template for Letter of Authorization. The private label device licence application must include a letter signed by an authorized senior official of the original manufacturer on the* ***original manufacturer's letterhead*** *in the format below.*

(Original Manufacturer's Letterhead)

Manager, Licensing Services Division
Medical Devices Bureau
Therapeutic Products Directorate
Health Products and Food Branch
Health Canada
1st Floor, Main Stats Building
Tunney's Pasture Address Locator: 0301H1
Ottawa, Ontario
K1A 0K9

(Date)

Dear Madam or Sir:

RE: (Name of medical device manufactured by original manufacturer)
Licence No. xxxx
Quality Systems (QS) Certificate No. xxxx
Name of QS Registrar:

Please accept this letter as authorization for (name of private label manufacturer) and Health Canada to cross-reference the original medical device licence 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), licensed by Health Canada under Licence No. (licence number for medical device manufactured by original manufacturer), in support of medical device licence application for (name of private label medical device) to be filed with the Therapeutic Products 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 licensed by Health Canada under Licence No. (licence 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)