# Fax-back (minor change) application content and classification guidance

Health Canada Santé Canada

Canada

**Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health.** Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

Également disponible en français sous le titre :
Lignes directrices sur le contenu et la classification des demandes d'homologation d'instruments à retourner par télécopieur (changement mineur)

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# Table of Contents

# Chapter 1: Regional administrative

Folder name: 1-REGADMIN

**Note:** No files or content should be included at this level. Only sub-folders of this folder should contain documents.

## 1.01 Cover Letter

Folder name: 1.01-CoverLetter

### IMDRF common content

a) The cover letter should state applicant or sponsor name and/or their authorized representative, the type of submission, the common name of the device (if applicable), device trade name or proprietary name (both of the base device and a new name if one is given to the new version/model of the device) and include the purpose of the application, including any changes being made to existing approvals

b) If applicable and accepted by the regulator, it should include information pertaining to any Master Files referenced by the submission

c) If applicable, acknowledgement that a device sample has been submitted or offered alternatives to allow the regulator to view or access the device (when the regulator requests a sample)

d) If the submission is requesting approval of a change that is the result of CAPA due to a recall, this should be stated

e) If the submission is in response to a request for information from the regulator this should be stated and the date of that letter should be included as well as any reference number(s)

f) If the submission is unsolicited information (where accepted), this should be stated and any related reference number(s) provided

g) Identification of the regulatory jurisdiction(s) in which marketing is sought

**Note:** The cover letter should not contain any detailed scientific information.

### Health Canada guidance

Any information submitted to Health Canada should be accompanied by a cover letter. The cover letter should include the purpose of the application and a brief description of the package being submitted. It may also include information pertaining to Proprietary Information Submission. When applicable, identify the licence/application number and section associated with the submission (i.e. Section 36 or Section 39 of the Medical Devices Regulations).

When responding to Screening Deficiency Notice, applicants should provide their responses in a question-and-answer format accompanied by a copy of this notice. This information is to be filed within Folder 1.01 – 'Cover Letter'.

### Classification

For all fax-backs (minor changes): Required

## 1.04 Application form/administrative information

Folder name: 1.04-ApplicationForm-AdministrativeInfo

### IMDRF Health Canada content

Health Canada application forms should be included here.

### Health Canada guidance

Obtain the appropriate medical device licence application form. For more information on how to complete the application form for a medical device licence, consult:

- Guidance on how to complete the application for a new medical device licence

For applications submitted through the Regulatory Enrolment Process (REP), the Class II, III, or IV medical device licence application forms are not required. Instead, applicants must complete the Regulatory Transaction (RT) template and, if applicable, the Application Information (AI) template, which generate the required REP Extensible Markup Language (XML) files. These XML files replace the standard application forms and must be included in the regulatory transaction. Do not submit the standard application forms, as the information is already captured within the XML files. For more information, consult:

- Regulatory enrolment process (REP)

### Classification

For all fax-backs (minor changes): Required

## 1.05 Listing of devices

Folder name: 1.05-ListingofDevice(s)

### IMDRF common content

A table listing each variant/model/configuration/component/accessory that is the subject of the submission and the following information for each variant/model:

a) the identifier (for example, bar code, catalogue, model or part number, UDI)
b) a statement of its name/description that provides (for example, Trade name, size, material)

**Notes:**

i. A model/variant/configuration/component/accessory of a device has common specifications, performance and composition, within limits set by the applicant.
ii. Typically each item listed should be available for sale. For example, if everything is sold as part of a kit, then this list would only include the kit. You do not need to list all components that may be sold within a kit/set, unless the component is available for sale independently of the kit.

### Health Canada guidance

The listing of devices is part of the medical device licence application form. A separate file in this folder is not required for submissions sent on physical media or by email until REP becomes mandatory. Once REP becomes mandatory, all Medical Device Licence (MDL) submissions must be submitted electronically via the Common Electronic Submission Gateway (CESG). At that time, submissions via physical media or email will no longer be accepted.

For applications that are submitted through the REP, applicants should complete the Device Details spreadsheet found in the REP for medical devices page.

Please ensure that there are no additional security settings applied to submitted files. This includes password protection, restricted access, Digital Rights Management (DRM), or

Information Rights Management (IRM). Files with these settings may be blocked by Health Canada's security policies, preventing these documents from being accessed.

### Classification

Add, delete or change device identifier: Conditionally required – If submitted through REP

## 1.06 Quality management system, full quality system or other regulatory certificates

Folder name: 1.06-QMSFullQSorOtherRegulatoryCerts

### IMDRF Health Canada content

Health Canada will only accept MDSAP certificates that have been issued by recognized auditing organizations.

### Health Canada guidance

A copy of the quality management system certificate should be included here if applicable.

### Classification

Add, delete or change device identifier (All classes except addition to Class III/IV): Not required

Change to licence/device name: Not required

Change to manufacturer's name/address: Required

## 1.10 Pre-submission correspondence and previous regulator interactions

Folder name: 1.10-Pre-SubmissionCorrespondence-PreviousRegulatorInteractions

### IMDRF common content

a) During the product lifecycle, pre-submission correspondence, including teleconferences or meetings, may be held between the regulator and the applicant. Further, the specific subject device may have been subject to previous regulatory

submissions to the regulator. The contents should be limited to the subject device as similar devices are addressed in other areas of the submission. If applicable, the following elements should be provided:

i. List prior submission or pre-submissions where regulator feedback was provided
ii. Prior submissions should include identification of submission number
iii. For any pre-submission activities that have not previously been assigned any tracking/reference number, include the information package that is submitted prior to pre-submission meetings, the meeting agenda, any presentation slides, final meeting minutes, responses to any action items arising from the meetings, and any email correspondence related to specific aspects of the application
iv. Issues identified by the regulator in prior submissions (that is, clinical study applications, withdrawn/deleted/denied regulatory submission) for the subject device
v. Issues identified and advice provided by the regulator in pre-submission interactions between the regulator and the applicant/sponsor
vi. Explain how and where the prior advice was addressed within the submission

**Or**

b) Affirmatively state there has been no prior submissions and/or pre-submission interactions for the specific device that is the subject of the current submission

**Note**: The scope of this section is limited to the particular regulator to which the submission is being submitted (for example Health Canada does not need pre-submission information relating to interactions with ANVISA).

### Classification

For all fax-backs (minor changes): Conditionally required – If applicable

## 1.15 Other regional administrative information

Folder name: 1.15-OtherRegionalAdministrativeInfo

### IMDRF common content

Heading for other administrative information that may be important to the submission but that does not fit in any of the other headings of this chapter.

**Note:** To ensure all elements of your submission are adequately reviewed, please be sure that any content placed here does not belong under any heading described above.

### Health Canada guidance

For all fax-backs (minor changes), include a copy of the front page of each affected licence.

### Classification

For all fax-backs (minor changes): Required

## Chapter 5: Labelling and promotional material

Folder name: 5-LABELLING

Note: No files or content should be included at this level. Only sub-folders of this folder should contain documents.

### 5.02 Product/package labels

Folder name: 5.02-Product-PackageLabels

### IMDRF common content

Samples of the primary and secondary packaging labels.

Notes:

i. Do not include shipping labels.

ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to labelling the subject nIVD medical device.

### IMDRF Health Canada content

a) All labelling must comply with sections 21 to 23 of the Medical Devices Regulations.

b) Consult the guidance for the labelling of medical devices, not including in vitro diagnostic devices or the guidance for the labelling of in vitro diagnostic devices as applicable.

### Health Canada guidance

Include samples of the primary and secondary packaging labels but exclusive of labels for shipping.

**Notes:**

1. All labelling must be provided in English or French, both official languages are to be available upon request.
2. Labelling for near-patient devices must also be provided in French and English.

### Classification

For change to licence/device name: Required

For all other fax-backs (minor changes): Optional

## 5.03 Package insert/instructions for use

Folder name: 5.03-PackageInsert-InstructionsforUse

### IMDRF common content

Package insert/instructions for use included in the package, when required or provide support for why this element is not applicable.

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to labelling the subject device.

### IMDRF Health Canada content

a) All labelling must comply with sections 21 to 23 of the Medical Devices Regulations.
b) Consult the guidance for the labelling of medical devices, not including in vitro diagnostic devices or the guidance for the labelling of in vitro diagnostic devices as applicable.

c) The current version and date of the instructions for use must be stated.

### Health Canada guidance

The package insert or instructions for use must be included when required. If this element is not applicable, justification should be provided for its exclusion.

a) All labelling must be provided in English or French, both official languages are to be available upon request.
b) Labelling for near-patient devices must also be provided in French and English.
c) For IVD devices, package inserts must include a summary of the performance specifications, in addition to all other relevant information.

### Classification

For all fax-backs (minor changes): Optional

## 5.04 E-labelling

Folder name: 5.04-e-labelling

### IMDRF common content

In addition to the e-labelling itself, the following should be provided:

a) For eligible medical devices and Software as a Medical Device, the applicant needs to identify which form of e-labelling is being used (for example electronic storage system or built-in system, website)
b) Details of risk management in relation to e-labelling. If this is part of the overall risk management, refer to it here
c) When IFUs are requested, a description of the procedure and operations on providing IFU's when requested
d) Written information for users on the webpage identifying where the IFU and further information can be found in relevant languages
e) A description on how the e-labelling requirements for the website have been met

f) If a video/app is available to demonstrate how the device is intended to function, provide a link as well as details about how it is maintained and updated throughout the life cycle of the device

### IMDRF Health Canada content

For devices that are not sold to the general public, IFUs may be provided as downloadable from the internet and/or on electronic data storage devices, for example compact disc, digital video disc, USB flash drive, etc. The electronic label or URL must accompany the device at the time of sale and/or delivery and be displayed in a manner that alerts the user to its purpose. A Letter of Attestation must also be included with the application. Refer to the guidance for the labelling of medical devices, not including in vitro diagnostic devices or the guidance for the labelling of in vitro diagnostic devices, for additional information.

If a video/app is available as described in f) above, the video should be available in both French and English.

### Classification

For all fax-backs (minor changes): Optional

## 5.05 Healthcare professional labelling

Folder name: 5.05-HCP Labelling

### IMDRF common content

Labelling directed at the healthcare professional other than the package insert, such as the surgical manual.

### Classification

For all fax-backs (minor changes): Optional

## 5.06 Patient labelling

Folder name: 5.06-PatientLabelling

### IMDRF common content

Labelling directed at the patient other than the package insert, such as informational material written to be comprehended by the patient or lay caregiver.

### Classification

For all Fax-backs (Minor Changes): Optional

## 5.07 Technical and/or operators manual

Folder name: 5.07-Technical-OperatorManual

### IMDRF common content

Labelling directed at the technical users and operators of medical devices focusing on the proper use and maintenance of the device and surgical technique instructions.

### Classification

For all fax-backs (minor changes): Optional

## 5.08 Patient file stickers, cards and implant registration cards

Folder name: 5.08-PatientFileStickersCardsImplantRegistrationCards

### IMDRF Health Canada content

a) If applicable, stickers/cards intended to be place in the patient's chart identifying the implant (for example serial #, lot #, make, model)
b) If applicable, implant registration cards

### Classification

For all fax-backs (minor changes): Optional

## 5.09 Product brochures

Folder name: 5.09-ProductBrochures

### IMDRF Health Canada content

Draft product brochures available at the time of application

### Classification

For all fax-backs (minor changes): Optional

## 5.10 Other labelling and promotional material

Folder name: 5.10-OtherLabelling-PromotionalMaterial

### IMDRF common content

Heading for other information that may be important to the submission but that does not fit in any of the other headings of this chapter.

Individual jurisdictions may have their own regulations or requirements regarding other labelling elements or advertising and promotional materials. If necessary, this section can be used to address jurisdiction-specific regulations or requirements involving other labelling elements other than those described elsewhere in this section, including advertising and promotional materials.

### Health Canada guidance

Include any other relevant labelling or promotional material that does not fit in any other folder.

### Classification

For all fax-backs (minor changes): Optional