Class IV nIVD applications content and classification guidance

Health Canada Santé Canada

Canada

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Également disponible en français sous le titre :
Lignes directrices sur le contenu et la classification des demandes d'homologation d’instruments autres que les instruments diagnostique in vitro de classe IV

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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 proprietary information pertaining to the submission. The Table of Contents (ToC) structure requirements also apply to information packages created in support of all Screening Deficiency Responses, Clarification Responses, and Additional Information Responses. Summaries and full reports, when applicable, should be provided in a ToC-compliant package.

Classification

New and amendment applications: Required

1.03 Terms and acronyms

Folder name: 1.03-ListofTerms-Acronyms

IMDRF common content

Terms or acronyms used in the submission that require definition, should be defined here.

Classification

New and amendment applications: 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 should 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

New and amendment applications: 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

New applications: Conditionally required – If application is submitted through REP

Amendment applications: Conditionally required – If application impacts the manufacturer's device identifier listing and is submitted through REP

1.06 Quality management system, full quality system, 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.

Classification

New licence applications: Required

Amendment licence applications: Conditionally required – Include the quality management certificate if the amendment includes a change in the manufacturer's name.

1.09 User fees

Folder name: 1.09-UserFees

IMDRF Health Canada content

Health Canada user fee forms should be included here.

Health Canada guidance

When submitting an application for a medical device licence, please include the medical device licence application fee form to avoid delays in the processing of your application. Guidance on fees for the review of medical device licence applications can be found in the Guidance document: Fees for the review of medical device licence applications.

Classification

New and amendment applications: 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 #

   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

New and amendment applications: Conditionally required – When relevant to the application

1.13 Letters of reference

Folder name: 1.13-LettersofReference

IMDRF common content

Where applicable, letter from the owner of any separate document referenced in the submission (for example, master file or previous regulatory submission), granting access to the information in the referenced document. The letter should include the information of the applicant who cited the separate document (for example, master file or previous regulatory submission), the product name, the document number that has been filed, and the page number/chapter information of the separate document authorized to be cited.

Classification

New and amendment applications: Conditionally required: When a master file is referenced

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.

Classification

New and amendment applications: Conditionally required – When information is requested by the regulator (through guidance documents or other communication) but does not belong elsewhere in this chapter.

Chapter 2: Submission context

Folder name: 2-CONTEXT

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

2.02 General summary of submission

Folder name: 2.02-GeneralSummaryofSubmission

IMDRF common content

a) Statement of the device type (for example, hip implant, infusion pump, standalone software) and name (for example, trade name, proprietary name), its general purpose, and a high-level summary of key supporting evidence (that is, studies that are unique to the risks of this device type, for example burst testing of a ceramic femoral head; electrical safety evaluation (IEC 60601) testing for an infusion pump)

b) Summary of submission, including

   i. the type of submission (for example, new, amendment, change of existing application, renewal)

   ii. if amendment/supplement, the reason of the amendment/supplement

   iii. if a change to existing approval, description of the change requested (for example, changes in design, performance, indications, changes to manufacturing processes, manufacturing facilities, suppliers);

   iv. any high-level background information or unusual details that the manufacturer wishes to highlight in relation to the device, its history or relation to other approved devices or previous submissions (provides context to submission)

IMDRF Health Canada content

If amendment or new submission based on currently licenced device(s), the Canadian medical device licence number(s) should be provided along with the description of the change requested.

If amendment, there may be multiple sections where there is “no change”. These folders would thus be considered “not applicable”. A list of these sections may be provided here, identified as “no change” and then the appropriate folders would be excluded from the submission.

If amendment or new submission, if a report can fit into multiple sections, only one copy should be included and references to the single copy provided in other sections where the information might be applicable.

If requesting priority review per Section 15 of the application form, the justification should be provided here.

Classification

New and amendment applications: Required

2.04 Device description

Folder name: 2.04-DeviceDescription

No content at this level.

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

Classification

New and amendment applications: Required

2.04.01 Comprehensive device description and principle of operation

Folder name: 2.04.01-ComprehensiveDeviceDesc-PrincipleofOp

IMDRF common content

a) A general description of the device, including:
    i. A statement of the device name
    ii. What the device does

iii. Who uses it and for what (high level statement)
iv. Where to use it (places/environment where the device is intended to be used)
v. How it works. Including a description of the features/variants/operating modes that enable the device to be used for indications/intended use (principle of operation/mechanism of action) and if not readily apparent or typical for the device type, a brief description of the underlying science/technology, design concepts, and/or theoretical principles supporting the device's function
vi. If applicable, labelled pictorial representation (diagrams, photos, drawings).
vii. If system, how the components relate
viii. If applicable, identify if the device incorporates software/firmware and its role

b) Product specification, including:
   i. Physical characteristics or relevance to the end user (dimensions, weight)
   ii. Features and operating modes
   iii. Input specifications (for example, electrical power requirements, settings and associated allowable ranges/limits)
   iv. Output and performance characteristics (for example, range and type of energy delivered, resolution of images)
   v. If applicable, an indication of the variants/models of the devices and a summary of the differences in specifications of the variants (comparison table and/or pictures/diagrams with supporting text).
c) List of accessories intended to be used in combination with the devices
d) Indication of any other medical devices or general product intended to be used in combination with the medical device (for example, infusion sets and infusion pumps, bipolar electrode and RF equipment)
e) Components or accessories that can be sold separately should be identified
f) If approved by the regulator, provide the approval number and identification for each component or accessory

g) If the device is to be sterilized, an indication of who is to perform the sterilization and by what method (for example, EtO, gamma irradiation, dry heat) **or** an affirmative statement that the device is non-sterile when used

    Note: The validation report is not expected be presented at this point, only the device sterility condition shall be indicated here. If appropriate, for the validation report, see Chapter 3: Non-clinical studies

h) Summary of the composition of the device including, at minimum, the material specification and/or chemical composition of the materials that have direct or indirect contact with the user and/or patient. When required, full details to support how these specifications are met are to be provided in 3.5.02 –Chemical/Material Characterization

    Note: If applicable, chemicals may be identified using either the IUPAC (International Union of Pure and Applied Chemistry) or the CAS (Chemical Abstract Service) Registry number. Reference to applicable material standards may also be useful in this description

i) If applicable, indication of biological material or derivate used in the medical device, including:
    a. origin (human, animal, recombinant or fermentation products or any other biological material)
    b. source (for example, blood, bone, heart, any other tissue or cells)
    c. the intended reason for its presence and, if applicable, its primary mode of action.

j) If the device contains an active pharmaceutical ingredient (API) or drug, an indication of the substance, should be provided. This should include its identity and source, and the intended reason for its presence and its primary mode of action

k) Engineering diagrams/prints/schematics of the device (should be provided as a separate file within the submission)

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the comprehensive device description and principles of operations provided in this section regarding the subject device

IMDRF Health Canada content

If the application is an amendment, this section should describe both the device as currently on the licence as well as the modifications proposed. Modifications (for example, changes in design, performance and indications) should be further detailed in Section 2.04.04 below.

Health Canada guidance

For devices containing an API or drug, refer to Health Canada's policies about the classification of combination products, for example:

- Policy on drug/medical device combination products - Decisions
- Drug/medical device combination products

Classification

New and amendment applications: Required

2.04.02 Description of device packaging

Folder name: 2.04.02-DescriptionofDevicePackaging

IMDRF common content

a) Information regarding the packaging of the devices, including, when applicable, primary packaging, secondary and any other packaging associated
b) Specific packaging of accessories marketed together with the medical devices shall also be described
c) If the user needs to package the medical device or its accessories before they perform sterilization, information about the correct packaging (for example, material, composition, dimension) should be provided

Health Canada guidance

Describe the packaging of the device (or its components, if any), including the materials used. It should be clear what protective characteristics the packaging provides (for example, maintains sterility, humidity, light sensitivity, transportation protection).

Classification

New and amendment applications: Required

2.04.03 History of development

Folder name: 2.04.03-HistoryofDevelopment

IMDRF common content

For any device versions/prototypes referenced in the evidence presented in the submission, a table describing the version/name, with 4 columns (device name and/or version; description of changes from previous row; motivation for the change; list of verification/validation activities, including clinical studies, conducted using this version).

For any design verification or validation activities presented in this submission (including clinical studies) performed on any earlier versions of the subject device, include a justification for why the changes do not impact the validity of the data collected under those activities in supporting the safety and effectiveness of the final device design.

IMDRF Health Canada content

It is highly recommended that a description of all changes made to the device since the issuance of the last medical device licence or licence amendment be provided for a device that has had a previous version licensed in Canada.

Classification

New and amendment applications: Required

2.04.04 Reference and comparison to similar and/or previous generations of the device

Folder name: 2.04.04-Ref-ComparisontoSimilarand-orPreviousGen

IMDRF common content

a) A list of similar devices (available on local and international market) and/or previous generation of the devices (if existent) relevant to the submission. This should include any similar/previous generation devices that were previously reviewed and refused by the subject regulator
b) Description of why they were selected

c) A key specification comparison, preferably in a table, between the references (similar and/or previous generation) considered and the device

IMDRF Health Canada content

a) If the application is an amendment to a licenced device or is based on a modification of a licensed device, a description of the modifications is required (for example, changes in design, performance, and indications)
b) Comparisons can be used to support the safety and effectiveness of the device if they are made to a currently licensed device in Canada. If this method is used, ensure the Canadian medical device licence number of the comparator is stated. The comparison device does not need to be manufactured by the same manufacturer

Health Canada guidance

When adding a device identifier, comparative information is necessary to validate compliance with licence type requirements. Include a comparison table that outlines all differences between the devices represented by the new identifiers and a closely related licensed comparator(s).

Classification

New and amendment applications: Required

2.05 Indications for use and/or intended use and contraindications

Folder name: 2.05-Indications-IntendedUse-Contraindications

Note: No content at this level

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

Classification

New and amendment applications: Required

2.05.01 Intended use, intended purpose, intended user, indications for use

Folder name: 2.05.01-IntendedUseandIndications

IMDRF common content

This section should include, as appropriate:

a) **Intended use:** The statement of intended use should specify the therapeutic or diagnostic function provided by the device and may describe the medical procedure in which the device is to be used (for example, Diagnosis *in vivo* or *in vitro*, treatment monitoring rehabilitation, contraception, disinfection).
b) **Intended purpose:** What is expected with the use of this medical device? Which results are expected?
c) **Intended user** and skills/knowledge/training that the user should have to operate or use the device.
d) Identify if the device is intended for **single or multiple use**
e) **Indications for use:**
    i. Disease or medical condition that the device will diagnose, treat, prevent, mitigate, or cure, parameters to be monitored and other considerations related to indication for use
    ii. If applicable, information about patient selection criteria
    iii. If applicable, information about intended patient population (for example, adults, pediatrics or newborn) or a statement that no subpopulations exist for the disease or condition for which the device is intended
f) For amendments/supplements or changes to existing approvals, identify any changes to the previously approved intended use/intended purpose/intended user/indications. If there are no changes, this should be stated, and a reference should be made to the precise regional regulatory tracking number associated with the previous submission/approval

Notes:

i. The statements of intended use and purpose and the intended user and indications for use must be as presented in the labelling.
ii. If more than one device is included, the information should be provided for each device.

Classification

New and amendment applications: Required

2.05.02 Intended environment, setting for use

Folder name: 2.05.02-IntendedEnvironment-Setting

IMDRF common content

a) The setting where the device is intended to be used (for example, domestic use, hospitals, medical/clinical laboratories, ambulances, medical/dental offices). Multiple options can be indicated
b) If applicable, environmental conditions that can affect the device's safety and/or performance (for example, temperature, humidity, power, pressure, movement)

Classification

New and amendment applications: Required

2.05.04 Contraindications for use

Folder name: 2.05.04-Contraindications

IMDRF common content

If applicable, specify the disease or medical conditions that would make use of the device inadvisable due to unfavorable risk/benefit profile.

Note: The statement of contraindications for the device must be as presented in the labelling.

Classification

New and amendment applications: Required

2.06 Global market history

Folder name: 2.06-GlobalMarketHistory

Note: No content at this level.

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

Classification

New and amendment applications: Required

2.06.01 Global market history

Folder name: 2.06.01-GlobalMarketHistory

IMDRF common content

a) Up to date identification of the markets (all countries or jurisdictions) where the device is approved for marketing
b) Should include history of the marketing of the device by any other entity, acknowledging that detailed information may not be available in all cases
c) Include a list of all countries in which the device has been removed from marketing for any reason related to the safety or effectiveness of the device

IMDRF Health Canada content

a) If the subject device is different in any way (for example, design, labelling, specifications, indications) from those approved or marketed in other jurisdiction, the differences should be described
b) The month and year of market approval in each country or jurisdiction where the device is marketed. If the device has been marketed for greater than 10 years, a statement of greater than 10 years can be made
c) For each of the markets listed in (a) above, and statement of the commercial names used in those markets **or** a clear statement that the commercial names are the same in all jurisdictions
d) State the date of data capture for the market history data
e) If the subject device has been the subject of any previous compassionate use and/or clinical trials this should be identified and, if applicable, relevant reference numbers provided

If there is any approval number, given to the device by the regulator authority of the markets (country or jurisdictions) where the device is already marketed, this identification must be provided.

Marketing history of a Health Canada licensed, previous version of the device can sometimes be used in support of safety or effectiveness of the subject device. If this is to be the case, then the name of the comparator, its medical device licence number and the number of units sold should be provided.

In this context, compassionate use includes **any** Special Access Authorizations.

Classification

New and amendment applications: Required

2.06.02 Incident reports and recalls

Folder name: 2.06.02-IncidentReports-Recalls

IMDRF common content

a) List adverse events/incidents associated with the device and a statement of the period associated with this data
b) If the number of adverse events is voluminous, provide a summary by event type that state the number of reported events for each event type
c) List of the medical device recalls and/or advisory notice, and a discussion of the handling and solution given by the manufacturer in each case
d) A description of any analysis and/or corrective actions undertaken in response to items listed above
e) If there have been no adverse events/incidents, recalls and/or advisory notice to date, provide an attestation from device owner on company letterhead, that there have been no adverse events/incidents, recalls and/or advisory notice since commercial introduction of the device

Notes:

i. It is acknowledged that the definition of recall may vary from one jurisdiction to another.

IMDRF Health Canada content

a) The jurisdiction(s) associated with the incident should be clearly indicated.
b) Incidents should include any Canadian incidents through SAP or other previous Canadian applications, if known.
c) If marketing history is presented for a previously licensed device, then the associated recalls, and incident reports for that device should also be summarized here.

Classification

New and amendment applications: Required

2.06.03 Sales, incident and recall rates

Folder name: 2.06.03-SalesIncident-RecallRates

IMDRF common content

a) A summary of the number of units sold in each country/region and a statement of the period associated with this data
b) Provide the rates calculated for each country/region, for example:
    i. Incident rate = # adverse events/incidents divided by # units sold, expressed as a percentage
    ii. Recall rate = # recalls divided by # units sold, expressed as a percentage

    Rates may be presented in other appropriate units such as per patient year of use or per use. In this case, methods for determining these rates should be presented and any assumptions supported.

c) Critical analyses of the rates calculated (for example, Why are they acceptable? How do they break down in terms of incidents? Is there some outlier data that has driven the rates up? Are there any trends associated with any sub-groups of the devices that are subject of the submission (for example, size, version)?).

Notes:

i. It is acknowledged that the definition of recall may vary from one jurisdiction to another.
ii. Sales in this context should be reported as the number of units sold.
iii. The summary of sales should be broken down by components when appropriate.

Classification

New and amendment applications: Required

2.07 Post-market study plans

Folder name: 2.07-Post-MarketStudyPlans

IMDRF common content

Post-market study plans may include clinical or nonclinical study plans. The documentation provided here will not include final reports and analysis, and instead includes study plan information only. This may include:

a) Study objectives
b) Study design
c) Subjects and sites information
d) Endpoints (primary and secondary)
e) Summary of data analysis plan
f) Length and frequency of follow-up

Note: Post-market non-clinical or clinical data from one region provided during the pre-market phase to a second region would be considered non-clinical or clinical data for the second region and would reside in Chapter 3 or Chapter 4, respectively.

Classification

New and amendment applications: Optional

2.08 Risk management

Folder name: 2.08 RiskManagement

IMDRF common content

a) A summary of the risks identified during the risk analysis process and how these risks have been controlled to an **acceptable** level. Plans can be considered part of the risk management documentation
b) The results of the risk analysis should provide a conclusion with evidence that remaining risks are acceptable when compared to the benefits
c) Where a standard is followed, identify the standard

Health Canada guidance

A risk assessment should be based on an analysis and an evaluation of the risks inherent in the use of the device, as well as the risk reduction measures adopted to satisfy safety and effectiveness requirements. The manufacturer should identify the individual or organization that carried out the risk analysis and it should be conducted on the version of the device under review.

If the application is for an amendment or modification of a previously licensed Class IV device (in Canada), then the risk assessment information should focus on new and/or modified risks and mitigation. If the original risk assessment is updated, the new risks or modified risks should be clearly highlighted.

It is recommended that the current version of ISO 14971-1, entitled Medical Devices- Application of Risk Management to Medical Devices, be consulted.

Classification

New and amendment applications: Required

2.10 Standards

Folder name: 2.10-Standards

IMDRF common content

No content at this level.

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

Classification

New and amendment applications: Conditionally required – If any sub-headings are required

2.10.01 List of standards and guidance documents

Folder name: 2.10.01-ListofStandards

IMDRF common content

This section should include:

a) If applicable, a list of the standards that have been complied with in full or in part in the design and/or manufacture of the device
    i. At a minimum should include the standard organization, standard number, standard title, year/version, and if full or partial compliance
    ii. If partial compliance, a list of the sections of the standard that:
        - are not applicable to the device, and/or
        - have been adapted, and/or
        - were deviated from for other reasons – discussion to accompany
b) If applicable, a list of relevant guidance documents published by regulators and referenced in the design and/or manufacture of the device with the jurisdiction of publication, publication date and title identified
c) If applicable, a list of relevant clinical guidelines referenced in the design and/or manufacture of the device, the publisher, publication date and title identified

Classification

New licence applications: Conditionally required – If demonstrating that device complies with standards

Amendment licence applications: Conditionally required – If there are standards that have been applied in relation to the amendment

2.10.02 Declaration and/or certification of conformity

Folder name: 2.10.02-Declarationand-orCertificationofConformity

IMDRF Health Canada content

The applicant is advised to prepare the Declaration of Conformity to recognized standards using Health Canada's Declaration of Conformity form. Refer to the Guidance document: Recognition and use of standards under the Medical Devices Regulations and the current list of recognized standards for medical devices.

Classification

New licence applications: Conditionally required – If demonstrating that device complies with standards

Amendment licence applications: Conditionally required – If declaration of conformity is being made relating to standards relevant to the amendment

2.11 Other submission context information

Folder name: 2.11-OtherSubmissionContextInformation

IMDRF common content

Heading for other submission context 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.

Classification

New and amendment applications: Conditionally required – When information is requested by the regulator (through guidance documents or other communication) but does not belong in any of the other headings of this chapter.

Chapter 3: Non-clinical evidence

Folder name: 3-NON-CLIN

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

3.05 Non-clinical studies

Folder name: 3.05-Studies

IMDRF common content

No content at this level.

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

Classification

New licence applications: Required

Amendment licence applications: Conditionally required – If any sub-headings are required

3.05.01 Physical and mechanical characterization

Folder name: 3.05.01-Physical-Mechanical

IMDRF common content

Evidence that supports the physical or mechanical properties of the subject device is to be included in this section. This should include:

a) A summary of the non-clinical evidence that falls within this category
b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (that is, what tests were considered and why they were or were not performed)
c) If applicable, particulate testing from wear or device coatings
d) Discussion to support why the evidence presented is sufficient to support the application

Or

e) A statement of why this category of non-clinical laboratory study is not applicable to this case

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.

Health Canada guidance

Applicants should include an Overview.pdf file at the parent heading level of the relevant subchapter. This document should provide a concise summary (typically 1 to 2 pages) of both the IMDRF common content and the IMDRF Health Canada content. In addition, the overview should include a brief rationale explaining how the submitted evidence supports the application.

Classification

New and amendment applications: Conditionally required – Not required when this type of evidence or testing is clearly not applicable to the device or submission. If scientific judgment is required to justify why no information is required, then the heading is considered required, and the justification should be provided.

3.05.01.01 Study description, study identifier, date of initiation

Folder name: 3.05.01.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level. This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

For example, the structure will look something like this

- Component A Fatigue Test, MT4203, 2010-10-10
  - Summary of MT4203
  - Full Report for MT4203
- Assembly B Compatibility Test, MT4584, 2011-01-23
  - Summary of MT4584
  - Full Report for MT4584

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders: the summary and full report (when required), for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions, these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (summary then full report).

Further, for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a fatigue test and wear test are being included, the application would include an overview file in the parent subchapter folder and two subfolders:

- a custom folder named "3.5.01.01-Component A Fatigue Test, MT4203, 2012-03-20" containing two subfolders with the appropriate files:
  - 1-Summ
    - MT4203Summ.pdf
  - 2-Report
    - MT420Report.pdf
- a custom folder named "3.5.01.02-Assembly B Wear Testing, MT4584, 2012-04-12" containing:
  - 1-Summ
    - MT4584Summ.pdf
  - 2-Report
    - MT4584Report.pdf

Classification

New and amendment applications: Conditionally required: **Required** for each study or test presented in this section

3.05.01.01.01 Summary

Folder name: 3.05.01.01.01-Summ

IMDRF common content

A summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study or test presented in this section

The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.05.01.01.02 Full report

Folder name: 3.05.01.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Required

3.05.02 Chemical/material characterization

Folder name: 3.05.02-Chemical-Material

IMDRF common content

Tests that describe the chemical or structural composition of the device and its components are to be included in this section. This should include:

a) A summary of the non-clinical evidence that falls within this category
b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in

this category (that is, what tests were considered and why they were or were not performed)

c) Discussion to support why the evidence presented is sufficient to support the application

Or

d) A statement of why this category of non-clinical laboratory study is not applicable to this case

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.

Health Canada guidance

Applicants should include an Overview.pdf file at the parent heading level of the relevant subchapter. This document should provide a concise summary (typically 1 to 2 pages) of both the IMDRF common content, and the IMDRF Health Canada content. In addition, the overview must include a brief rationale explaining how the submitted evidence supports the application.

Classification

New and amendment applications: Conditionally required – Not required when this type of evidence or testing is clearly not applicable to the device or submission. If scientific judgment is required to justify why no information is required, then the heading is considered required and the justification should be provided.

3.05.02.01 Study description, study identifier, date of initiation

Folder name: 3.05.02.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders: the summary and full report (when required), for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions, these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (summary then full report).

Further, for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a fatigue test and wear test are being included, the application would include an overview file in the parent subchapter folder and two subfolders:

- a custom folder named "3.5.01.01-Component A Fatigue Test, MT4203, 2012-03-20" containing two subfolders with the appropriate files:
  - 1-Summ
    - MT4203Summ.pdf
  - 2-Report
    - MT420Report.pdf
- a custom folder named "3.5.01.02-Assembly B Wear Testing, MT4584, 2012-04-12" containing:
  - 1-Summ
    - MT4584Summ.pdf
  - 2-Report
    - MT4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.05.02.01.01 Summary

Folder name: 3.05.02.01.01–Summ

IMDRF common content

This is a summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study or test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.05.02.01.02 Full report

Folder name: 3.05.02.01.02–Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Required

3.05.03 Electrical systems: Safety, mechanical and environmental protection, electromagnetic compatibility

Folder name: 3.05.03-ElectricalSystems

IMDRF common content

Evidence supporting electrical safety, mechanical and environmental protection, and electromagnetic compatibility are to be included in this section. This should include:

a) A summary of the non-clinical evidence that falls within this category
b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in

this category (that is, what tests were considered and why they were or were not performed)

c) Discussion to support why the evidence presented is sufficient to support the application

Or

d) A statement of why this category of study is not applicable to this case

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.

Health Canada guidance

A medical device licence issued by Health Canada does not mean that the licensed device has been assessed to meet all relevant regulations. It only means that the device has been deemed to meet the requirements of the Medical Device Regulations.

The onus is on manufacturers to ensure that their devices meet all of the national or provincial regulations that apply to their product.

Applicants should also include an Overview.pdf file at the parent heading level of the relevant subchapter. This document should provide a concise summary (typically 1 to 2 pages) of both the IMDRF common content, and the IMDRF Health Canada content. In addition, the overview should include a brief rationale explaining how the submitted evidence supports the application.

Classification

New and amendment applications: Conditionally required – Not required when this type of evidence or testing is clearly not applicable to the device or submission. If scientific judgment is needed to justify why no information is required, then the heading is considered required and the justification should be provided.

3.05.03.01 Study description, study identifier, date of initiation

Folder name: 3.05.03.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders: the summary and full report (when required), for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions, these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (summary then full report).

Further, for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a fatigue test and wear test are being included, the application would include an overview file in the parent subchapter folder and two subfolders:

- a custom folder named "3.5.01.01-Component A Fatigue Test, MT4203, 2012-03-20" containing two subfolders with the appropriate files:
  - 1-Summ
    - MT4203Summ.pdf
  - 2-Report
    - MT420Report.pdf
- a custom folder named "3.5.01.02-Assembly B Wear Testing, MT4584, 2012-04-12" containing:
  - 1-Summ
    - MT4584Summ.pdf
  - 2-Report
    - MT4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.05.03.01.01 Summary

Folder name: 3.05.03.01.01-Summ

IMDRF common content

This is a summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Conditionally required: A comprehensive summary is **required** for each study or test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.05.03.01.02 Full report

Folder name: 3.05.03.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Required

3.05.04 Radiation safety

Folder name: 3.05.04-RadiationSafety

IMDRF common content

Studies supporting radiation safety, where the device emits ionizing and/or non-ionizing radiation or where the device is exposed to radiation are to be included in this section. This includes bench tests ensuring safety and performance to support the MRI safety labelling of the device. This should include:

a) A summary of the non-clinical evidence that falls within this category
b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (that is, what tests were considered and why they were or were not performed)
c) Discussion to support why the evidence presented is sufficient to support the application

Or

d) A statement of why this category of non-clinical laboratory study is not applicable to this case

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.

Health Canada guidance

A medical device licence issued by Health Canada does not mean that the licensed device has been assessed to meet all relevant regulations. It only means that the device has been deemed to meet the requirements of the Medical Device Regulations.

The onus is on manufacturers of radiation-emitting medical devices to ensure that their devices meet all of the national or provincial regulations that apply to their product. For example, the device may be subject to the Radiation Emitting Devices Act and Regulations.

Applicants should also include an Overview.pdf file at the parent heading level of the relevant subchapter. This document should provide a concise summary (typically 1 to 2 pages) of both the IMDRF common content, and the IMDRF Health Canada content. In addition, the overview should include a brief rationale explaining how the submitted evidence supports the application.

Classification

New and amendment applications: Conditionally required – Not required when this type of evidence or testing is clearly not applicable to the device or submission. If scientific judgment is needed to justify why no information is required, then the heading is considered required and the justification should be provided.

3.05.04.01 Study description, study identifier, date of initiation

Folder name: 3.05.04.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders: the summary and full report (when required), for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions, these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (summary then full report).

Further, for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a fatigue test and wear test are being included, the application would include an overview file in the parent subchapter folder and two subfolders:

- a custom folder named "3.5.01.01-Component A Fatigue Test, MT4203, 2012-03-20" containing two subfolders with the appropriate files:
  - 1-Summ
    - MT4203Summ.pdf
  - 2-Report
    - MT420Report.pdf
- a custom folder named "3.5.01.02-Assembly B Wear Testing, MT4584, 2012-04-12" containing:
  - 1-Summ
    - MT4584Summ.pdf
  - 2-Report
    - MT4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.05.04.01.01 Summary

Folder name: 3.05.04.01.01-Summ

IMDRF common content

This is a summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study or test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.05.04.01.02 Full report

Folder name: 3.05.04.01.02-Report

IMDRF common content

The test report for the test is described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Required

3.05.05 Software/firmware/programmed or programmable medical device

Folder name: 3.05.05-Software-Firmware

IMDRF common content

No content at this level. Studies and supporting information on the software design, development process and evidence of the validation of the software, as used in the finished device, are to be included in this section and the associated sub-sections. It should also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling. Documentation should be organized according to software or hardware systems.

Classification

New and amendment applications: Conditionally required – Not required when this type of evidence or testing is clearly not applicable to the device or submission

3.05.05.01 Software/firmware description

Folder name: 3.05.05.01-Description

IMDRF common content

The software description should include:

a) A comprehensive overview of significant software features and functions, which may include images, flow charts, and state diagrams as needed to adequately explain the software functionality
b) The version of the software. The version tested must be clearly identified and should match the release version of the software, otherwise justification must be provided
c) Identification of the device features that are controlled by the software, the programming language, hardware platform, operating system (if applicable), use of off-the-shelf software (if applicable), a description of the realization process

If the product is a machine learning-enabled medical device (such as adaptive models, natural language processing, neural networks, and related approaches), please provide, as applicable:

i. a detailed description of each algorithm/model, including its inputs, outputs, data selection and management for training, testing, and validation (terminology may differ in different regions)
ii. model selection and evaluation
iii. risk management activities
iv. materials/approaches used to provide transparency
v. post-market performance monitoring activities

Health Canada guidance

If a device includes software, provide a description of that software and its impact on the safety and effectiveness of the device.

If the software or a previous version of the software has been reviewed by Health Canada, state this clearly and provide the appropriate references (for example, application and/or licence number).

Classification

New and amendment applications: Conditionally required – **Required** if the device includes software

3.05.05.02 Risk management file (including hazard analysis)

Folder name: 3.05.05.02-HazardAnalysis

IMDRF common content

The risk management file should be provided and include the risk management plan, risk assessment (for example, hazard analysis), and risk management report.

The risk assessment (for example, hazard analysis) should take into account all device hazards associated with the device's intended use.

For software that is part of a system, a risk assessment should be performed on the system comprising the software and its whole hardware environment and noted in the software documentation with reference to the particular section of the premarket submission.

IMDRF Health Canada content

The risk management file in this section should specifically relate to the software/hardware. Overall risk analysis should be placed in section 2.08.

For the risk control measures in the risk assessment or hazard analysis, there should be verification of the implementation of the risk control measures and verification of the effectiveness of the implemented risk control measures (that is, the implemented risk control measure reduces risk). This can be accomplished by tracing the identified hazard to the verified specific risk control measures (for example, a requirement ID in the SRS and SDS, a test name and identifier in the testing documentation that shows pass/fail results, a user manual name and identifier, a training manual name and identifier).

Classification

New licence applications: Conditionally required – **Required** if the device includes software

Amendment licence applications: Conditionally required – When relevant to the amendment

3.05.05.03 Software requirement specification (SRS)

Folder name: 3.05.05.03-SRS

IMDRF common content

The Software Requirements Specifications (SRS) documentation should describe the needs or expectations for a system or software, presented in an organized format, at the software system level or subsystem level, as appropriate, and with sufficient information to understand the traceability of the information with respect to the other software documentation elements (for example, risk management file, software design specification, system and software architecture design chart, software testing).

The SRS documents the requirements for the software which typically specifies inputs and outputs, functions that the software will perform, hardware, performance, interfaces, user interaction, error definition and handling, intended operating environment, safety and security related requirements derived from a risk assessment (hazard analysis) and all ranges, limits, defaults, and specific values that the software will accept.

Classification

New licence applications: Conditionally required – **Required** if the device includes software

Amendment licence applications: Conditionally required – When relevant to the amendment

3.05.05.04 System and software architecture design (SAD) chart

Folder name: 3.05.05.04-SADChart

IMDRF common content

The System and Software Architecture Design (SAD) Chart should consist of detailed diagrams of the modules, layers, and interfaces that comprise the device, their relationships, the data inputs/outputs and flow of data, and how users or external products (including information technology (IT) infrastructure and peripherals) interact with the system and software. If the System and Software Architecture Design Chart is included in another document, such as the SRS, a reference to the location of the System and Software Architecture Design Chart in the submission should be included.

Classification

New licence applications: Conditionally required – **Required** if the device includes software

Amendment licence applications: Conditionally required – When relevant to the amendment

3.05.05.05 Software design specification (SDS)

Folder name: 3.05.05.05-SDS

IMDRF common content

Software Design Specification (SDS) documentation should be provided, including sufficient information to understand the technical design details of how the software functions, how the software design completely and correctly implements all the requirements of the SRS, and how the software design traces to the SRS in terms of intended use, functionality, safety, and effectiveness.

In terms of the relationship between the SRS and the SDS, the SRS describes what the software function will do and the SDS describes how the requirements in the SRS are implemented. The information presented in the SDS should be sufficient to ensure that the work performed by the software engineers who created the device software function was clear and unambiguous, with minimal ad hoc design decisions.

Classification

New licence applications: Conditionally required – **Required** if the device includes software

Amendment licence applications: Conditionally required – When relevant to the amendment

3.05.05.06 Traceability analysis

Folder name: 3.05.05.06-TraceabilityAnalysis

IMDRF common content

A Traceability Analysis links together your product design requirements, design specifications, and testing requirements. It also provides a means of tying together identified hazards with the implementation and testing of the mitigations.

IMDRF Health Canada content

The Traceability Analysis can be incorporated into the SRS documentation.

Classification

New licence applications: Conditionally required – **Required** if the device includes software

Amendment licence applications: Conditionally required – When relevant to the amendment

3.05.05.07 Software lifecycle process description, software development, configuration management and maintenance practices

Folder name: 3.05.05.07-SoftwLifeCycleProcessDesc

IMDRF common content

The software life cycle process description / software development, configuration management, and maintenance practices description should describe the software development life cycle and the processes that are in place to manage the various life cycle activities.

Classification

New licence applications: Conditionally required – **Required** if the device includes software

Amendment licence applications: Conditionally required – When relevant to the amendment

3.05.05.08 Software testing as part of verification and validation

Folder name: 3.05.05.08-SoftwareTestingV-V

IMDRF common content

You should provide an overall description of the verification and validation activities performed for the final software version. You should provide the applicable test protocols and reports including the expected results, observed results and pass/fail determination.

Note: The discussion should address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.

Health Canada guidance

Applicants should also include an Overview.pdf file at the parent heading level of the relevant subchapter. This document should provide a concise summary (typically 1 to 2 pages) of both the IMDRF common content, and the IMDRF Health Canada content. In addition, the overview should include a brief rationale explaining how the submitted evidence supports the application.

Classification

New and amendment applications: Conditionally required – Not required when this type of evidence or testing is clearly not applicable to the device or submission. If scientific judgment is needed to justify why no information is required, then the heading is considered required and the justification should be provided.

3.05.05.08.01 Study description, study identifier, date of initiation

Folder name: 3.05.05.08.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders: the summary and full report (when required), for the study presented. As described in the Health Canada adapted assembly and technical

guide for IMDRF Table of Contents submissions, these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (summary then full report).

Further, for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a fatigue test and wear test are being included, the application would include an overview file in the parent subchapter folder and two subfolders:

- a custom folder named "3.5.01.01-Component A Fatigue Test, MT4203, 2012-03-20" containing two subfolders with the appropriate files:
  - 1-Summ
    - MT4203Summ.pdf
  - 2-Report
    - MT420Report.pdf
- a custom folder named "3.5.01.02-Assembly B Wear Testing, MT4584, 2012-04-12" containing:
  - 1-Summ
    - MT4584Summ.pdf
  - 2-Report
    - MT4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.05.05.08.01.01 Summary

Folder name: 3.05.05.08.01.01-Summ

IMDRF common content

A summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study or test presented in this section

The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.05.05.08.01.02 Full report

Folder name: 3.05.05.08.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Required

3.05.05.09 Software version/revision level history

Folder name: 3.05.05.09-RevisionLevelHistory

IMDRF common content

The software version / revision level history documentation should include the history of software versions that were tested and documented as part of verification and validation activities. This typically takes the form of a line-item tabulation including the date, version number that was tested and a brief description of all changes in the version relative to the previously tested version.

The last entry in a line-item tabulation should be the final version to be incorporated in the released device. This entry should also include any differences between the tested version of software and the released version.

Classification

New licence applications: Conditionally required – When software is part of the device

Amendment licence applications: Conditionally required – When relevant to the amendment

3.05.05.10 Unresolved software anomalies

Folder name: 3.05.05.10-UnresolvedAnomalies

IMDRF common content

Documentation should include a list of unresolved anomalies present in the software with the following items (for example, in tabular format) for each unresolved anomaly:

i. A description of what the anomaly is and what root cause(s) of the anomaly could be
ii. Identification of how the anomaly was discovered and, where possible, identification of the root cause(s) of the anomaly
iii. Evaluation of the impact of the anomaly on the device's safety and effectiveness, including operator usage and human factors considerations
iv. Outcome of the evaluation
v. Risk-based rationale for not correcting or fixing the anomaly in alignment with the risk management plan or procedure(s)

Classification

New licence applications: Conditionally required – When software is part of the device

Amendment licence applications: Conditionally required – When relevant to the amendment

3.05.05.11 Cybersecurity

Folder name: 3.05.05.11-Cybersecurity

IMDRF common content

For a description of the cybersecurity common content, please refer to IMDRF/CYBER WG/N60 FINAL:2020 “Principles and Practices for Medical Device Cybersecurity”

IMDRF Health Canada content

Guidance document: Pre-market requirements for medical device cybersecurity

Health Canada guidance

Cybersecurity considerations should be included when a medical device contains or consists of software. If cybersecurity considerations are not addressed, the manufacturer should supply evidence to support this decision.

This should include, but is not limited to, the following:

- Cybersecurity vulnerabilities and risk analysis
- Cybersecurity control measures
- Traceability matrix linking cybersecurity controls to identified vulnerabilities and risks

This documentation ensures that all relevant cybersecurity risks have been properly assessed and managed throughout the development lifecycle.

Classification

New licence applications: Conditionally required – When the device contains or consisting of software

Amendment licence applications: Conditionally required – When relevant to the amendment

3.05.05.12 Interoperability

Folder name: 3.05.05.12-Interoperability

IMDRF common content

If the device can communicate with other devices. Evidence to support the interoperability should be provided.

Classification

New licence applications: Conditionally required – When the results of a risk assessment suggest that there are safety and effectiveness concerns relating to the interoperability of the device

Amendment licence applications: Conditionally required – When relevant to the amendment

3.05.06 Biocompatibility and toxicology evaluation

Folder name: 3.05.06-Biocomp-Toxicology

IMDRF common content

Studies supporting biocompatibility and assessing toxicology are to be included in this section. Studies to assess the immunological response to animal or human tissues, tissue components or derivatives are to be included in this section. This should include:

a) A list of all materials in direct or indirect contact with the patient or user
b) State conducted tests, applied standards, test protocols, the analysis of data and the summary of results
c) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (that is, what tests were considered and why they were or were not performed)
d) Discussion to support why the evidence presented is sufficient to support the application

Or

e) A statement of why this category of non-clinical laboratory study is not applicable to this case

Notes:

i. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.

ii. Tests should be conducted on samples from the finished, sterilized (when supplied sterile) device.

Health Canada guidance

Biocompatibility testing characterizes biological responses to materials. If the device comes in contact with the patient, then the biocompatibility of all materials that are potentially in contact with the patient is required. Tests should be conducted on samples from the final product after all manufacturing and processing has been completed (for example, sterilization). Deviations from this must be justified. Generic claims from the raw material supplier are generally insufficient.

Summaries should cover the tests conducted, standards applied, test methodology, pass-fail criteria chosen with justification and provide a summary of the results and conclusions. In general, ISO 10993 standards are taken as the gold standards for biocompatibility. Use of other standards should be justified and compared against ISO 10993 methods.

If a Declaration of Conformity to ISO 10993 standards is used to support the methodology, you must provide:

- a summary of the results
- a conclusion
    - for example, cytotoxicity testing found mild toxicity (average score 1) for patient-contacting material, therefore the device is considered biocompatible for its intended use

MSDS are not sufficient to demonstrate biocompatibility.

Applicants should also include an Overview.pdf file at the parent heading level of the relevant subchapter. This document should provide a concise summary (typically 1 to 2 pages) of both the IMDRF common content, and the IMDRF Health Canada content. In addition, the overview should include a brief rationale explaining how the submitted evidence supports the application.

Classification

New and amendment applications: Conditionally required – Not required when this type of evidence or testing is clearly not applicable to the device or submission. If scientific judgment is needed to justify why no information is required, then the heading is considered required and the justification should be provided.

3.05.06.01 Study description, study identifier, date of initiation

Folder name: 3.05.06.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders: the summary and full report (when required), for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions, these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (summary then full report).

Further, for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a fatigue test and wear test are being included, the application would include an overview file in the parent subchapter folder and two subfolders:

- a custom folder named "3.5.01.01-Component A Fatigue Test, MT4203, 2012-03-20" containing two subfolders with the appropriate files:
  - 1-Summ
    - MT4203Summ.pdf
  - 2-Report
    - MT420Report.pdf
- a custom folder named "3.5.01.02-Assembly B Wear Testing, MT4584, 2012-04-12" containing:
  - 1-Summ
    - MT4584Summ.pdf
  - 2-Report
    - MT4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.05.06.01.01 Summary

Folder name: 3.05.06.01.01–Summ

IMDRF common content

This is a summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study or test presented in this section The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.05.06.01.02 Full report

Folder name: 3.05.06.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Required

3.05.07 Non-material-mediated pyrogenicity

Folder name: 3.05.07-Pyrogenicity

IMDRF common content

Studies to support pyrogenicity evaluation of final release, such as endotoxin levels, are to be included in this section. This should include:

a) A summary of the non-clinical evidence that falls within this category
b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (that is, what tests were considered and why they were or were not performed)
c) Discussion to support why the evidence presented is sufficient to support the application

Or

d) A statement of why this category of non-clinical laboratory study is not applicable to this case

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.

Health Canada guidance

When biocompatibility assessment includes systemic toxicity concerns (for instance, acute, subacute or subchronic), pyrogen test data and methods should also be summarized. They should cover frequency of testing, number of units tested, methods of testing, any deviations from this testing and test results.

Applicants should include an Overview.pdf file at the parent heading level of the relevant subchapter. This document should provide a concise summary (typically 1 to 2 pages) of both the IMDRF common content, and the IMDRF Health Canada content. In addition, the overview should include a brief rationale explaining how the submitted evidence supports the application.

Classification

New and amendment applications: Conditionally required – Not required when this type of evidence or testing is clearly not applicable to the device or submission. If scientific

judgment is needed to justify why no information is required, then the heading is considered required and the justification should be provided.

3.05.07.01 Study description, study identifier, date of initiation, date of completion

Folder name: 3.05.07.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders: the summary and full report (when required), for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions, these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (summary then full report).

Further, for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a fatigue test and wear test are being included, the application would include an overview file in the parent subchapter folder and two subfolders:

- a custom folder named "3.5.01.01-Component A Fatigue Test, MT4203, 2012-03-20" containing two subfolders with the appropriate files:
  - 1-Summ
    - MT4203Summ.pdf
  - 2-Report
    - MT420Report.pdf
- a custom folder named "3.5.01.02-Assembly B Wear Testing, MT4584, 2012-04-12" containing:
  - 1-Summ
    - MT4584Summ.pdf
  - 2-Report

- MT4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.05.07.01.01 Summary

Folder name: 3.05.07.01.01–Summ

IMDRF common content

This is a summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study or test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.05.07.01.02 Full report

Folder name: 3.05.07.01.02-Report

IMDRF common content

The test report for the test is described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Required

3.05.08 Safety of materials of biological origin (human/animal)

Folder name: 3.05.08-BioMaterialSafety

IMDRF common content

Evaluations performed to demonstrate the safety of materials of biological origin (for example, animal sourced, human sourced material) are to be included in this section. This should include:

a) A description of biological material or derivate
b) State the harvesting, processing, preservation, testing and handling of tissues, cells and substances
c) If applicable, discussion of infectious agents/transmissible agents known to infect the source animal
d) Clarify the origin (including details of donor screening and source country) and describe the tests on validation of removal or inactivation methods of viruses and other pathogens in the manufacturing process
e) A brief summary of process validation should be included to substantiate that manufacturing and screening procedures are in place to minimize biological risks, in particular, with regard to viruses and other transmissible agents
f) The system for recordkeeping to allow traceability from sources to the finished device should be fully described
g) Discussion to support why the evidence presented is sufficient to support the application

Or

h) A statement of why this category of non-clinical laboratory study is not applicable to this case

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device

IMDRF Health Canada content

Refer to the guidance on the regulation of medical devices manufactured from or incorporating viable or non-viable animal tissue or their derivatives.

Health Canada guidance

Applicants should include an Overview.pdf file at the parent heading level of the relevant subchapter. This document should provide a concise summary (typically 1 to 2 pages) of both the IMDRF common content, and the IMDRF Health Canada content. In addition, the overview should include a brief rationale explaining how the submitted evidence supports the application.

Classification

New and amendment applications: Conditionally required: Not required when this type of evidence or testing is clearly not applicable to the device or submission. If scientific judgment is needed to justify why no information is required, then the heading is considered required and the justification should be provided.

3.05.08.02 Study description, study identifier, date of initiation

Folder name: 3.05.08.02-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders: the summary and full report (when required), for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions, these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (summary then full report).

Further, for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a fatigue test and wear test are being included, the application would include an overview file in the parent subchapter folder and two subfolders:

- a custom folder named "3.5.01.01-Component A Fatigue Test, MT4203, 2012-03-20" containing two subfolders with the appropriate files:
    - 1-Summ
        - MT4203Summ.pdf
    - 2-Report
        - MT420Report.pdf
- a custom folder named "3.5.01.02-Assembly B Wear Testing, MT4584, 2012-04-12" containing:
    - 1-Summ
        - MT4584Summ.pdf
    - 2-Report
        - MT4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.05.08.02.01 Summary

Folder name: 3.05.08.02.01–Summ

IMDRF common content

This is a summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study or test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.05.08.02.02 Full report

Folder name: 3.05.08.02.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Required

3.05.09 Sterilization and reprocessing validation

Folder name: 3.05.09-SterilityValidation

No content at this level.

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

Classification

New and amendment applications: Conditionally required – If any sub-headings are required

3.05.09.01 End-user sterilization

Folder name: 3.05.09.01-End-User

IMDRF common content

Information and validation of end-user sterilization where it is necessary for the end-user to sterilize the device. This should include:

a) A description of the sterilization process (method, parameters) and Sterility Assurance Level (SAL)
b) A summary of the non-clinical evidence that falls within this category

c) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (that is, what tests were considered and why they were or were not performed)
d) If applicable, the rationale on the durability of the product against two or more sterilization.
e) Discussion to support why the evidence presented is sufficient to support the application

Or

f) A statement of why this category of non-clinical laboratory study is not applicable to this case

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.

Health Canada guidance

The recommended, validated sterilization method should be stated in the device labelling information.

Applicants should also include an Overview.pdf file at the parent heading level of the relevant subchapter. This document should provide a concise summary (typically 1 to 2 pages) of both the IMDRF common content, and the IMDRF Health Canada content. In addition, the overview should include a brief rationale explaining how the submitted evidence supports the application.

Classification

New and amendment applications: Conditionally required – Not required when this type of evidence or testing is clearly not applicable to the device or submission. If scientific judgment is required to justify why no information is required, then the heading is considered required and the justification should be provided.

3.05.09.01.01 Study description, study identifier, date of initiation

Folder name: 3.05.09.01.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders: the summary and full report (when required), for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions, these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (summary then full report).

Further, for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a fatigue test and wear test are being included, the application would include an overview file in the parent subchapter folder and two subfolders:

- a custom folder named "3.5.01.01-Component A Fatigue Test, MT4203, 2012-03-20" containing two subfolders with the appropriate files:
    - 1-Summ
        - MT4203Summ.pdf
    - 2-Report
        - MT420Report.pdf
- a custom folder named "3.5.01.02-Assembly B Wear Testing, MT4584, 2012-04-12" containing:
    - 1-Summ
        - MT4584Summ.pdf
    - 2-Report
        - MT4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.05.09.01.01.01 Summary

Folder name: 3.05.09.01.01.01–Summ

IMDRF common content

This is a summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study or test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.05.09.01.01.02 Full report

Folder name: 3.05.09.01.01.02-Report

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Required

3.05.09.02 Manufacturer sterilization validation

Folder name: 3.05.09.02-Manufacturer

IMDRF common content

Information and validation of manufacturer sterilization where the device is provided sterile. This should include:

a) A description of the sterilization process (method, parameters) and Sterility Assurance Level (SAL)
b) State if parametric release is used
c) A summary of the non-clinical evidence that falls within this category
d) Information on the ongoing revalidation of the process. Typically, this would consist of arrangements for, or evidence of, revalidation of the packaging and sterilization processes.
e) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (that is, what tests were considered and why they were or were not performed)
f) Discussion to support why the evidence presented is sufficient to support the application

Or

g) A statement of why this category of non-clinical laboratory study is not applicable to this case

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.

Health Canada guidance

If the subject device is sold sterile or is to be sterilized, process validation data should include sterility test data, reference to a standardized test method and attestation or evidence of successful validation under real-life conditions under which the product is to be sterilized.

Bioburden determination, culture media used, time and temperature of incubation, controls, number of samples examined and frequency of testing should also be presented. A sterility assurance level (SAL) of 10^{-6} is generally required. If a biological indicator was used, its placement must be described and rationalized (for example, "most difficult to sterilize" location). If a group of devices is to be sterilized together, the worst-case scenario or most difficult to sterilize product should be validated.

An attestation can be used. The manufacturer should also demonstrate that they have a process in place to monitor bioburden levels on a regular basis to confirm that the sterilization method remains valid. Alternatively, a method of parametric release maybe proposed and validated. If a process challenge device was used to assess the sterilization process, it must be shown to have comparative resistance or a greater challenge to sterilization than the biological indicators placed inside the product/packaging.

Applicants should also include an Overview.pdf file at the parent heading level of the relevant subchapter. This document should provide a concise summary (typically 1 to 2 pages) of both the IMDRF common content, and the IMDRF Health Canada content. In addition, the overview should include a brief rationale explaining how the submitted evidence supports the application.

Classification

New and amendment applications: Conditionally required – Not required when this type of evidence or testing is clearly not applicable to the device or submission. If scientific judgment is required to justify why no information is required, then the heading is considered required and the justification should be provided.

3.05.09.02.01 Study description, study identifier, date of initiation

Folder name: 3.05.09.02.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders: the summary and full report (when required), for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions, these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (summary then full report).

Further, for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a fatigue test and wear test are being included, the application would include an overview file in the parent subchapter folder and two subfolders:

- a custom folder named "3.5.01.01-Component A Fatigue Test, MT4203, 2012-03-20" containing two subfolders with the appropriate files:
  - 1-Summ
    - MT4203Summ.pdf
  - 2-Report
    - MT420report.pdf
- a custom folder named "3.5.01.02-Assembly B Wear Testing, MT4584, 2012-04-12" containing:
  - 1-Summ
    - MT4584Summ.pdf
  - 2-Report
    - MT4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.05.09.02.01.01 Summary

Folder name: 3.05.09.02.01.01–Summ

IMDRF common content

This is a summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study or test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.05.09.02.01.02 Full report

Folder name: 3.05.09.02.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Required

3.05.09.03 Residual toxicity

Folder name: 3.05.09.03-ResidualTox

IMDRF common content

Contain the information on the testing for sterilant residues, where the device is supplied sterile and sterilized using a method susceptible to residues. This should include:

a) A summary of the non-clinical evidence that falls within this category
b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (that is, what tests were considered and why they were or were not performed)
c) Discussion to support why the evidence presented is sufficient to support the application.

Or

d) A statement of why this category of non-clinical laboratory study is not

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.

Health Canada guidance

For ethylene oxide residuals, levels should be within the acceptable levels (recommended by the most current version of ISO 10993-7) in consideration of the body or tissue contact duration of the device. If another sterilization method was used, a description of how residual toxicity concerns were addressed should be provided.

Applicants should also include an Overview.pdf file at the parent heading level of the relevant subchapter. This document should provide a concise summary (typically 1 to 2 pages) of both the IMDRF common content, and the IMDRF Health Canada content. In addition, the overview should include a brief rationale explaining how the submitted evidence supports the application.

Classification

New and amendment applications: Conditionally required – Not required when this type of evidence/testing is clearly not applicable to the device or submission. If scientific judgment is required to justify why no information is required, then the heading is considered required and the justification should be provided.

3.05.09.03.01 Study description, study identifier, date of initiation

Folder name: 3.05.09.03.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders: the summary and full report (when required), for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions, these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (summary then full report).

Further, for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a fatigue test and wear test are being included, the application would include an overview file in the parent subchapter folder and two subfolders:

- a custom folder named "3.5.01.01-Component A Fatigue Test, MT4203, 2012-03-20" containing two subfolders with the appropriate files:
  - 1-Summ
    - MT4203Summ.pdf
  - 2-Report
    - MT420Report.pdf
- a custom folder named "3.5.01.02-Assembly B Wear Testing, MT4584, 2012-04-12" containing:
  - 1-Summ
    - MT4584Summ.pdf
  - 2-Report
    - MT4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.05.09.03.01.01 Summary

Folder name: 3.05.09.03.01.01–Summ

IMDRF common content

This is a summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study or test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.05.09.03.01.02 Full report

Folder name: 3.05.09.03.01.02-Report

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Required

3.05.09.04 Cleaning and disinfection validation

Folder name: 3.05.09.04-Clean-DisinfectVal

IMDRF common content

Contains information on the validation of cleaning and disinfection instructions for reusable devices. This should include:

a) A summary of the non-clinical evidence that falls within this category
b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (that is, what tests were considered and why they were or were not performed)
c) Discussion to support why the evidence presented is sufficient to support the application.

Or

d) A statement of why this category of non-clinical laboratory study is not applicable to this case

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.

Health Canada guidance

Applicants should include an Overview.pdf file at the parent heading level of the relevant subchapter. This document should provide a concise summary (typically 1 to 2 pages) of both the IMDRF common content, and the IMDRF Health Canada content. In addition, the overview should include a brief rationale explaining how the submitted evidence supports the application.

Classification

New and amendment applications: Conditionally required – Not required when this type of evidence or testing is clearly not applicable to the device or submission. If scientific judgment is needed to justify why no information is required, then the heading is considered required and the justification should be provided.

3.05.09.04.01 Study description, study identifier, date of initiation

Folder name: 3.05.09.04.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created for each study under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders: the summary and full report (when required), for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions, these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (summary then full report).

Further, for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a fatigue test and wear test are being included, the application would include an overview file in the parent subchapter folder and two subfolders:

- a custom folder named "3.5.01.01-Component A Fatigue Test, MT4203, 2012-03-20" containing two subfolders with the appropriate files:
    - 1-Summ
        - MT4203Summ.pdf
    - 2-Report
        - MT420report.pdf
- a custom folder named "3.5.01.02-Assembly B Wear Testing, MT4584, 2012-04-12" containing:
    - 1-Summ
        - MT4584Summ.pdf
    - 2-Report
        - MT4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.05.09.04.01.01 Summary

Folder name: 3.05.09.04.01.01–Summ

IMDRF common content

This is a summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study or test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.05.09.04.01.02 Full report

Folder name: 3.05.09.04.01.02-Report

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Required

3.05.09.05 Reprocessing of single-use devices, validation data

Folder name: 3.05.09.05-ReprocessingofSUDs

IMDRF common content

The required validation data including cleaning and sterilization data, and functional performance data demonstrating that each single use device (SUD) will continue to meet specifications after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification.

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.

Health Canada guidance

Applicants should include an Overview.pdf file at the parent heading level of the relevant subchapter. This document should provide a concise summary (typically 1–2 pages) of both the IMDRF common content, and the IMDRF Health Canada content. In addition, the overview should include a brief rationale explaining how the submitted evidence supports the application.

Classification

New and amendment applications: Conditionally required – When the purpose of the submission includes seeking a licence for a reprocessed single-use device

3.05.09.05.01 Study description, study identifier, date of initiation

Folder name: 3.05.09.05.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders: the summary and full report (when required), for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions, these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (summary then full report).

Further, for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a fatigue test and wear test are being included, the application would include an overview file in the parent subchapter folder and two subfolders:

- a custom folder named "3.5.01.01-Component A Fatigue Test, MT4203, 2012-03-20" containing two subfolders with the appropriate files:
  - 1-Summ
    - MT4203Summ.pdf
  - 2-Report
    - MT420report.pdf
- a custom folder named "3.5.01.02-Assembly B Wear Testing, MT4584, 2012-04-12" containing:
  - 1-Summ
    - MT4584Summ.pdf
  - 2-Report
    - MT4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.05.09.05.01.01 Summary

Folder name: 3.05.09.05.01.01–Summ

IMDRF common content

This is a summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study or test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.05.09.05.01.02 Full report

Folder name: 3.05.09.05.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Required

3.05.10 Animal testing

Folder name: 3.05.10-AnimalTesting

IMDRF common content

Contains information about any animal studies conducted to support the submission. This should include:

a) A summary of the non-clinical evidence that falls within this category
b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (that is, what tests were considered and why they were or were not performed)
c) Discussion to support why the evidence presented is sufficient to support the application.

Or

d) A statement of why this category of non-clinical laboratory study is not applicable to this case.

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.

Health Canada guidance

Animal studies should be undertaken using good laboratory practices. The study conclusion should consider the device's interaction with animal fluids and tissues and the safety and functional effectiveness of the device in the experimental animal model. The rationale (and limitations) of selecting the particular animal model should be discussed.

This section should not include animal studies supporting biocompatibility.

Applicants should also include an Overview.pdf file at the parent heading level of the relevant subchapter. This document should provide a concise summary (typically 1–2 pages) of both the IMDRF common content, and the IMDRF Health Canada content. In addition, the overview should include a brief rationale explaining how the submitted evidence supports the application.

Classification

New and amendment applications: Conditionally required – Not required when this type of evidence or testing is clearly not applicable to the device or submission. If scientific judgment is needed to justify why no information is required, then the heading is considered required and the justification should be provided.

3.05.10.01 Study description, study identifier, date of initiation, date of completion

Folder name: 3.05.10.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders: the summary and full report (when required), for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions, these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (summary then full report).

Further, for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a fatigue test and wear test are being included, the application would include an overview file in the parent subchapter folder and two subfolders:

- a custom folder named "3.5.01.01-Component A Fatigue Test, MT4203, 2012-03-20" containing two subfolders with the appropriate files:
  - 1-Summ
    - MT4203Summ.pdf
  - 2-Report
    - MT420report.pdf
- a custom folder named "3.5.01.02-Assembly B Wear Testing, MT4584, 2012-04-12" containing:
  - 1-Summ

        - MT4584Summ.pdf
    - 2-Report
        - MT4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.05.10.01.01 Summary

Folder name: 3.05.10.01.01–Summ

IMDRF common content

This is a summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study or test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.05.10.01.02 Full report

Folder name: 3.05.10.01.02-Report

IMDRF common content

The test report for the test is described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Required

3.05.11 Usability/human factors

Folder name: 3.05.11-Usability-HumanFactors

IMDRF common content

Studies specifically assessing the instructions and/or device design in terms of impact of human behaviour, abilities, limitations, and other characteristics on the ability of the device to perform as intended should be included here. This should include:

a) A summary of the non-clinical evidence that falls within this category
b) A statement of the test environment and relation to the intended use environment
c) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (that is, what tests were considered and why they were or were not performed)
d) If a clinical study has been conducted that includes human factors/usability endpoints, reference to the studies and endpoints should be made, but full results do not need to be repeated
e) Discussion to support why the evidence presented is sufficient to support the application.

Or

f) A statement of why this category of non-clinical laboratory study is not applicable to this case

Notes:

i. If a clinical study has been conducted that includes usability/human factors endpoints, reference to the studies and endpoints should be made, but full results do not need to be repeated and should be included in Chapter 4: Clinical evidence.

ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.

Health Canada guidance

Applicants should include an Overview.pdf file at the parent heading level of the relevant subchapter. This document should provide a concise summary (typically 1 to 2 pages) of both the IMDRF common content, and the IMDRF Health Canada content. In addition, the overview should include a brief rationale explaining how the submitted evidence supports the application.

Classification

New and amendment applications: Conditionally required – Not required when this type of evidence or testing is clearly not applicable to the device or submission. If scientific judgment is needed to justify why no information is required, then the heading is considered required and the justification should be provided.

3.05.11.01 Study description, study identifier, date of initiation

Folder name: 3.05.11.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders: the summary and full report (when required), for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions, these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (summary then full report).

Further, for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a fatigue test and wear test are being included, the application would include an overview file in the parent subchapter folder and two subfolders:

- a custom folder named "3.5.01.01-Component A Fatigue Test, MT4203, 2012-03-20" containing two subfolders with the appropriate files:
  - 1-Summ
    - MT4203Summ.pdf
  - 2-Report
    - MT420report.pdf
- a custom folder named "3.5.01.02-Assembly B Wear Testing, MT4584, 2012-04-12" containing:
  - 1-Summ
    - MT4584Summ.pdf
  - 2-Report
    - MT4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.05.11.01.01 Summary

Folder name: 3.05.11.01.01–Summ

IMDRF common content

This is a summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study or test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.05.11.01.02 Full report

Folder name: 3.05.11.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Required

3.06 Non-clinical bibliography

Folder name: 3.06-Non-ClinBibliography

IMDRF common content

This heading should include:

a) A listing of published non-clinical studies involving this specific device (for example, cadaveric evaluations, biomechanical assessments)
b) Legible copies of key articles, including translation where applicable to meet the regulators language requirements
c) Discussion to support why the evidence presented is sufficient to support the application

Or

d) A statement that no literature related to the device was found

Health Canada guidance

To facilitate the review process, the manufacturer should provide a bibliography (list of references) of all relevant non-clinical published literature dealing with the use, safety and effectiveness, and indications for use of the device in question. If information in the article is being provided as key evidence of safety or effectiveness, you should provide a summary of the relevant sections, including data used to draw the conclusions, and copies of the articles.

Take care to ensure that the references are timely and relevant to the current application. A bibliography may not be necessary if the device or its technology is well known with a long history of use.

Classification

New licence applications: Conditionally required – Not required when this type of evidence or testing is clearly not applicable to the device or submission. If scientific judgment is needed to justify why no information is required, then the heading is considered required and the justification should be provided.

Amendment licence applications: Conditionally required – When relevant to the amendment

3.07 Expiration period and package validation

Folder name: 3.07-ExpirationPeriod-PackageVal

IMDRF common content

This heading should include:

a) An indication of environmental conditions for correct storage of the device (for example, temperature, pressure, humidity, luminosity)
b) A statement of the expiration period considering the materials and sterilization (when applicable), indicated as a period of time or any other means of appropriate quantification

Or

c) A rationale that storage conditions could not affect device safety or effectiveness

IMDRF Health Canada content

For devices that do not have an expiration period (for example, electromedical equipment or other devices of multiple use), information regarding the estimated mean “lifetime”. This mean “lifetime” can be indicated as number of procedures to be performed with the device and/or its accessories, as a period of time or any other means of appropriate quantification.

Classification

New and amendment applications: Conditionally required – Not required when this type of evidence or testing is clearly not applicable to the device or submission. If scientific judgment is needed to justify why no information is required, then the heading is considered required and the justification should be provided.

3.07.01 Product stability

Folder name: 3.07.01-ProductStability

IMDRF common content

Contains details relating to product stability under specified storage conditions and in final packaging or simulated conditions. This should include:

a) A statement of the shelf-life (for each component if there are differences between components) and the proposed storage condition for the device
b) A summary of the non-clinical evidence, covering shelf-life period when stored at the proposed storage condition, that falls within this category
c) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (that is, what tests were considered and why they were or were not performed)
d) Discussion to support why the evidence presented is sufficient to support the application
e) Evidence to support stability of the medicinal substance contained in the device at the proposed storage condition
f) Evidence of in-use stability supporting the stability during actual routine use of the device (real or simulated)

Or

g) A statement of why this category of non-clinical laboratory study is not applicable to this case

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.

Health Canada guidance

If the product is subject to a shelf-life, shelf-life testing should be provided and the claimed shelf-life clearly stated. The method used (for example, accelerated versus real time) should be provided along with the storage conditions used and the state of the product when tested (for example, sterilized, production version, prototype, transportation, simulation). Devices containing materials of unknown stability should have real-time data.

Applicants should also include an Overview.pdf file at the parent heading level of the relevant subchapter. This document should provide a concise summary (typically 1 to 2 pages) of both the IMDRF common content, and the IMDRF Health Canada content. In addition, the overview should include a brief rationale explaining how the submitted evidence supports the application.

Classification

New and amendment applications: Conditionally required: Not required when this type of evidence or testing is clearly not applicable to the device or submission. If scientific judgment is needed to justify why no information is required, then the heading is considered required, and the justification should be provided.

3.07.01.01 Study description, study identifier, date of initiation

Folder name: 3.07.01.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders: the summary and full report (when required), for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions, these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (summary then full report).

Further, for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a fatigue test and wear test are being included, the application would include an overview file in the parent subchapter folder and two subfolders:

- a custom folder named "3.5.01.01-Component A Fatigue Test, MT4203, 2012-03-20" containing two subfolders with the appropriate files:
  - 1-Summ
    - MT4203Summ.pdf
  - 2-Report
    - MT420report.pdf
- a custom folder named "3.5.01.02-Assembly B Wear Testing, MT4584, 2012-04-12" containing:
  - 1-Summ
    - MT4584Summ.pdf
  - 2-Report
    - MT4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.07.01.01.01 Summary

Folder name: 3.07.01.01.01–Summ

IMDRF common content

This is a summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study or test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.07.01.01.02 Full report

Folder name: 3.07.01.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Required

3.07.02 Package validation

Folder name: 3.07.02-PackageVal

IMDRF common content

Contains details relating to package integrity over the claimed shelf-life and in the packaging and distribution environment (transport and packaging validation) and when applicable, following exposure to the sterilization process. This should include:

a) A summary of the non-clinical evidence, covering shelf-life period, that falls within this category
b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in

this category (that is, what tests were considered and why they were or were not performed)

c) Discussion to support why the evidence presented is sufficient to support the application

Or

d) A statement of why this category of non-clinical laboratory study is not applicable to this case

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.

Health Canada guidance

If the device requires special packaging (for example, considerations related to sterility, humidity, light sensitivity, pressure or oxidative reaction under irradiation), you should provide evidence that this has been addressed.

Likewise, evidence should be provided to demonstrate that the integrity of the device and the internal environment are maintained by the device packaging during handling, transport and storage (for the claimed shelf life).

In the case of sterility, ensure that the test methods address both seal integrity and sterility (for example, bubble test, dye penetration test, etc.).

Applicants should also include an Overview.pdf file at the parent heading level of the relevant subchapter. This document should provide a concise summary (typically 1 to 2 pages) of both the IMDRF common content, and the IMDRF Health Canada content. In addition, the overview should include a brief rationale explaining how the submitted evidence supports the application.

Classification

New and amendment applications: Conditionally required – Not required when this type of evidence or testing is clearly not applicable to the device or submission. If scientific judgment is needed to justify why no information is required, then the heading is considered required and the justification should be provided.

3.07.02.01 Study description, study identifier, date of initiation

Folder name: 3.07.02.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders: the summary and full report (when required), for the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions, these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (summary then full report).

Further, for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a fatigue test and wear test are being included, the application would include an overview file in the parent subchapter folder and two subfolders:

- a custom folder named "3.5.01.01-Component A Fatigue Test, MT4203, 2012-03-20" containing two subfolders with the appropriate files:
  - 1-Summ
    - MT4203Summ.pdf
  - 2-Report
    - MT420report.pdf
- a custom folder named "3.5.01.02-Assembly B Wear Testing, MT4584, 2012-04-12" containing:
  - 1-Summ
    - MT4584Summ.pdf
  - 2-Report
    - MT4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.07.02.01.01 Summary

Folder name: 3.07.02.01.01–Summ

IMDRF common content

This is a summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study or test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.07.02.01.02 Full report

Folder name: 3.07.02.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Required

3.08 Other non-clinical evidence

Folder name: 3.08-OtherNon-ClinEvidence

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. This section is specifically intended for tests performed to ensure the safety and/or effectiveness of the device **that are not delineated in the rest of the Chapter 3.** This should include:

a) A description of the purpose of the test, the risk/safety issue the test is addressing; the test methods and results of the test

Note: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device

Health Canada guidance

Applicants should include an Overview.pdf file at the parent heading level of the relevant subchapter. This document should provide a concise summary (typically 1 to 2 pages) of both the IMDRF common content, and the IMDRF Health Canada content. In addition, the overview should include a brief rationale explaining how the submitted evidence supports the application.

Classification

New and amendment applications: Conditionally required: When information is requested by the regulator (through guidance documents or other communication) but does not belong in any of the other headings of this chapter

3.08.01 Study description, study identifier, date of initiation

Folder name: 3.08.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone.

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders: the summary and full report (when required), for

the study presented. As described in the Health Canada adapted assembly and technical guide for IMDRF Table of Contents submissions, these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (summary then full report).

Further, for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a fatigue test and wear test are being included, the application would include an overview file in the parent subchapter folder and two subfolders:

- a custom folder named "3.5.01.01-Component A Fatigue Test, MT4203, 2012-03-20" containing two subfolders with the appropriate files:
  - 1-Summ
    - MT4203Summ.pdf
  - 2-Report
    - MT420Report.pdf
- a custom folder named "3.5.01.02-Assembly B Wear Testing, MT4584, 2012-04-12" containing:
  - 1-Summ
    - MT4584Summ.pdf
  - 2-Report
    - MT4584Report.pdf

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

3.08.01.01 Summary

Folder name: 3.08.01.01–Summ

IMDRF common content

This is a summary of the specific study described in the custom heading above.

Health Canada guidance

For detailed information on summary content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study or test presented in this section. The test summary should be sufficiently detailed to stand alone in describing the evidence.

3.08.01.02 Full report

Folder name: 3.08.01.02-Report

IMDRF common content

The test report for the test described in the custom heading above.

Health Canada guidance

For information on full report content requirements and expectations, refer to the Definitions section of the Health Canada IMDRF Table of Contents for medical device applications guidance.

Classification

New and amendment applications: Required

Chapter 4: Clinical evidence

Folder name: 4-CLINICAL

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

4.02 Overall clinical evidence summary

Folder name: 4.02-OverallClinicalEvidenceSumm

IMDRF common content

a) This should be a brief (1 to 2 page) summary of the available clinical evidence being presented in support of the submission. The document should list the

evidence presented, its characteristics (RCT, case study, literature review, post market data from another jurisdiction or from a marketed device) and provide a discussion of how this is considered sufficient to support request for marketing for the requested indications. A tabular listing of clinical studies may be included in this section

b) If any of the study devices differ from the devices to be marketed, including competitor's devices, a description of these differences and their impact on the validity of the evidence in terms of support for the application for any device referenced in the application. This may include a detailed comparison of the clinical, technical and biological characteristics of the two devices, with a detailed critical analysis demonstrating the devices to be similar to such an extent that there would be no clinically significant difference in safety or performance
c) A discussion of the clinical evidence considered for the device and support for their selection (that is, what type of evidence was considered and why they were or were not used)
d) Discussion to support why the evidence presented is sufficient to support the application

Note: Human factors testing that include patients should be included here.

IMDRF Health Canada content

a) Provide the Investigational Testing Authorization reference number for any clinical trials conducted under an Investigational Testing Authorization in Canada.
b) If applicable, provide the clinicaltrials.gov reference number for any clinical studies registered with clinicaltrials.gov.
c) Consult the guidance on clinical evidence requirements for medical devices for additional requirements.

Health Canada guidance

An evaluation of clinical evidence is necessary to help establish the clinical safety and effectiveness of a medical device for each claimed indication for use. A clinical evaluation considers available, relevant clinical data from published sources or device-related

investigations. It may be necessary to generate additional clinical data to address specific issues for certain medical devices.

If a clinical history has been well established with a given device technology, evidence may be provided in the form of a literature review of relevant peer-reviewed scientific publications. Reference to devices other than the subject device in support of safety or effectiveness requires a thorough comparison to the subject device design, features and performance capabilities to demonstrate relevance. This may be provided in a table. Leveraged publications should be referenced but you only need to provide copies if they are pivotal in supporting safety or effectiveness.

Clinical evidence in the form of device-specific clinical investigations conducted in Canada or other countries should be summarized. Summaries should cover, clearly and meaningfully, the objectives, methodology and results presented in context. The conclusions on the outcome of the clinical investigations should be preceded by a discussion, with reference to the published literature. Both statistical and clinical significance should be considered and critically analyzed.

Classification

New and amendment applications: Conditionally required– Not required when this type of evidence or testing is clearly not applicable to the device or submission. If scientific judgment is needed to justify why no information is required, then the heading is considered required and the justification should be provided.

4.02.01 Clinical evaluation report

Folder name: 4.02.01-ClinicalEvaluationReport

IMDRF common content

a) A clinical evaluation report reviewed and signed by an expert in the relevant field that contains an objective critical evaluation of all of the clinical data submitted in relation to the device
b) A complete curriculum vitae, or similar documentation, to justify the manufacturer's choice of the clinical expert

Classification

New and amendment applications: Optional

4.02.02 Device-specific clinical trials

Folder name: 4.02.02-DeviceSpecific

IMDRF common content

No content at this level. Clinical trial information under this heading should be grouped by trial.

Classification

New and amendment applications: Conditionally required – If any sub-headings are required

4.02.02.01 Trial description, protocol number, date of initiation

Folder name: 4.02.02.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

IMDRF common content

No content at this level

This heading should be custom and based on study details and created **for each study** under the parent heading. The sub headings below would be for this study alone. For example, the structure will look something like this

Level 3: EU Pilot Study, CT4203, 2010-10-10
- Level 4: Clinical Trial Summary
- Level 4: Clinical Trial Report

Level 3: NA RCT Study, CT4584, 2011-01-23
- Level 4: Clinical Trial Summary
- Level 4: Clinical Trial Report

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders, namely the summary and full report (when required) for the study presented. As described in the Health Canada Adapted Assembly and Technical Guide for IMDRF Table of Contents Submissions these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (that is, summary first followed by the full report second).

Further, for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a pilot study and a controlled pivotal study are being presented, the application would include two subfolders:

- a custom folder named "4.02.02.01-EU Pilot Study, CT4203, 2010-10-10" containing:
  - 1-Summary
    - CT4203Summ.pdf
  - 2-Trial report
    - CT4203Report.pdf
- a custom folder named "3.5.01.02-NA RCT Study, CT4584, 2011-01-23" containing:
  - 1-Summary
    - CT4584Summ.pdf
  - 2-Trial report
    - CT4584Report.pdf

As per IMDRF content guidance, the summary should contain:

- A summary of the specific study described in the custom heading
- A summary (2 to 3 pages) of:
  - the key characteristics of the study (for example, title of study, investigators, sites, study period (date of enrollment/date of last completed), objectives, methods, number of patients, inclusion/exclusion criteria)
  - the results of the analysis
  - conclusions related to the endpoints

Note: You should explicitly address any existing regional regulatory guidance related to the components of the clinical trial summary.

Classification

New and amendment applications: Conditionally required – **Required** for each study or test presented in this section

4.02.02.01.01 Clinical trial summary

Folder name: 4.02.02.01.01-Summ

IMDRF common content

a) A summary of the specific study described in the custom heading above that includes:
    i. The key characteristics of the study (for example, title of study, investigators, sites, study period (date of enrollment/date of last completed), objectives, methods, number of patients, inclusion/exclusion criteria)
    ii. Summary of the results of the analysis
    iii. Summary of conclusions related to the endpoints

Notes:

i. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the components of the clinical trial summary.
ii. The sponsor/applicant should explicitly state whether the data are sex-, gender-, age-, race-, and ethnicity-disaggregated. If the data are not disaggregated, the sponsor/applicant should provide a rationale why.

IMDRF Health Canada content

Consult:

- Guidance on clinical evidence requirements for medical devices

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study or test presented in this section

4.02.02.01.02 Clinical trial report

Folder name: 4.02.02.01.02-TrialReport

IMDRF common content

a) A clinical trial report of the specific study described in the custom heading above.

Notes:

i. The clinical study report should include elements such as the investigational plan/study protocol, protocol changes and deviations, description of patients, data quality assurance, analysis/results.
ii. The sponsor/applicant should explicitly address any relevant existing regional regulatory guidance related to the components of the clinical trial report.

Classification

New and amendment applications: Conditionally required – A comprehensive full report is **required** for each study or test presented in this section

4.02.03 Clinical literature review and other reasonable known information

Folder name: 4.02.03-LitReview-OtherKnownInfo

IMDRF common content

a) A critical evaluation of the relevant scientific literature currently available relating to the safety and/or effectiveness of the device. This should incorporate:
    i. A documented search protocol to a level of detail that allows the search to be reproduced
    ii. A selection strategy (inclusion/exclusion criteria)
    iii. Criteria for appraising the data (both favourable and unfavourable) to determine the contribution of each data set to support the conclusions;
    iv. Results of the literature search
    v. A documentation of the appraisal to the extent that it can be critically reviewed by others
b) A legible copy of key articles, including translation where applicable to meet the regulators language requirements

Or

c) A statement that no literature related to the device was found

Notes:

i. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the clinical study and data provided in this section regarding the subject device.

ii. Please see Chapter 2.07 for post-market study plans.

Health Canada guidance

For more information on the use of scientific literature or published clinical data in support of the device safety and effectiveness, please refer to the **clinical data and evaluation** section of the Guidance on clinical evidence requirements for medical devices.

Classification

New and amendment applications: Conditionally required – When applicable to submission

4.05 Real world data

Folder name: 4.05-RWD

IMDRF common content

Include, where applicable, other clinical experience data/real world data (including device registries, post-market studies conducted in other jurisdictions).

Health Canada guidance

For more information on the use of real-world data and evidence in support of the device safety and effectiveness, please refer to the **clinical data and evaluation** section of the Guidance on clinical evidence requirements for medical devices.

Classification

New and amendment applications: Conditionally required – When applicable to submission

4.07 Other clinical evidence

Folder name: 4.07-OtherClinicalEvidence

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.

Health Canada guidance

This section is specifically intended for studies performed to ensure the safety and/or effectiveness of the device that are not delineated in the rest of Chapter 4.

Applicants should also include an Overview.pdf file at the parent heading level of the relevant subchapter. This document should provide a concise summary (typically 1 to 2 pages) of both the IMDRF common content, and the IMDRF Health Canada content. In addition, the overview should include a brief rationale explaining how the submitted evidence supports the application.

Classification

New and amendment applications: Conditionally required – If any sub-headings are required.

4.07.01 Trial description, protocol number, date of initiation

Folder name: 4.07.01-StudyTitle,Identifier,Date(yyyy-mm-dd)

Health Canada guidance

This folder should be customized to represent the details of the study. The contents of this folder should be limited to two subfolders, namely the summary and full report (when required) for the study presented. As described in the *Health Canada Adapted Assembly and Technical Guide for IMDRF Table of Contents Submissions* these subfolders are to be named to ensure the sequence remains as described in the IMDRF ToC (that is, summary first followed by the full report second).

Further, for each additional custom folder created, the final digit of the heading number should be incremented by 1.

For example, when a pilot study and a controlled pivotal study are being presented, the application would include two subfolders:

- A custom folder named "4.02.02.01-EU Pilot Study, CT4203, 2010-10-10" containing:
    - 1-Summary

        - CT4203Summ.pdf
    - 2-Trial report
        - CT4203Report.pdf
- A custom folder named "3.5.01.02-NA RCT Study, CT4584, 2011-01-23" containing:
    - 1-Summary
        - CT4584Summ.pdf
    - 2-Trial report
        - CT4584Report.pdf

As per IMDRF content guidance, the summary should contain:

- A summary of the specific study described in the custom heading
- A summary (2 to 3 pages) of:
    - the key characteristics of the study (for example, title of study, investigators, sites, study period (date of enrollment/date of last completed), objectives, methods, number of patients, inclusion/exclusion criteria)
    - the results of the analysis
    - conclusions related to the endpoints

Note: You should explicitly address any existing regional regulatory guidance related to the components of the clinical trial summary.

Classification

New and amendment applications: Conditionally required – This is required for each study presented in this section

4.07.01.01 Clinical trial summary

Folder name: 4.07.01.01-Summ

Health Canada guidance

The summary should contain:

- A summary of the specific study described in the custom heading

- A summary (2 to 3 pages) of:
  - the key characteristics of the study (for example, title of study, investigators, sites, study period (date of enrollment/date of last completed), objectives, methods, number of patients, inclusion/exclusion criteria)
  - the results of the analysis
  - conclusions related to the endpoints

Classification

New and amendment applications: Conditionally required – A comprehensive summary is **required** for each study or test presented in this section

4.07.01.02 Clinical trial report

Folder name: 4.07.01.02-Report

Health Canada guidance

Include a clinical trial report of the specific study described in the custom heading above.

Classification

New and amendment applications: Conditionally required – A comprehensive full report is **required** for each study or test presented in this section

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.

Health Canada guidance

While draft labelling may be provided initially in the licence application, final labelling will be required before a licence is issued.

The statements of indications for use and/or intended use must be clearly stated in the device labelling, and will be the official claims against which authorization will be assessed. All expressed or implied claims made elsewhere in the labelling (such as instructions of use, advertising, or promotional material) must be consistent with the official statement.

Labelling materials should include, as appropriate, recommended disposal techniques, the nature of combustion products the risk of explosion, etc.

Devices sold in non-sterile condition, but intended to be used sterilized, must specify the recommended sterilization process in the labelling.

If the labelling material covers components or devices not currently licensed in Canada this should be identified in the labelling.

Classification

New and amendment applications: Required

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

Classification

New and amendment applications: Required

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, identification of 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 IFUs 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-labeling requirements for the website have been met

f) If a video/app is available to demonstrate how the device is intended to function, 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, 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

New and amendment applications: Optional

5.05 Health care professional labelling

Folder name: 5.05-HealthcareProfessionalLabelling

IMDRF common content

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

Classification

New and amendment applications: Conditionally required – If applicable for the device

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

New and amendment applications: Conditionally required – If applicable for the device

5.07 Technical and/or operators manual

Folder name: 5.07-Technical-OperatorManual

IMDRF common content

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

Classification

New and amendment applications: Conditionally required – If applicable for the device

5.08 Patient file stickers, cards, and implant registration cards

Folder name: 5.08-PatientFileStickers-Cards-ImplantRegistrationCards

IMDRF Health Canada content

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

Health Canada guidance

This section applies to implants as defined in Schedule 2 of the Medical Devices Regulations:

- Heart valve
- Annuloplasty ring
- Active implantable device systems
    - all models of implantable pacemakers and leads

    - all models of implantable defibrillators and leads
    - artificial heart
    - implantable ventricular support system
    - implantable drug infusion system
- Devices of human origin
    - human dura mater
    - wound covering containing human cells

If the subject device requires an implant registration system, the manufacturer must comply with Sections 66 to 68 of the Regulations. In the submission, the manufacturer is to provide samples of the implant registration cards, which must meet the requirements outlined in Section 66.

Classification

New and amendment applications: Conditionally required – If applicable for the device

5.09 Product brochures

Folder name: 5.09-ProductBrochures

IMDRF Health Canada content

Draft product brochures available at the time of application.

Classification

New and amendment applications: Conditionally required – If applicable for the device

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

New and amendment applications: Conditionally required – When information is requested by the regulator (through guidance documents or other communication) but does not belong in any of the other headings of this chapter.

Chapter 6: Quality management system

Folder name: 6-QMS

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

6.12 Production and service controls

Folder name: 6.12-Production-ServCtrlsProcedures

IMDRF common content

ISO 13485 Elements –SOPs and device specific documentation implementing sub clause 7.5.

IMDRF Health Canada content

a) Detailed manufacturing flow diagram
b) Summary of in-process acceptance activities for subject device
c) Process validation master plan
d) List of processes that have not been validated

e) For each process validation considered critical to the safety and effectiveness of the device:
    i. Protocols/procedures for the validated process
    ii. Process validation report
    iii. The procedures for monitoring and controlling the process parameters of a validated process should be fully described
    iv. State the frequency of re-validation

Note:

a) Manufacturing flow diagram is required to describe the methods used in, and quality controls used for, the manufacture, processing, packaging, storage and, where appropriate, the installation of the device. Sufficient detail must be provided to enable the judgement of the appropriateness of the quality controls in place.
b) If multiple facilities are involved in the manufacture of a device, the applicable information for each facility must be submitted. If the information is identical for a number of sites, this should be stated.

Heath Canada guidance

If process results could not be fully verified during routine production by inspection or testing, the results of process validation studies must be presented. Process validation data should include test data and methods, information on controls, number of samples examined, frequency of testing, and why process validation was used (for example, routine end product tests have insufficient sensitivity, reliability of a changed process is unknown, etc.). The procedures for monitoring and controlling the process parameters of a validated process should also be fully described. Process validation related to sterilization or shelf life should be captured under separate headings of sterilization or shelf and need not be included in this section. Also: reference may be made to a product's proprietary information submission for this information.

Classification

New applications: Required

Amendment applications: Conditionally required – If applicable to the amendment

6.15 Device-specific quality plan

Folder name: 6.15-DeviceSpecificQualityPlan

IMDRF Health Canada content

The review requirement for a quality plan is not met by the ISO 13485 certificate alone, instead refer to ISO 10005. A quality plan should specify “which processes, procedures and associated resources will be applied by whom and when to meet the requirements of a specific project, product, process or contract…”. This information may be provided in an application in the form of a flow chart, process map, document matrix, table or text description. A quality plan specific for the subject device should link device requirements to the processes, resources and projects used by the manufacturer in producing that device.

Classification

New applications: Required

Amendment applications: Conditionally required – If applicable to the amendment

6.17 Other quality system information

Folder name: 6.17-OtherQualitySystemInformation

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.

Classification

New and amendment applications: Conditionally required – When information is requested by the regulator (through guidance documents or other communication) but does not belong in any of the other headings of this chapter.