



**Final**

IMDRF/RPS WG/N9 FINAL:2024 (Edition 4)

# **Non-In Vitro Diagnostic Device Regulatory Submission Table of Contents (nIVD ToC)**

**AUTHORING GROUP**

**Regulated Product Submissions Table of Contents  
Working Group**

# Preface

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A handwritten signature in blue ink, appearing to read 'Rys', is centered within a white rectangular box.

**Andrzej Rys, IMDRF Chair**

# Contents

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<b>Preface</b>	<b>4</b>
<b>Introduction</b>	<b>5</b>
Scope	5
Purpose	5
Definitions	5
Language requirements	7
Other general notes	7
Acronyms	8
Hierarchy presentation	9

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<b>1. Chapter 1 – Regional Administrative</b>	<b>15</b>
<b>2. Chapter 2 – Submission Context</b>	<b>44</b>
<b>3. Chapter 3 – Non-clinical evidence</b>	<b>69</b>
<b>4. Chapter 4 – Clinical evidence</b>	<b>125</b>
<b>5. Chapter 5 – Labelling and promotional material</b>	<b>135</b>
<b>6. Chapter 6 – Quality management system</b>	<b>145</b>
<b>7. Document revision history</b>	<b>163</b>

# Preface

The document herein was produced by the International Medical Device Regulators Forum (IMDRF), a voluntary group of global medical device regulators from around the world. The document has been subject to consultation throughout its development.

There are no restrictions on the reproduction, distribution or use of this document; however, incorporation of this document, in part or in whole, into any other document, or its translation into languages other than English, does not convey or represent an endorsement of any kind by the International Medical Device Regulators Forum. It is also worth noting that it is the intent of IMDRF to continue to monitor use of this structure and work to continually improve the documents.

# Introduction

The Regulated Product Submission (RPS) proposal was endorsed as a New Work Item (NWI) by IMDRF at its inaugural meeting in Singapore (March 2012). The proposal, as endorsed, included the objective of establishing a comprehensive harmonized structure for regulated medical device submissions.

The submission content in this document is primarily organized to accommodate a submission package structured with nested folders. The best method to accommodate this type of nested folder structure is to prioritize where to place and find documents/information within multiple levels of folders. As a result, the order of content in this document is not intended to convey or describe the order in which content would be assembled or reviewed. Instead, content is organized by type, which may in places follow the order of submission assembly or review. The primary Chapters are few in number to facilitate easier navigation.

This document provides an internationally harmonized, modular, structure for use when filing medical device submissions to regulatory authorities for marketing. This document is comprehensive in scope in that it defines the location of both common (IMDRF) and regional content for all submission types. As a consequence, not all headings are required for all submission types and/or IMDRF jurisdictions. Revisions to this document since its initial release reflect input from the public and experience gained from use of the initial version.

## Scope

This document was developed for non-In-vitro diagnostics device (nIVD) regulatory submissions. While regulatory submissions for combination products are out of scope, this document can be used to address the device-related aspects of products that incorporate both drug and device components; refer to each specific regulator for guidance regarding combination products. Submissions to request approval to conduct clinical trials are not within the scope of this document.

The document is intended to provide guidance for industry with flexibility to adapt to the variety of products and future products.

## Purpose

To create a comprehensive submission structure that minimizes regional divergences and indicates where regional variation exists. This document is intended to provide guidance regarding the location of submission elements in the internationally defined structure.

This document is not intended to introduce any new regulatory requirements.

## Definitions

**Accessory** – Means an article intended specifically by its manufacturer to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended use (see GHTF SG1 N71:2012). Be aware that each jurisdiction has a more specific definition.

**COMMON CONTENT** – The content shared by jurisdictions for the respective subchapter.

**FULL REPORT** - Typically includes a complete, detailed description of the objective of the assessment, the methods and procedures including when applicable why a regional or harmonized/recognized standard/guidance has or has not been complied with, study endpoint(s), pre-defined pass/fail criteria, deviations, results, discussion and conclusions, and may include data. Complete, detailed support of method selection, worst case justification, study endpoint selection, and pass/fail criteria should be included.

*Note:* In some jurisdictions (e.g. EU), full reports are always required as evidence. This does not mean that manufacturers may not add summaries as explanation(s) why specific test reports are included or not included in a specific chapter; they may also include explanations why specific test methods were used or not used, or explanations why an outdated or newer standard was used to generate the test results.

**REGIONAL CONTENT** – The specific content of each jurisdiction for the respective subchapter. The content descriptions are divided according to each region that shares content of the respective subchapter. If only one region uses the subchapter, the Regional Content will include the content descriptions for only that region.

**SUBMISSION** – A regulatory submission can be any type of information related to a medical device regulatory process. This includes but is not limited to a request for approval/authorization to market a device, any communications relating to the original submission, and any request for modification to an existing approval. The submission types that will be accepted in the format described in this document will be dictated by regional policy.

*Note:* Some regions may use Classification Matrices that further specify the required contents, please consult regional regulator websites for further information.

**SUMMARY** - A summary should include a brief synopsis of the (1) purpose, (2) methods, (3) acceptance criteria, (4) results and (5) discussion and conclusions. Outliers and deviations should be reported with the results. Results should be stated quantitatively with appropriate statistical context where applicable (e.g. value  $\pm$  SD, confidence intervals, etc.).

The summary should specifically address:

- Why the characteristic being evaluated is of interest;
- Why the particular methods are being used to evaluate the characteristic, if applicable including why a regional or harmonized/recognized standard/guidance has or has not been complied with;
- How the stated acceptance criteria and sample size are scientifically supported;
- What device was tested and how it relates to the devices that will be marketed;
- Why the tested components are representative of the range of devices that will be marketed;

- Whether the summary has been previously submitted and reviewed by the regulator, including identification of the device and the reference number for the submission; and
- The extent to which the duties and functions of a study (e.g. testing, monitoring, etc.) have been conducted by an external organization (e.g. contract research organisation or individual contractor).

## Language requirements

Each jurisdiction has its own language requirements. Regional guidance should be sought to ensure that content is provided in a language that is acceptable for the jurisdiction to which the submission will be submitted. Any translated material submitted should be verified for accuracy.

## Other general notes

This outline of documentation is to support a smooth documentation process. It remains the applicant's responsibility to ensure all regulatory requirements are met, and that clear and transparent evidence of conformity to these requirements are provided.

Regional regulatory guidance will vary between the IMDRF member regulators and can be found in a variety of locations including the individual regulator's laws, directives, regulations, guidance documents, etc. When any requirements are conflicting between this document and regional documents (e.g. the regional laws, directives, regulations, guidance documents), the regional requirement will take precedence.

For the USFDA and ANVISA, regional regulatory guidance includes the categories (1) special controls in a device specific regulation, (2) device-specific guidance document, (3) special controls guidance, (4) special controls guideline, and/or (5) statutory or regulatory criteria.

When submitting to the USFDA please refer to the current version of the following guidance documents to ensure the content for each heading and the overall electronic format of the submission is sufficient to be accepted for review by the USFDA. For example:

- Electronic Submission Template for Medical Device 510(k) Submissions Guidance for Industry and Food and Drug Administration Staff
- Acceptance and Filing Reviews for Premarket Approval Applications (PMAs): Guidance for Industry and Food and Drug Administration Staff
- eCopy Program for Medical Device Submissions: Guidance for Industry and Food and Drug Administration Staff

For the EU, manufacturers are required to draw up and keep up to date technical documentation for their devices (see Art. 10 (4) of Regulation (EU) 2017/745 on medical devices (MDR), i.e., the “technical documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed. The technical documentation shall include the elements set out in Annexes II and III”. Implementing and delegated acts published under the MDR as well as guidance documents endorsed by the Medical Device Coordination Group (MDCG) in accordance with Article 105 of the MDR should be taken into account<sup>1</sup>. The latest EN ISO version and related Annex Z of harmonised standards should be taken as reference to verify the correct presumption of conformity with the general safety and performance requirement of (GSPRs) of the MDR.

## Acronyms

ANVISA	National Health Surveillance Agency – Brazil
CAPA	Corrective Action and Preventive Action
EMDN	European Medical Device Nomenclature
EU	European Union
GMDN	Global Medical Device Nomenclature
HC	Health Canada
HSA	Health Sciences Authority – Singapore
IMDRF	International Medical Device Regulators Forum
JP	Japan
MDSAP	Medical Device Single Audit Program
MFDS	Ministry of Food and Drug Safety - Korea
MHRA	Medicines and Healthcare products Regulatory Agency - UK
NB	Notified Body
NMPA	National Medical Products Administration – China
PMDA	Pharmaceuticals and Medical Devices Agency – Japan
RCT	Randomized Controlled Trial
SUD	Single Use Device

<sup>1</sup> See e.g. [https://ec.europa.eu/health/md\\_sector/new\\_regulations\\_en](https://ec.europa.eu/health/md_sector/new_regulations_en) and [https://ec.europa.eu/health/md\\_sector/new\\_regulations/guidance\\_en](https://ec.europa.eu/health/md_sector/new_regulations/guidance_en)



TGA	Therapeutic Goods Administration – Australia
ToC	Table of Contents
UK	United Kingdom
USFDA	United States Food and Drug Administration

## Hierarchy presentation

The following is a hierarchical presentation of the submission structure. The numbering should remain consistent regardless of whether the heading is required or not. For example, if heading 1.02 is not required for the submission type or jurisdiction, but headings 1.01 and 1.03 are, then the numbering would remain 1.01 followed by 1.03.

More detailed guidance regarding where elements belong is provided following this table.

<b>CHAPTER 1 – REGIONAL ADMINISTRATIVE</b>	
<a href="#">1.01</a>	Cover Letter
<a href="#">1.02</a>	Submission Table of Contents
<a href="#">1.03</a>	List of Terms/Acronyms
<a href="#">1.04</a>	Application Form/Administrative Information
<a href="#">1.05</a>	Listing of Device(s)
<a href="#">1.06</a>	Quality Management System, Full Quality System or Other Regulatory Certificates
<a href="#">1.07</a>	Free Sale Certificate/ Certificate of Marketing authorization
<a href="#">1.08</a>	Expedited Review Documentation
<a href="#">1.09</a>	User Fees
<a href="#">1.10</a>	Pre-Submission Correspondence and Previous Regulator Interactions
<a href="#">1.11</a>	Acceptance for Review Checklist
<a href="#">1.12</a>	Statements/Certifications/Declarations of Conformity
<a href="#">1.12.01</a>	Performance and Voluntary Standard
<a href="#">1.12.02</a>	Environmental Assessment
<a href="#">1.12.03</a>	Clinical Trial Certifications
<a href="#">1.12.04</a>	Indications for Use Statement with Rx and/or OTC designation Enclosure
<a href="#">1.12.05</a>	Truthful and Accurate Statement
<a href="#">1.12.06</a>	USFDA Class III Summary and Certification
<a href="#">1.12.07</a>	Declaration of Conformity
<a href="#">1.13</a>	Letters of Reference
<a href="#">1.14</a>	Letter of Authorization
<a href="#">1.15</a>	Other Regional Administrative Information
<b>CHAPTER 2 – SUBMISSION CONTEXT</b>	
<a href="#">2.01</a>	Chapter Table of Contents
<a href="#">2.02</a>	General Summary of Submission

<a href="#">2.03</a>	Summary and Certifications for Regulatory Submissions
<a href="#">2.04</a>	Device Description
<a href="#">2.04.01</a>	Comprehensive Device Description and Principle of Operation
<a href="#">2.04.02</a>	Description of Device Packaging
<a href="#">2.04.03</a>	History of Development
<a href="#">2.04.04</a>	Reference and Comparison to Similar and/or Previous Generations of the Device
<a href="#">2.04.05</a>	Substantial Equivalence Discussion
<a href="#">2.05</a>	Indications for Use and/or Intended Use and Contraindications
<a href="#">2.05.01</a>	Intended Use; Intended Purpose; Intended User; Indications for Use
<a href="#">2.05.02</a>	Intended Environment/Setting for use
<a href="#">2.05.03</a>	Pediatric Use
<a href="#">2.05.04</a>	Contraindications For Use
<a href="#">2.06</a>	Global Market History
<a href="#">2.06.01</a>	Global Market History
<a href="#">2.06.02</a>	Incident Reports and Recalls
<a href="#">2.06.03</a>	Sales, Incident and Recall Rates
<a href="#">2.06.04</a>	Evaluation/Inspection Reports
<a href="#">2.07</a>	Post-Market Study Plans
<a href="#">2.08</a>	Risk Management
<a href="#">2.09</a>	Essential Principles (EP) Checklist
<a href="#">2.10</a>	Standards
<a href="#">2.10.01</a>	List of Standards and Guidance Documents
<a href="#">2.10.02</a>	Declaration and/or Certification of Conformity
<a href="#">2.11</a>	Other Submission Context Information
<b>CHAPTER 3 – NON-CLINICAL EVIDENCE</b>	
<a href="#">3.01</a>	Chapter Table of Contents
<a href="#">3.02</a>	Chapter Retired
<a href="#">3.03</a>	Chapter Retired
<a href="#">3.04</a>	Chapter Retired
<a href="#">3.05</a>	Non-clinical Studies
<a href="#">3.05.01</a>	Physical and Mechanical Characterization
<a href="#">3.05.01.01</a>	[Study description, study identifier, date of initiation]
<a href="#">3.05.01.01.01</a>	Summary
<a href="#">3.05.01.01.02</a>	Full Report
<a href="#">3.05.01.01.03</a>	Statistical Data
<a href="#">3.05.02</a>	Chemical/Material Characterization
<a href="#">3.05.02.01</a>	[Study description, study identifier, date of initiation]
<a href="#">3.05.02.01.01</a>	Summary
<a href="#">3.05.02.01.02</a>	Full Report
<a href="#">3.05.02.01.03</a>	Statistical Data
<a href="#">3.05.03</a>	Electrical Systems: Safety, Mechanical and Environmental Protection, and Electromagnetic Compatibility
<a href="#">3.05.03.01</a>	[Study description, study identifier, date of initiation]
<a href="#">3.05.03.01.01</a>	Summary
<a href="#">3.05.03.01.02</a>	Full Report

<a href="#">3.05.03.01.03</a>	Statistical Data
<a href="#">3.05.04</a>	Radiation Safety
<a href="#">3.05.04.01</a>	[Study description, study identifier, date of initiation]
<a href="#">3.05.04.01.01</a>	Summary
<a href="#">3.05.04.01.02</a>	Full Report
<a href="#">3.05.04.01.03</a>	Statistical Data
<a href="#">3.05.05</a>	Software/Firmware/Programmed or programmable medical devices
<a href="#">3.05.05.01</a>	Software/Firmware Description
<a href="#">3.05.05.02</a>	Risk Management File (including Hazard Analysis)
<a href="#">3.05.05.03</a>	Software Requirement Specification (SRS)
<a href="#">3.05.05.04</a>	System and Software Architecture Design (SAD) Chart
<a href="#">3.05.05.05</a>	Software Design Specification (SDS)
<a href="#">3.05.05.06</a>	Traceability Analysis
<a href="#">3.05.05.07</a>	Software Life Cycle Process Description / Software Development, Configuration Management, and Maintenance Practices
<a href="#">3.05.05.08</a>	Software Testing as Part of Verification and Validation
<a href="#">3.05.05.09</a>	Software Version / Revision Level History
<a href="#">3.05.05.10</a>	Unresolved Software Anomalies
<a href="#">3.05.05.11</a>	Cybersecurity
<a href="#">3.05.05.12</a>	Interoperability
<a href="#">3.05.06</a>	Biocompatibility and Toxicology Evaluation
<a href="#">3.05.06.01</a>	[Study description, study identifier, date of initiation]
<a href="#">3.05.06.01.01</a>	Summary
<a href="#">3.05.06.01.02</a>	Full Report
<a href="#">3.05.06.01.03</a>	Statistical Data
<a href="#">3.05.07</a>	Non-Material-Mediated Pyrogenicity
<a href="#">3.05.07.01</a>	[Study description, study identifier, date of initiation]
<a href="#">3.05.07.01.01</a>	Summary
<a href="#">3.05.07.01.02</a>	Full Report
<a href="#">3.05.07.01.03</a>	Statistical Data
<a href="#">3.05.08</a>	Safety of Materials of Biological Origin (human/animal)
<a href="#">3.05.08.01</a>	Certificates
<a href="#">3.05.08.02</a>	[Study description, study identifier, date of initiation]
<a href="#">3.05.08.02.01</a>	Summary
<a href="#">3.05.08.02.02</a>	Full Report
<a href="#">3.05.08.02.03</a>	Statistical Data

<a href="#">3.05.09</a>	Sterilization and Reprocessing Validation
<a href="#">3.05.09.01</a>	End-User Sterilization
<a href="#">3.05.09.01.01</a>	[Study description, study identifier, date of initiation]
<a href="#">3.05.09.01.01.01</a>	Summary
<a href="#">3.05.09.01.01.02</a>	Full Report
<a href="#">3.05.09.01.01.03</a>	Statistical Data
<a href="#">3.05.09.02</a>	Manufacturer Sterilization Validation
<a href="#">3.05.09.02.01</a>	[Study description, study identifier, date of initiation]
<a href="#">3.05.09.02.01.01</a>	Summary
<a href="#">3.05.09.02.01.02</a>	Full Report
<a href="#">3.05.09.02.01.03</a>	Statistical Data
<a href="#">3.05.09.03</a>	Residual Toxicity
<a href="#">3.05.09.03.01</a>	[Study description, study identifier, date of initiation]
<a href="#">3.05.09.03.01.01</a>	Summary
<a href="#">3.05.09.03.01.02</a>	Full Report
<a href="#">3.05.09.03.01.03</a>	Statistical Data
<a href="#">3.05.09.04</a>	Cleaning and Disinfection Validation
<a href="#">3.05.09.04.01</a>	[Study description, study identifier, date of initiation]
<a href="#">3.05.09.04.01.01</a>	Summary
<a href="#">3.05.09.04.01.02</a>	Full Report
<a href="#">3.05.09.04.01.03</a>	Statistical Data
<a href="#">3.05.09.05</a>	Reprocessing of Single Use Devices Validation Data
<a href="#">3.05.09.05.01</a>	[Study description, study identifier, date of initiation]
<a href="#">3.05.09.05.01.01</a>	Summary
<a href="#">3.05.09.05.01.02</a>	Full Report
<a href="#">3.05.09.05.01.03</a>	Statistical Data
<a href="#">3.05.10</a>	Animal Testing
<a href="#">3.05.10.01</a>	[Study description, study identifier, date of initiation]
<a href="#">3.05.10.01.01</a>	Summary
<a href="#">3.05.10.01.02</a>	Full Report
<a href="#">3.05.10.01.03</a>	Statistical Data
<a href="#">3.05.11</a>	Usability/Human Factors
<a href="#">3.05.11.01</a>	[Study description, study identifier, date of initiation]
<a href="#">3.05.11.01.01</a>	Summary
<a href="#">3.05.11.01.02</a>	Full Report
<a href="#">3.05.11.01.03</a>	Statistical Data
<a href="#">3.05.12</a>	Evidence for devices with preservatives or antimicrobial claims
<a href="#">3.06</a>	Non-clinical Bibliography
<a href="#">3.07</a>	Expiration Period and Packaging Validation
<a href="#">3.07.01</a>	Product Stability

<a href="#">3.07.01.01</a>	[Study description, study identifier, date of initiation]
<a href="#">3.07.01.01.01</a>	Summary
<a href="#">3.07.01.01.02</a>	Full Report
<a href="#">3.07.01.01.03</a>	Statistical Data
<a href="#">3.07.02</a>	Package Validation
<a href="#">3.07.02.01</a>	[Study description, study identifier, date of initiation]
<a href="#">3.07.02.01.01</a>	Summary
<a href="#">3.07.02.01.02</a>	Full Report
<a href="#">3.07.02.01.03</a>	Statistical Data
<a href="#">3.08</a>	Other non-clinical Evidence
<a href="#">3.08.01</a>	[Study description, study identifier, date of initiation]
<a href="#">3.08.01.01</a>	Summary
<a href="#">3.08.01.02</a>	Full Report
<a href="#">3.08.01.03</a>	Statistical Data
<b>CHAPTER 4 – CLINICAL EVIDENCE</b>	
<a href="#">4.01</a>	Chapter Table of Contents
<a href="#">4.02</a>	Overall Clinical Evidence Summary
<a href="#">4.02.01</a>	Clinical Evaluation Report
<a href="#">4.02.02</a>	Device Specific Clinical Trials
<a href="#">4.02.02.01</a>	[Trial description, protocol #, date of initiation]
<a href="#">4.02.02.01.01</a>	Clinical Trial Summary
<a href="#">4.02.02.01.02</a>	Clinical Trial Report
<a href="#">4.02.02.01.03</a>	Clinical Trial Data
<a href="#">4.02.03</a>	Clinical Literature Review and Other Reasonable Known Information
<a href="#">4.03</a>	Informed Consent Information
<a href="#">4.04</a>	Investigators Sites and IRB Contact Information
<a href="#">4.05</a>	Real World Data (RWD)
<a href="#">4.06</a>	Post-Market Surveillance Data
<a href="#">4.07</a>	Other Clinical Evidence
<b>CHAPTER 5 – LABELLING AND PROMOTIONAL MATERIAL</b>	
<a href="#">5.01</a>	Chapter Table of Contents
<a href="#">5.02</a>	Product/Package Labels
<a href="#">5.03</a>	Package Insert/Instructions for Use
<a href="#">5.04</a>	e-labelling
<a href="#">5.05</a>	Healthcare Professional Labelling
<a href="#">5.06</a>	Patient Labelling
<a href="#">5.07</a>	Technical and/or Operators Manual
<a href="#">5.08</a>	Patient File Stickers/Cards and Implant Registration Cards
<a href="#">5.09</a>	Product Brochures
<a href="#">5.10</a>	Other Labelling and Promotional Material
<b>CHAPTER 6 – QUALITY MANAGEMENT SYSTEM</b>	
<a href="#">6.01</a>	Cover Letter
<a href="#">6.02</a>	Chapter Table of Contents
<a href="#">6.03</a>	Product Descriptive Information
<a href="#">6.04</a>	General Manufacturing Information
<a href="#">6.05</a>	Required Forms

<a href="#">6.06</a>	Quality management system
<a href="#">6.07</a>	Management responsibilities
<a href="#">6.08</a>	Resource management
<a href="#">6.09</a>	Planning of Product Realization and Customer Related Processes
<a href="#">6.10</a>	Design and development
<a href="#">6.11</a>	Purchasing
<a href="#">6.12</a>	Production and service controls
<a href="#">6.13</a>	Control of monitoring and measuring equipment
<a href="#">6.14</a>	QMS measurement, analysis and improvement
<a href="#">6.15</a>	Device Specific Quality Plan
<a href="#">6.16</a>	Quality management system verification document
<a href="#">6.17</a>	Other Quality System Information

# 1. Chapter 1 – Regional Administrative

Row ID	Regions & Level	Heading	Common Content	Regional Content
1.01	IMDRF 1	Cover Letter	<p>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.</p> <p>b) If applicable and accepted by the regulator, it should include information pertaining to any Master Files referenced by the submission.</p> <p>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).</p>	<p><b><u>USFDA PMA and 510(k)</u></b></p> <p>a) mailing address,                      b) official correspondent(s),                      c) phone/fax number(s),                      d) email address(es)                      e) cover letter shall be signed by applicant and an authorized rep (if the applicant does not reside or have a place of business in US) – 21 CFR 814.20(a) <b>(PMA Only)</b>                      f) Device class and panel or classification regulation or statement that the device has not been classified with rationale for that conclusion <b>(510(k) only)</b></p> <p><b><u>TGA</u></b>                      The covering letter of application should be prepared on company letterhead and include;</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p>d) If the submission is requesting approval of a change that is the result of CAPA due to a recall, this should be stated.</p> <p>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).</p> <p>f) If the submission is unsolicited information (where accepted), this should be stated and any related reference number(s) provided.</p> <p>g) Identification of the regulatory jurisdiction(s) in which marketing is sought.</p> <p><b>NOTE:</b> The cover letter should not contain any detailed scientific information.</p>	<p>a) Submission or Application ID that is generated electronically when completing the application form in <a href="#">eBusiness</a></p> <p>b) Contact details of the person authorised to liaise with TGA during the evaluation process</p> <p>c) Signed by the authorised person for the company</p> <p>d) Where applicable, details about the similarities and differences between the new device and the predicate device in a tabular format with respect to their design, construction, materials (including formulation), intended purpose, administration, packaging materials, sterilisation process and shelf-life</p> <p>e) Where a reduction of assessment fees is sought, a written request for reduced fees must be provided detailing each of the relevant application ID numbers to be considered for abridged assessment fees; and an explanation on why and how the assessment can be abridged. Refer to guidance on the TGA website: <a href="https://www.tga.gov.au/publication/reduction-assessment-fees-medical-devices">https://www.tga.gov.au/publication/reduction-assessment-fees-medical-devices</a></p>



Row ID	Regions & Level	Heading	Common Content	Regional Content
				<b><u>EU</u></b> Consult relevant Notified Body (NB)
1.02	IMDRF	1 Submission Table of Contents	a) Includes at least level 1 & 2 headings for the entire submission b) Specifies the page number for each item referred to in the table.  <b>NOTE:</b> Refer to the Pagination Section of this document for information about submission pagination.	
1.03	IMDRF	1 List of Terms/Acronyms	Terms or acronyms used in the submission that require definition, should be defined here.	
1.04	ANVISA, NMPA, EU, HC, JP, TGA, USFDA	1 Application Form/Administrative Information		<b><u>ANVISA</u></b> ANVISA's Online Application Form containing general information related to the application shall be filled out by the authorized representative.  <b><u>NMPA</u></b> Application form shall be filled out and submitted on line

Row ID	Regions & Level	Heading	Common Content	Regional Content
				<p><b><u>EU</u></b>  NBs will each have their application form, including details of manufacturer (per MDR Article 2 (30)), manufacturer’s SRN (per MDR Article 31), details of authorised representative if manufacturer not resident in EU (per MDR Article 2 (32)), route to conformity (refer to MDR Article 52), device details including classification (per MDR Annex VIII) and European Medical Device Nomenclature (EMDN) code (per MDR Article 26), details of design and manufacturing sites and subcontractor/supplier sites and copies of certificates.</p> <p>The application form should be signed by the manufacturer or the authorised representative.</p> <p>Content of technical documentation is determined by MDR Annexes II and III. See also section “Other general notes” on page 7. Consult relevant NB for guidance on documentation submissions.</p> <p><b><u>HC</u></b>  Health Canada application forms should be included here.</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				<p><b><u>JP</u></b>  PMDA's "Application form" – from <a href="https://www.pmda.go.jp/">https://www.pmda.go.jp/</a></p> <p><b><u>TGA</u></b>  Application forms to include administrative data of the applicant, application scope (including applicable conformity assessment procedure and type of application (initial, substantial change notification and application or recertification)), current certification details, manufacturer details, critical supplier details and device details including device classification. Refer to <a href="http://www.tga.gov.au">www.tga.gov.au</a> for the most up to date information.</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
1.05	ANVISA, NMPA, HC, HSA, TGA, USFDA	1 Listing of Device(s)	<p>A table listing each variant/model/configuration/component/accessory that is the subject of the submission and the following information for each variant/model:</p> <p>a) the identifier (e.g. bar code, catalogue, model or part number, UDI)</p> <p>b) a statement of its name/description that provides (e.g. Trade name, size, material)</p> <p><b>NOTE:</b></p> <p>i. A model/variant/configuration/component/accessory of a device has common specifications, performance and composition, within limits set by the applicant.</p> <p>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</p>	<p><b><u>ANVISA</u></b> The grouping (family, set and systems) of medical devices may apply and shall be in compliance with the requirements set in the specific regulation.</p> <p><b><u>HSA</u></b> The list of devices to be included in an application is to be submitted in an excel sheet format and inclusion of devices should be based on grouping criteria specified in GN-12 guidance document. The excel format “Annex 2 for GN17 and GN18 List of Configurations” is available online at <a href="http://www.hsa.gov.sg">www.hsa.gov.sg</a></p> <p><b><u>Russia</u></b> Any model/variant/configuration of device(s) listed should be limited (covered) by a single Global Medical Device Nomenclature (GMDN) Code and Term. The components within a kit/set can have their own GMDN Codes/Terms.</p> <p><b><u>TGA</u></b> For all classes of devices the applicant needs to include:</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p>available for sale independently of the kit.</p>	<p>a) The Global Medical Device Nomenclature (GMDN) Code and Term</p> <p>b) The classification and the applicable classification rule</p> <p>For class III devices this table should also identify the following:</p> <p>a) Unique Product Identifiers (see the Therapeutic Goods (Medical Devices) Regulations 2002)</p> <p>b) Variants (as defined in the Therapeutic Goods (Medical Devices) Regulations 2002)</p> <p><b>JP</b></p> <p>For devices that fit the definition of a JMDN code, the applicant needs to include the Japanese Medical Device Nomenclature (JMDN) Code and Term.</p> <p>For medical devices that do not fit the definition of a JMDN code, the applicant needs to include a Dummy Code and Term</p> <p>JMDN information is available at <a href="https://www.std.pmda.go.jp/stdDB/index_en.html">https://www.std.pmda.go.jp/stdDB/index_en.html</a>.</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content

Row ID	Regions & Level		Heading	Common Content	Regional Content
1.06	ANVISA, NMPA, EU, HC, HSA, TGA	1	Quality Management System, Full Quality System or Other Regulatory Certificates		<p><b><u>ANVISA</u></b>  Good Manufacturing Practice Certificate (GMPC) issued by ANVISA covering the product range. This document or the requirement protocol number must be provided by the authorized representative at the time of application.</p> <p>a) A product registration or a submission for change/inclusion of the manufacturer of products in classes III or IV requires a valid GMP certificate issued by ANVISA. However, review of the submission may be initiated prior to GMP certification. In such cases, the document proving that the application for GMP certification has been submitted to ANVISA must be provided, indicating the name of the manufacturer, the address of the site to be certified and the identification number of the GMP certification application to ANVISA. The registration or amendment shall be approved only after the GMP certificate has been issued.</p> <p>b) A valid GMP certificate issued by ANVISA is also required for renewal of product</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				<p>registration of products in classes III or IV. The document proving that the GMP certificate has been applied to ANVISA will be accepted if the GMP certificate has not been issued yet. However, if the outcome of the GMP certification process results in a rejection, the registration of the product will be canceled.</p> <p><b><u>NMPA</u></b></p> <p>a) Domestic applicant shall provide:</p> <ul style="list-style-type: none"> <li>i) Copies of the duplicate of Enterprise Business License or the Legal Person Certificate of Public Institution.</li> <li>ii) Where production is entrusted to another enterprise, the qualification document of the entrusted enterprise (a copy of the duplicate of Enterprise Business License), the entrustment contract and the quality assurance agreement shall be provided.</li> </ul> <p>b) Imported Medical Device applicant shall provide:</p> <ul style="list-style-type: none"> <li>iii) Enterprise qualification certificate: the certificate that is issued by the competent authority for enterprise registration or the</li> </ul>



Row ID	Regions & Level	Heading	Common Content	Regional Content
				<p>competent authority for medical devices in the country (region) where the overseas applicant is registered, and can prove that the overseas applicant exists and has the corresponding medical device production qualification; or the certificate that is issued by a third-party certification authority and can prove that the overseas applicant has the corresponding medical device production qualification.</p> <p>iv) Where production is entrusted to another enterprise, the qualification document of the entrusted enterprise, the entrustment contract and the quality assurance agreement shall be provided.</p> <p><b><u>EU</u></b>  If manufacturer holds MDD or MDR certificate(s) issued by another NB covering the products in the application</p> <p>If manufacturer does not hold EN ISO 13485 with the NB, the EN ISO 13485 certificate/s will need to be provided</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				<p><b><u>HC</u></b> Health Canada will only accept MDSAP certificates that have been issued by recognized auditing organizations.</p> <p><b><u>TGA</u></b> Copies of any current TGA or other regulatory authority certification including full audit or surveillance reports, technical reports (e.g. MDR certification report, details of MDSAP certification held) referenced within the submission or required for the submission type. The reference certificates requirements will vary based on the submission type, refer to <a href="#">TGA guidance</a> for these requirements.</p> <p>For Class III medical devices containing a medicinal substance or Active Pharmaceutical Ingredient (API), provide valid <a href="#">GMP evidence</a> for the medical substance or API contained in the device.</p> <p><b><u>HSA</u></b> ISO 13485 certificates are to be provided for manufacturing and sterilisation sites of finished</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				devices. For sites without ISO 13485 certification, comparable audit reports for the actual site e.g. US FDA Quality Systems Regulations or Japan MHLW Ordinance 169 can be submitted.
1.07	ANVISA, NMPA, HSA	1 Free Sale Certificate/ Certificate of Marketing authorization	<p>a) List of the Regulatory Authorities that have provided current regulatory approval for the supply of this product in their country/region of authority</p> <p>b) Details of the type of regulatory approval obtained from each Regulatory Authority</p> <p>c) Current evidence of the regulatory approval, such as certificates provided by the Regulatory Authority</p> <p>Copies can be certified by a notary public or by the manufacturer. The manufacturer may be asked to present the original copy at any time. Information relating to export-only regulatory approvals should be clearly identifiable as export-only approvals.</p>	<p><b><u>ANVISA</u></b> Document/certificate from the regulatory authority in whose jurisdiction the medical device is marketed confirming that the device can be sold and used without restriction. This document must be presented by the authorized representative at the time of application.</p> <p><b><u>NMPA</u></b> Imported Medical Device applicant shall provide: The certificate issued by the competent authority for medical devices of the country (region) where the overseas applicant is registered or where the production address is located that permits the marketing of the product, and the innovative medical device that has not been marketed in the country (region) where the overseas applicant is registered or the production address is located may not be submitted.</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
					<p>If the country (region) where the overseas applicant is registered or the production address is located does not manage this product as medical device, the applicant needs to provide the relevant certificates, including the certificate issued by the said country (region) permitting the marketing of this product. Innovative medical devices that have not been marketed in the country (region) where the overseas applicant is registered or the production address is located may not be submitted.</p> <p><b><u>HSA</u></b> Where available, approval letters or certificates of marketing authorisation from our reference regulatory agencies (Health Canada, Japan MHLW, US FDA, TGA, and EU NB) can be submitted.</p>
1.08	HSA, NMPA, TGA	1	Expedited Review Documentation		<p><b><u>HSA</u></b> For applications with approvals from HSA's reference regulatory agencies and applying for</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				<p>faster evaluation routes, following information is required:</p> <p>a) Declaration of no safety issues globally (refer to GN-15 for the template)</p> <p>b) Proof of marketing history in the independent reference regulatory agency's jurisdictions i.e., Invoice with date, proof of sale or a declaration on marketing history (refer to GN-15 for the declaration template)</p> <p>Refer to GN-15 available at <a href="http://www.hsa.gov.sg">www.hsa.gov.sg</a> for more information</p> <p><b><u>NMPA:</u></b></p> <p>a) For the registration application of medical devices reviewed and approved in accordance with the Special Review Procedure for Innovative Medical Devices, relevant explanations on passing the review for innovative medical devices shall be submitted.</p> <p>b) For the registration application of medical devices reviewed and approved in accordance with the Emergency Review and Approval Procedure for Medical Devices, relevant explanations on passing the emergency review and approval of medical devices shall be submitted.</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
					<p><b><u>TGA</u></b>  Where a priority applicant determination has been made for an application for a conformity assessment certificate issued by the TGA, the following information is required:</p> <ul style="list-style-type: none"> <li>• Notification of the delegate’s decision of priority applicant determination</li> </ul> <p>More information is available at:  <a href="https://www.tga.gov.au/resource/priority-applicant-guidelines-medical-devices-including-ivds">https://www.tga.gov.au/resource/priority-applicant-guidelines-medical-devices-including-ivds</a></p>
1.09	ANVISA, HC, USFDA	1	User Fees		<p><b><u>ANVISA</u></b>  User fee form must be obtained by the authorized representative at the time of application. It will not be available in advance to include here.</p> <p><b><u>HC</u></b>  Health Canada user fee forms should be included here.</p> <p><b><u>USFDA PMA and 510(k)</u></b>  FDA User Fee Form 3601</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
					<p><b><u>JP</u></b>            Attach a copy of receipt of the user fee payment to the application form.            Information about user fee available at;  <a href="https://www.pmda.go.jp/review-services/drug-reviews/user-fees/0001.html">https://www.pmda.go.jp/review-services/drug-reviews/user-fees/0001.html</a></p>
1.10	IMDRF	1	Pre-Submission Correspondence and Previous Regulator Interactions	<p>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:</p> <ul style="list-style-type: none"> <li>i. List prior submission or pre-submissions where regulator feedback was provided</li> </ul>	

Row ID	Regions & Level	Heading	Common Content	Regional Content
			<ul style="list-style-type: none"> <li data-bbox="920 244 1397 304">ii. Prior submissions should include identification of submission #</li> <li data-bbox="920 320 1420 719">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.</li> <li data-bbox="920 735 1435 927">iv. Issues identified by the regulator in prior submissions (i.e., clinical study applications, withdrawn/deleted/denied regulatory submission) for the subject device.</li> <li data-bbox="920 943 1391 1102">v. Issues identified and advice provided by the regulator in pre-submission interactions between the regulator and the applicant/sponsor.</li> </ul>	



Row ID	Regions & Level		Heading	Common Content	Regional Content
				<p>vi. Explain how and where the prior advice was addressed within the submission.</p> <p><b>OR</b></p> <p>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.</p> <p><b>NOTE</b> The scope of this section is limited to the particular regulator to which the submission is being submitted (e.g. Health Canada does not need pre-submission information relating to interactions with ANVISA).</p>	
1.11	TGA, USFDA	1	Acceptance for Review Checklist		<p><b><u>USFDA PMA</u></b> Optionally, you may complete the checklist and provide section and pages numbers indicating where every item on the check is addressed in the submission. See Appendix A of the <b><i>Acceptance and Filing Reviews for Premarket Approval Applications (PMAs): Guidance for Industry and Food and Drug Administration Staff Guidance</i></b></p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				<b>TGA</b> Includes the <a href="#">Supporting data checklists</a>
1.12	ANVISA, EU, HC, HSA, TGA, USFDA	1 Statements/Certifications/Declarations of Conformity	<b>NO CONTENT AT THIS LEVEL</b>	<b>NO CONTENT AT THIS LEVEL</b>
1.12.0 1	USFDA	2 Chapter Retired	Content redundant with 2.10	
1.12.0 2	USFDA	2 Environmental Assessment		<b>USFDA PMA</b> a) If claiming categorical exclusion, information to justify the exclusion  <b>OR</b> b) Provide the environmental assessment (only required for devices that present new environmental concerns)
1.12.0 3	USFDA	2 Clinical Trial Certifications		<b>USFDA PMA and 510(k)</b> a) Certification of Compliance with Requirements of ClinicalTrials.gov (Form FDA 3674) b) Financial Certification or Disclosure Statement (Form FDA 3454 and Form FDA 3455)

Row ID	Regions & Level	Heading	Common Content	Regional Content
1.12.04	USFDA	2	Indications for Use Statement with Rx and/or OTC designation Enclosure	<b><u>USFDA 510(k)</u></b> Use FDA Form FDA 3881
1.12.05	ANVISA, NMPA, HC, TGA, USFDA	2	Truthful and Accurate Statement	<b><u>ANVISA</u></b> A dated statement signed by the legal representative and technical manager of the authorized representative must be submitted at the time of application. The statement must certify that the information provided in the application is true and that the information provided in the attached documents is correct and complete.  <b><u>NMPA</u></b> The authenticity of the documents submitted (domestic product materials are issued by the applicant, and imported product materials are issued by the applicant and the agent respectively) shall be guaranteed.

Row ID	Regions & Level	Heading	Common Content	Regional Content
				<p><b><u>HC</u></b> The attestation that statements in the application are true and that the information provided in this application and in any attached documentation is accurate and complete is a component of the application form. Consult current Health Canada guidance for specific language.</p> <p><b><u>TGA</u></b> <b>Conformity Assessment - Manufacturer's statutory declaration</b> a) A statutory declaration is a written statement allowing a person to declare something to be true. The declaration is signed in the presence of a witness. Giving false or misleading information as part of a statutory declaration is a criminal offence under the Criminal Code.</p> <p><a href="#">Manufacturer statutory Declarations</a></p> <p>Statements of undertaking by the manufacturer as required by conformity assessment procedures set in the Therapeutic Goods (Medical Devices) Regulations 2002</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
					<p><b><u>USFDA 510(k)</u></b>  a) Truthful and Accurate statement per 21 CFR 807.87(k). Text:</p> <p><i>I certify that, in my capacity as (the position held in company) of (company name), I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.</i></p> <p><b>NOTE:</b> Signed by a responsible person of the firm (not a consultant)</p>
1.12.0 6	USFDA	2	USFDA Class III Summary and Certification		<p><b><u>USFDA 510(k)</u></b>  Class III Certification and Summary per 21 CFR 807.94. Text:</p> <p><i>I certify that, in my capacity as (the position held in company) of (company name) that I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety and/or effectiveness problems that have been</i></p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
					<p><i>reported for the (device name). I further certify that I am aware of the types of problems to which the (device name) is susceptible and that, to the best of my knowledge, the following summary of the types and causes of safety and/or effectiveness problems about the (device name) is complete and accurate.</i></p> <p><i>(Attach the summary of problem data, bibliography or other citations upon which the summary is based.)</i></p>
1.12.0 7	NMPA, EU, HSA, JP, TGA	2	Declaration of Conformity	<p>As part of the conformity assessment procedures, the manufacturer of a medical device is required to make a Declaration of Conformity that declares that the device complies with:</p> <ul style="list-style-type: none"> <li>a) the applicable provisions of the Essential Principles/Requirements</li> <li>b) the classification rules</li> <li>c) an appropriate conformity assessment procedure</li> </ul>	<p><b><u>NMPA</u></b> Applicants shall make statement on the following contents:</p> <ul style="list-style-type: none"> <li>a) The proposed product shall meet the requirements of the Measures for the Administration of Registration and Filing of Medical Devices and other relevant regulations.</li> <li>b) The proposed product shall meet the requirements related to the classification in the Rules for the Classification of Medical Devices.</li> <li>c) The proposed product conforms to the current national standards and industry standards. Also, a list of conforming to standards shall be provided.</li> </ul>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				<p><b><u>EU</u></b> See MDR Annex IV and Article 19 for requirements Note: Accessories and components of a device/system that can be sold separately shall be identified</p> <p><b><u>JP</u></b> Declaration and/or certificate that the relevant product is manufactured to conform to the essential principles and/or the quality management system. The applicant is advised to prepare the declaration of conformity according to ISO 17050-1 “Conformity Assessment - Supplier’s Declaration of Conformity - Part 1: General Requirement.”</p> <p><b><u>TGA</u></b> The wording of the Declaration of Conformity will depend on the conformity assessment procedure chosen by the manufacturer. Templates for each of the four possible types of Declarations of Conformity under Schedule 3 of the Therapeutic Goods (Medical Devices)</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
					<p>Regulations 2002 are available at <a href="#">Australian declaration of conformity templates (medical devices)   Therapeutic Goods Administration (TGA)</a>.</p> <p><b><u>HSA</u></b>  There is an online declaration of conformity to safety, quality and efficacy requirements that every applicant submits on our MEDICS online system at the point of submission of the application. In addition, the Singapore Declaration of Conformity – refer to GN-11 available at <a href="http://www.hsa.gov.sg">www.hsa.gov.sg</a>, is to be submitted. Alternatively, the Declaration of Conformity for the devices with marketing authorisation from reference regulatory agencies (e.g. EC DoC) can be submitted.</p>
1.13	IMDRF	1	Letters of Reference	Where applicable, letter from the owner of any separate document referenced in the submission (e.g. 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 (e.g. Master File or previous	



Row ID	Regions & Level		Heading	Common Content	Regional Content
				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.	
1.14	ANVISA , NMPA, HSA	1	Letter of Authorization		<p><b><u>ANVISA</u></b> Letter of authorization from the manufacturer authorizing the local representative to submit the application to ANVISA and place its product on the Brazilian market, according to the template available at <a href="http://www.anvisa.gov.br">www.anvisa.gov.br</a>.</p> <p><b><u>NMPA</u></b> A)When the imported medical device registrant applies for registration through its foreign-invested enterprise established within the territory of China in accordance with relevant provisions on the production of imported medical devices in enterprises within the territory of China, the applicant shall submit not only the letter of statement or authorization showing the consent of the imported medical device registrant for the registration application, but also the documents explaining the relationship (including legal liability) between the applicant and the imported medical device</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
					<p>registrant, with relevant agreements, quality liability documents, equity certificates, etc. attached.</p> <p>b) Copies of the Power of Attorney and Letter of Commitment of the appointed agent within the territory of China and the duplicate of Business License.</p> <p><b><u>HSA</u></b>  Letter of Authorisation of Registrant by the Product Owner for all the products to be registered, using the latest template as per GN-15 Letter of Authorisation template – available at <a href="http://www.hsa.gov.sg">www.hsa.gov.sg</a>. Registrant refers to a Singapore-based company that is registered with the Accounting and Corporate Regulatory Authority (ACRA) of Singapore and Product owner refers to the legal manufacturer of the device.</p>
1.15	IMDRF	1	Other Regional Administrative Information	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.	

Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p><b>NOTE:</b> 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.</p>	

## 2. Chapter 2 – Submission Context

Row ID	Regions & Level		Heading	Common Content	Regional Content
2.01	IMDRF	1	Chapter Table of Contents	<ul style="list-style-type: none"> <li>a) Includes all headings and sub-headings for the chapter.</li> <li>b) Specifies the page number for each item referred to in the table.</li> </ul>	
2.02	IMDRF	1	General Summary of Submission	<ul style="list-style-type: none"> <li>a) Statement of the device type (e.g. hip implant, infusion pump, standalone software) and name (e.g. trade name, proprietary name), its general purpose, and a high-level summary of key supporting evidence (i.e., 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).</li> <li>b) Summary of submission, including                             <ul style="list-style-type: none"> <li>i. The type of submission (e.g. new, amendment, change of existing application, renewal);</li> <li>ii. if amendment/supplement, the reason of the amendment/supplement;</li> <li>iii. if a change to existing approval, description of the change requested (e.g. changes in design, performance, indications, changes to manufacturing</li> </ul> </li> </ul>	<p><b><u>ANVISA</u></b> If renewal, amendment or change, identification of the registration/notification number issued by ANVISA.</p> <p><b><u>NMPA</u></b></p> <ul style="list-style-type: none"> <li>a) If product registration, the applicant shall describe the general name and the basis for its determination,</li> <li>b) If product registration, the applicant shall describe the management category, including the name of the category sub-category, the first-level product category, the second-level product category, the management category, and the classification code.</li> <li>c) If product registration, the applicant shall describe the scope.</li> <li>d) if applicable, any high-level background information or unusual details that the manufacturer wishes to highlight in relation to the device, its history or previous submissions or relation to other approved devices.</li> </ul>

Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p>processes, manufacturing facilities, suppliers);</p> <p>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).</p>	<p><b><u>HC</u></b>  If <u>amendment</u> 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.</p> <p><b><u>TGA</u></b>  If recertification or substantial change notification and application for a conformity assessment certificate, identification of the affected TGA certificate number(s) must be provided.</p> <p><b><u>USFDA 510(k)</u></b>  Executive Summary as described in the <a href="#">“Guidance for Industry and Food and Drug Administration Staff - Format for Traditional and Abbreviated 510(k)s”</a></p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
					<b>HSA</b> Executive summary as per GN-17 available at <a href="http://www.hsa.gov.sg">www.hsa.gov.sg</a>
2.03	USFDA	1	Summary and Certifications for Regulatory Submissions		<b>USFDA PMA</b> a) Summary of the Content of the Whole PMA per 21 CFR 814.20(b)(3)  <b>USFDA 510(k)</b> a) 510(k) Summary contains all elements per 21 CFR 807.92 <b>OR</b> b) 510(k) Statement contains all elements per 21 CFR 807.93
2.04	IMDRF	1	Device Description	<b>NO CONTENT AT THIS LEVEL</b>	
2.04.01	IMDRF	2	Comprehensive Device Description and Principle of Operation	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,	<b>ANVISA</b> a) If a medical device accessory is itself considered a medical device, it may request a separate submission with ANVISA identifying the target medical device. b) For invasive, inhaled, ingested product, a list of ingredients, including their quantity, purity and or other relevant information.  <b>HC</b> 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 (e.g. changes in design, performance and indications) should be further detailed in Section 2.04.04 below.

Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p>design concepts, and/or theoretical principles supporting the device's function.</p> <ul style="list-style-type: none"> <li>vi. If applicable, labelled pictorial representation (diagrams, photos, drawings).</li> <li>vii. If system, how the components relate?</li> <li>viii. If applicable, identify if the device incorporates software/firmware and its role</li> </ul> <p>b) Product specification, including:</p> <ul style="list-style-type: none"> <li>i. Physical characteristics or relevance to the end user (dimensions, weight)</li> <li>ii. Features and operating modes</li> <li>iii. Input specifications (e.g. electrical power requirements, settings and associated allowable ranges/limits)</li> <li>iv. Output and performance characteristics (e.g. range and type of energy delivered, resolution of images)</li> <li>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).</li> </ul> <p>c) List of accessories intended to be used in combination with the devices.</p>	<p><b><u>EU</u></b> See MDR Annex II Section 1.1 for requirements. The Basic UDI-DI, as referred to in Annex VI Part C, assigned by the manufacturer should be provided. Refer to Annex VI Part C for definitions and requirements.</p> <p><b><u>JP</u></b> Explain that the established product specifications are necessary and sufficient to ensure the efficacy, safety, and quality of the product.</p> <p><b><u>TGA</u></b> In the case of products that incorporate a medicinal substance, a rationale of applicability of medical device regulations should be included.</p> <p><b><u>USFDA PMA</u></b> Color Additive information per item A 6.a.ii in Appendix A of the <b><i>Acceptance and Filing Reviews for Premarket Approval Applications (PMAs): Guidance for Industry and Food and Drug Administration Staff Guidance</i></b>; 21CFR 814.20(f)</p> <p><b><u>NMPA</u></b> For more detailed information, please find “Description of the devices and operating principles” in <i>Requirements for Registration Application Dossiers of Medical Devices and the Format of Approval Certificateds (No.121 in 2021)</i>.</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p>d) Indication of any other medical devices or general product intended to be used in combination with the medical device (e.g. infusion sets and infusion pumps, bipolar electrode and RF equipment).</p> <p>e) Components or accessories that can be sold separately should be identified.</p> <p>f) If approved by the regulator, provide the approval number and identification for each component or accessory.</p> <p>g) If the device is to be sterilized, an indication of who is to perform the sterilization and by what method (e.g. EtO, gamma irradiation, dry heat) <b>OR</b> an affirmative statement that the device is non-sterile when used.</p> <p><b>NOTE:</b> 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.</p> <p>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.</p>	



Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p><b>NOTE:</b> 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.</p> <ul style="list-style-type: none"> <li>i) If applicable, indication of biological material or derivate used in the medical device, including: origin (human, animal, recombinant or fermentation products or any other biological material), source (e.g. blood, bone, heart, any other tissue or cells), and the intended reason for its presence and, if applicable, its primary mode of action.</li> <li>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.</li> <li>k) Engineering diagrams/prints/schematics of the device (should be provided as a separate file within the submission).</li> </ul> <p><b>NOTE:</b> The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the comprehensive device description and</p>	

Row ID	Regions & Level	Heading	Common Content	Regional Content
			principles of operations provided in this section regarding the subject device	
2.04.02	ANVISA, NMPA, EU, HC, HSA, TGA, USFDA	2 Description of Device Packaging	<p>a) Information regarding the packaging of the devices, including, when applicable, primary packaging, secondary and any other packaging associated;</p> <p>b) Specific packaging of accessories marketed together with the medical devices shall also be described;</p> <p>c) If the user needs to package the medical device or its accessories before they perform sterilization, information about the correct packaging (e.g. material, composition, dimension) should be provided.</p>	<p><b><u>NMPA</u></b> For sterile medical devices, the information on the sterile barrier system should be stated; for medical devices with microbial limit requirements, the packaging information for maintaining the microbial limit should be stated. Explain how to ensure that the end user can clearly identify the integrity of the package.</p> <p><b><u>EU</u></b> See MDR Annex I GSPRs 11.4-11.7, 23.3, 23.4 (i), (m) and (n) for requirements.</p>
2.04.03	IMDRF	2 History of Development	<p>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).</p> <p>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</p>	<p><b><u>EU</u></b> MDR Annex II Section 3 (a) requires the manufacturer to provide “information to allow the design stages applied to the device” to be understood.</p> <p>For initial applications under the MDR, if the device has been previously marketed under the MDD, confirm whether any changes have been made in comparison to the MDD-certified device.</p> <p><b><u>JP</u></b></p> <p>a) State the beginning and ending dates of non-clinical and clinical studies-and the rationale for the decision of advancement from non-clinical studies to clinical studies.</p> <p>b) Describe work allocation in the development process (i.e., what commercial or non-</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
				device design.	<p>commercial entities were involved at what stages of development).</p> <p><b><u>USFDA 510(k)</u></b> It is highly recommended that a description of all changes made to the device since the last 510(k) clearance be provided for a device that has received prior 510(k) clearance.</p> <p><b><u>NMPA</u></b> Explain the research and development background and purpose of the product applied for registration. If there are similar products or predecessor products for reference, the information of the similar products or predecessor products should be provided, and the reasons for choosing them as R&amp;D reference should be explained.</p> <p><b><u>HC</u></b> 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.</p>
<b>2.04.04</b>	IMDRF	2	Reference and Comparison to Similar and/or Previous Generations of the Device	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	<b><u>EU</u></b> See MDR Annex II Section 1.2 for requirements.

Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p>reviewed and refused by the subject regulator.</p> <p>b) Description of why they were selected.</p> <p>c) A key specification comparison, preferably in a table, between the references (similar and/or previous generation) considered and the device.</p>	<p><b><u>HC</u></b></p> <p>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 (e.g. changes in design, performance, and indications).</p> <p>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.</p> <p><b><u>HSA</u></b></p> <p>If applicable, comparisons can be used to support the safety and effectiveness of the subject device. For similar devices previously reviewed by HSA, provide the MEDICS online application number of the previous submission or Singapore Medical Device Register (SMDR) device registration number.</p> <p><b><u>NMPA</u></b></p> <p>The comparison of the list shows the similarities and differences between the declared product and similar products and/or previous-generation products in terms of working principle, structural composition, manufacturing materials, performance indicators, mode of action (such as implantation, intervention), and scope of application.</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
2.04.05	USFDA, NMPA	2	Substantial Equivalence Discussion		<p><b><u>USFDA 510(k)</u></b></p> <ul style="list-style-type: none"> <li>a) Identify the predicate device(s), and optionally reference devices <ul style="list-style-type: none"> <li>i. 510(k) number, trade name and model number</li> <li>ii. Ensure the identified predicate device(s) is consistent throughout the submission (i.e., Substantial Equivalence discussion are the same as listed in the 510k) summary and the same as those used in comparative performance testing).</li> </ul> </li> <li>b) Include a comparison of indications for use and the technology (including features materials and principles of operation) between the predicate device(s) and subject device(s).</li> <li>c) Include an analysis of why any differences between the subject device(s) and the predicate device(s) do not render the subject device(s) Not Substantially Equivalent, affect safety or effectiveness or raise different questions of safety and effectiveness.</li> </ul> <p><b><u>NMPA</u></b></p> <p>For the class II and class III medical devices that are exempt from clinical evaluation, the applicant should follow the "Technical Guidelines for the Comparative Description of Products Listed in the Catalog of Medical Devices Exempt from Clinical Evaluation", in terms of basic principles, structural composition, performance, safety and scope of application, etc., to prove the safety and effectiveness of the product.</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
2.05	IMDRF	1	Indications for Use and/or Intended Use and Contraindications	
			<b>NO CONTENT AT THIS LEVEL</b>	
2.05.01	IMDRF	2	Intended Use; Intended Purpose; Intended User; Indications for Use	<p><b>EU</b> See MDR Annex II Sections 1.1 (a) and (c) for requirements. The intended use must include use of the device as a “medical device” as defined by MDR Article 2 unless the device is a product without a medical purpose as listed in MDR Annex XVI.</p> <p><b>NMPA</b> Describe other products that can be used in combination with it to achieve the intended use.</p>
			<p>This section should include, as appropriate:</p> <p>a) <b>Intended Use:</b> 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 (e.g. Diagnosis <i>in vivo</i> or <i>in vitro</i>, treatment monitoring rehabilitation, contraception, disinfection).</p> <p>b) <b>Intended Purpose:</b> What is expected with the use of this medical device? Which results are expected?</p> <p>c) <b>Intended user</b> and skills/knowledge/training that the user should have to operate or use the device.</p> <p>d) Identify if the device is intended for <b>single or multiple use</b></p> <p>e) <b>Indications for Use:</b></p> <p>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.</p> <p>ii. If applicable, information about patient selection criteria.</p>	

Row ID	Regions & Level		Heading	Common Content	Regional Content
				<p>iii. If applicable, information about intended patient population (e.g. adults, pediatrics or newborn) or a statement that no subpopulations exist for the disease or condition for which the device is intended.</p> <p>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.</p> <p><b>NOTES:</b></p> <p>i. The statements of intended use and purpose and the intended user and indications for use must be <b><u>as presented in the labelling.</u></b></p> <p>ii. If more than one device is included, the information should be provided for each device</p>	
2.05.02	IMDRF	2	Intended Environment/Setting for use	<p>a) The setting where the device is intended to be used (e.g. domestic use, hospitals, medical/clinical laboratories, ambulances, medical/dental offices). Multiple options can be indicated.</p> <p>b) If applicable, environmental conditions that can affect the device's safety and/or</p>	<p><b><u>USFDA PMA and 510(k)</u></b>            FDA includes this information in the indications for use and product labelling.</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
			performance (e.g. temperature, humidity, power, pressure, movement).	
2.05.03	USFDA, NMPA	2 Pediatric Use		<p><b><u>USFDA PMA</u></b></p> <p>a) Description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose or cure,</p> <p>b) The number of affected pediatric patients, as a whole and within each pediatric subpopulation.</p> <p><b>OR</b></p> <p>c) Statement that no pediatric subpopulation exists for the disease or condition for which the device is intended.</p> <p><b><u>NMPA</u></b></p> <p>If the target patient population of the declared product includes newborns, infants or children, the specific group of non-adults who are expected to use the declared product to treat, diagnose, prevent, alleviate or cure the disease or condition shall be described.</p>
2.05.04	IMDRF	2 Contraindications For Use	<p>If applicable, specify the disease or medical conditions that would make use of the device inadvisable due to unfavorable risk/benefit profile.</p> <p><b>NOTE:</b> The statement of contraindications for the device must be as presented in the labelling.</p>	<p><b><u>EU</u></b></p> <p>See MDR Annex II Section 1.1 (c) for requirements. MDR Annex I GSPR 23.4 (s) and (t) also contain additional requirements.</p> <p><b><u>USFDA PMA and 510(k)</u></b></p> <p>FDA includes this information in the indications for use and product labelling</p>



Row ID	Regions & Level		Heading	Common Content	Regional Content
					<p><b><u>NMPA</u></b>            If applicable, specify the disease or conditions or specific populations (e.g. children, the elderly, pregnant and lactating women, and people with liver and kidney dysfunction) that would make use of the device inadvisable due to unfavorable risk/benefit profile.</p>
<b>2.06</b>	IMDRF	1	Global Market History	<b>NO CONTENT AT THIS LEVEL</b>	
<b>2.06.01</b>	IMDRF	2	Global Market History	<p>a) Up to date identification of the markets (all countries or jurisdictions) where the device is approved for marketing.</p> <p>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.</p> <p>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.</p>	<p><b><u>All Regions but USFDA:</u></b></p> <p>a) If the subject device is different in any way (e.g. design, labelling, specifications, indications) from those approved or marketed in other jurisdiction, the differences should be described.</p> <p>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.</p> <p>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.</p> <p>d) State the date of data capture for the market history data</p> <p>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.</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				<p><b><u>EU</u></b> Link to section 2.04.04; see also MDR Annex II Section 1.2.</p> <p><b><u>HC</u></b> 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.</p> <p>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.</p> <p>In this context, compassionate use includes <b>any</b> Special Access Authorizations.</p> <p><b><u>TGA</u></b> Include any notifications to comparable overseas regulators of substantial change(s) to the device. Comparable overseas regulators are defined at: <a href="https://www.tga.gov.au/resources/resource/guidance/comparable-overseas-regulators-medical-device-applications">https://www.tga.gov.au/resources/resource/guidance/comparable-overseas-regulators-medical-device-applications</a></p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
2.06.02	IMDRF	2	Incident Reports and Recalls	<p>a) List adverse events/incidents associated with the device and a statement of the period associated with this data.</p> <p>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.</p> <p>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.</p> <p>d) A description of any analysis and/or corrective actions undertaken in response to items listed above.</p> <p>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.</p> <p><b>NOTES</b></p> <p>i. It is acknowledged that the definition of recall may vary from one jurisdiction to another.</p>	<p><b><u>EU</u></b> Link to sections 6.09 for procedures and 2.07; see also MDR CHAPTER VII Section 1 and Annex III for requirements relating to post-market surveillance.</p> <p><b><u>HC</u></b></p> <p>a) The jurisdiction(s) associated with the incident should be clearly indicated.</p> <p>b) Incidents should include any Canadian incidents through SAP or other previous Canadian applications, if known.</p> <p>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.</p> <p><b><u>USFDA 510(k)</u></b> Include when submitting a 510(k) to implement a design change to address a recall of a device in the US.</p> <p><b><u>HSA</u></b></p> <p>a) If there is an ongoing adverse event or field safety corrective action for the medical device that has been reported to HSA, provide the HSA reference number.</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
					<p><b><u>NMPA</u></b>            If applicable, List adverse events/incidents associated with the device and a statement of the period associated with this data. Provide the time of occurrence and a discussion of the handling and solution given by the manufacturer in each case, including measures to actively control product risks, reports to medical device adverse event monitoring technical institutions, and descriptions of investigations and handling by relevant departments.</p> <p>At the same time, the above-mentioned adverse events and recalls should be analyzed and evaluated, the reasons for the adverse events and recalls should be clarified, and the impact on their safety and effectiveness should be explained. If the number of adverse events or recalls is large, the number involved in each type should be summarized according to the type of event.</p>
2.06.03	EU, HC, HSA, JP, TGA	2	Sales, Incident and Recall Rates	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: <ol style="list-style-type: none"> <li>i. Incident rate = # adverse events/incidents divided by # units sold, expressed as a percentage</li> </ol>	<p><b><u>EU</u></b>            Link to sections 6.09 for procedures and 2.07; see also MDR CHAPTER VII Section 1 and Annex III for requirements relating to post-market surveillance.</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
				<p>ii. Recall rate = # recalls divided by # units sold, expressed as a percentage</p> <p>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.</p> <p>c) Critical analyses of the rates calculated (e.g. 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 (e.g. size, version)?).</p> <p><b>NOTES</b></p> <p>i. It is acknowledged that the definition of recall may vary from one jurisdiction to another.</p> <p>ii. Sales in this context should be reported as the number of units sold.</p> <p>iii. The summary of sales should be broken down by components when appropriate.</p>	
2.06.04	TGA	2	Evaluation/Inspection Reports		<p><b>TGA</b></p> <p>Copies of full audit reports and technical reports issued by other parties (e.g. Notified Body certification reports).</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
2.07	EU, HC, USFDA	1 Post-Market Study Plans	<p>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:</p> <ul style="list-style-type: none"> <li>a) Study Objectives</li> <li>b) Study Design</li> <li>c) Subjects and Sites information</li> <li>d) Endpoints (primary and secondary)</li> <li>e) Summary of Data Analysis plan</li> <li>f) Length and frequency of follow-up</li> </ul> <p>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.</p>	<p><b>EU</b> See Part B of MDR Annex XIV for requirements relating to post-market clinical follow-up (PMCF); procedures to be in section 6.09, records or outputs to be provided in section 4.06.</p>
2.08	IMDRF	1 Risk Management	<ul style="list-style-type: none"> <li>a) A summary of the risks identified during the risk analysis process and how these risks have been controlled to an <u>acceptable</u> level. Plans can be considered part of the risk management documentation.</li> <li>b) The results of the risk analysis should provide a conclusion with evidence that remaining risks are acceptable when compared to the benefits.</li> <li>c) Where a standard is followed, identify the standard.</li> </ul>	<p><b>EU</b> Risk management is addressed in MDR Annex I GSPR 3; see also MDR Annex I GSPRs 1, 2,4, 8 and Annex II Section 5. Guidance is also available in EN ISO 14971 Medical devices – Application of risk management to medical devices.</p> <p><b>NMPA</b> Product risk management data is the data formed by recording the product risk management process and the results of its review. The following content shall be provided and the</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
					<p>traceability of the following processes for each identified hazard shall be explained.</p> <p>a) Risk analysis: including identification of the scope of medical devices and safety-related features, identification of hazards, and estimation of the risk of each hazardous situation.</p> <p>b) Risk assessment: For each identified hazard situation, evaluate and decide whether the risk needs to be reduced, and if necessary, describe how to carry out corresponding risk control.</p> <p>c) Risk control: describe the related content of risk control implemented to reduce risk.</p> <p>d) Evaluation of the acceptability of any one or more residual risks.</p> <p>e) Compared with the product benefit, the comprehensive evaluation product risk is acceptable.</p>
2.09	ANVISA, NMPA, EU, HSA, JP, TGA	1	Essential Principles (EP) of Safety and Performance Checklist	<p>a) An EP checklist established for the medical devices, information about method(s) used to demonstrate conformity with each EP that applies, references for the method adopted and identification of the controlled document with evidence of conformity with each method used.</p> <p>b) For the controlled documents indicated which are required for inclusion in the submission: a cross-reference of the location of such evidence within the submission.</p> <p>c) If any EP indicated in the checklist does not apply to the device: a documented</p>	<p><b>EU</b> See MDR Annex I for the general safety and performance requirements (GSPRs) and MDR Annex II Section 4 which explains how a manufacturer should document their assessment.</p> <ul style="list-style-type: none"> <li>It is recommended that the above information is provided in the form of a checklist against the GSPRs to show how compliance with the individual GSPRs has been achieved.</li> <li>Identify the precise identity of documents supporting compliance with each GSPR.</li> </ul> <p><b>HSA</b> The checklist of conformity to the Singapore Essential Principles is to be submitted – refer to GN-16 available at <a href="http://www.hsa.gov.sg">www.hsa.gov.sg</a>.</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
				<p>rationale of the non-application of each EP that does not apply.</p> <p><b>NOTE:</b> Methods used to demonstrate conformity may include one or more of the following:</p> <ul style="list-style-type: none"> <li>a) conformity with recognised or other standards;</li> <li>b) conformity with a commonly accepted industry test method(s);</li> <li>c) conformity with an in-house test method(s);</li> <li>d) the evaluation of pre-clinical and clinical evidence; comparison to a similar device already available on the market.</li> </ul>	<p>Alternatively, the checklist to EU or Australian Essential Requirements can be submitted.</p> <p><b>TGA</b> The checklist of conformity to the Australian Essential Principles is to be submitted – checklist available at <a href="#">Australian declaration of conformity templates (medical devices)   Therapeutic Goods Administration (TGA)</a>.</p> <p><b>NMPA</b> For the documents included in the product registration application materials, the specific position in the application materials should be stated; for the documents not included in the product registration application materials, the name of the evidence file and its in the quality management system document should be indicated. Number for reference.</p>
<b>2.10</b>	IMDRF	1	Standards	<b>NO CONTENT AT THIS LEVEL</b>	
<b>2.10.01</b>	IMDRF	2	List of Standards and Guidance Documents	<p>This section should include:</p> <ul style="list-style-type: none"> <li>a) If applicable, a list the standards that have been complied with in full or in part in the design and/or manufacture of the device. <ul style="list-style-type: none"> <li>i. At a minimum should include the standard organization, standard number, standard title, year/version, and if full or partial compliance.</li> <li>ii. If partial compliance, a list the sections of standard that</li> </ul> </li> </ul>	<p><b>ANVISA</b> The list of standards complied can be submitted together with the Essential Principles Checklist.</p>



Row ID	Regions & Level	Heading	Common Content	Regional Content
			<ul style="list-style-type: none"> <li>• Are not applicable to the device, and/or</li> <li>• have been adapted, and/or</li> <li>• were deviated from for other reasons – discussion to accompany</li> </ul> <p>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.</p> <p>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.</p>	<p><b><u>NMPA</u></b>  When applicable, this should include reference to the device relevant NMPA registration compulsory standards. For compulsory industry standards, if the structural features, intended use, and use methods of the declared product are inconsistent with the scope of application of the compulsory standard, the applicant shall provide an explanation on the non-applicability of the compulsory standard and provide verified supporting materials.</p> <p><b><u>EU</u></b>  See MDR Annex I and Annex II Section 4 for requirements.</p> <ul style="list-style-type: none"> <li>• Devices that are in conformity with the relevant harmonised standards are presumed to be in conformity with the requirements of the MDR covered by those standards.</li> <li>• An overview of used standards, including versions, typically is added in the GSPR checklist.</li> <li>• The documentation should demonstrate that all relevant and available Common Specifications (CS) and relevant standards, both harmonised and other product specific standards, have been considered.</li> </ul>

Row ID	Regions & Level		Heading	Common Content	Regional Content
					<ul style="list-style-type: none"> <li>The technical documentation should continue to demonstrate that the files meet the state of the art, including consideration of revised or replaced standards or CS.</li> <li>Indicate other EU legislation which applies. If a device is governed by multiple regulations or directives, all applicable regulations / directives should be identified.</li> </ul> <p><b><u>TGA</u></b></p> <p>This list should include any medical device standard or conformity assessment standard that has been applied to the device; and, if no medical device standard or conformity assessment standard, or part only of such a standard, has been applied to the device — the solutions adopted to ensure that each device complies with the applicable provisions of the essential principles. The information in this section may be presented in the Essential Principle Checklist and, if so, needs only to be presented once in the application.</p> <p><b><u>HSA</u></b></p> <p>The list of standards complied to can be submitted together with the Essential Principles Checklist. This information needs only to be presented once.</p>
2.10.02	ANVISA, NMPA, HC, USFDA	2	Declaration and/or Certification of Conformity		<p><b><u>ANVISA</u></b></p> <p>a) Conformity Assessment Certification according to applicable standards, issued by a Third Party Organization (e.g. Notify Body)</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				<p>officially recognized by the Regulatory Authority. The certificate shall be issued under the SBAC - Sistema Brasileiro de Avaliação da Conformidade / Brazilian Conformity Assessment System - INMETRO.</p> <p>b) Certain types of devices (intra-uterine devices and blood bags) require pre-submission performance testing conducted by an official laboratory (INCQS/FioCruz – Instituto Nacional de Controle de Qualidade em Saúde) in Brazil. The report of these analyses shall be part of the submission.</p> <p><b><u>HC</u></b> The applicant is advised to prepare the Declaration of Conformity to recognized standards using Health Canada's Declaration of Conformity form. Refer to the <a href="#">Guidance Document: Recognition and Use of Standards under the Medical Devices Regulations</a> and the current list of recognized standards for medical devices.</p> <p><b><u>USFDA</u></b> Consider <a href="#">Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</a></p> <p><b><u>NMPA</u></b> a) product technical requirements</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
					<p>The technical requirements for medical device products shall be compiled in accordance with the relevant requirements.</p> <p>b) Product inspection report</p> <p>An inspection report in any of the following forms can be submitted:</p> <p>i: self-inspection report issued by the applicant.</p> <p>ii: an inspection report issued by a qualified medical device inspection agency.</p>
2.11	IMDRF	1	Other Submission Context Information	<p>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.</p> <p><b>NOTE:</b> 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.</p>	<p><b><u>NMPA</u></b></p> <p>If applicable, specify the detailed information of other products that are used in conjunction with the declared product to achieve the intended use. For approved parts or accessories used in conjunction, the registration certificate number and the registration certificate information published on the official website of the State Drug Administration shall be provided.</p>

### 3. Chapter 3 – Non-clinical evidence

Row ID	Regions & Level		Heading	Common Content	Regional Content
3.01	IMDRF	1	Chapter Table of Contents	<ul style="list-style-type: none"> <li>a) Includes major headings for the chapter, to the level of the custom headings.</li> <li>b) Specifies the page number for each item referred to in the table.</li> </ul>	
3.02			Chapter Retired	Original content moved to Chapter 2	
3.03			Chapter Retired	Original content moved to Chapter 2	
3.04			Chapter Retired	Original content moved to Chapter 2	
3.05	IMDRF	1	Non-clinical Studies	<b>NO CONTENT AT THIS LEVEL</b>	
3.05.01	IMDRF	2	Physical and Mechanical Characterization	<p>Evidence that supports the physical or mechanical properties of the subject device is to be included in this section. This should include:</p> <ul style="list-style-type: none"> <li>a) A summary of the non-clinical evidence that falls within this category</li> <li>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 (i.e., what tests were considered and why they were or were not performed)</li> <li>c) If applicable, particulate testing from wear or device coatings.</li> </ul>	<p><b><u>EU</u></b> For specific MDR requirements see MDR Annex II Sections 6.1 (a) and (b)</p> <p><b><u>NMPA</u></b> The basis for determining product chemical/material characterization, design input sources and clinical significance, standards or methods used, reasons for use, and theoretical basis should be provided.</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p>d) Discussion to support why the evidence presented is sufficient to support the application.</p> <p><b>OR</b></p> <p>e) A statement of why this category of non-clinical laboratory study is not applicable to this case.</p> <p><b>NOTE:</b> 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.</p>	
3.05.01.01	IMDRF	3 [Study description, study identifier, date of initiation]	<p><b>NO CONTENT AT THIS LEVEL.</b> This heading should be CUSTOM AND BASED ON STUDY DETAILS and created <b>for each study</b> under the parent heading. The sub headings below would be for this study alone.</p> <p>For example, the structure will look something like this</p> <p>Component A Fatigue Test, MT4203, 2010-10-10     Summary of MT4203     Full Report for MT4203</p> <p>Assembly B Compatibility Test, MT4584, 2011-01-23</p>	

Row ID	Regions & Level		Heading	Common Content	Regional Content
				Summary of MT4584 Full Report for MT4584	
3.05.01.01.01	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	
3.05.01.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	<b>USFDA 510(k)</b> If referencing a standard, refer to <a href="#">Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</a> .
3.05.01.01.03	USFDA	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. <b>The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.</b>  <b>NOTE: Do not place PDFs here.</b>
3.05.02	IMDRF	2	Chemical/Material Characterization	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>EU</b> For specific MDR requirements see MDR Annex II Sections 6.1 (b) and 6.2 (d).  In particular, for devices specified in MDR Annex I GSPR 10.4.1 containing or incorporating carcinogenic, mutagenic, or toxic to reproduction (“CMR”) substances of

Row ID	Regions & Level		Heading	Common Content	Regional Content
				<p>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 (i.e., what tests were considered and why they were or were not performed).</p> <p>c) Discussion to support why the evidence presented is sufficient to support the application.</p> <p><b>OR</b></p> <p>d) A statement of why this category of non-clinical laboratory study is not applicable to this case.</p> <p><b>NOTE:</b> 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.</p>	<p>category 1A or 1B (in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008), or substances having endocrine-disrupting properties must meet requirements in the MDR for justification of the presence of these substances. Specific labelling requirements must also be met for these substances (GSPR 10.4.5).</p> <p>Where this information on CMR or endocrine-disrupting substances is provided by suppliers, manufacturers should confirm the completeness of this information and describe any additional testing or analysis performed to confirm the information and the presence of these substances.</p>
3.05.02.01	IMDRF	3	[Study description, study identifier, date of initiation]	<p><b>NO CONTENT AT THIS LEVEL</b>  This heading should be CUSTOM AND BASED ON STUDY DETAILS and created <b>for each study</b> under the parent heading. The sub headings below would be for this study alone.</p>	



Row ID	Regions & Level		Heading	Common Content	Regional Content
3.05.02.01.01	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	
3.05.02.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	<b>USFDA 510(k)</b> If referencing a standard, refer to <a href="#">Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</a> .
3.05.02.01.03	USFDA	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. <b>The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.</b>  <b>NOTE: Do not place PDFs here.</b>
3.05.03	IMDRF	2	Electrical Systems: Safety, Mechanical and Environmental Protection, and Electromagnetic Compatibility	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	<b>EU</b> For specific MDR requirements see MDR Annex II Section 6.1 (b). Guidance is also available in EN 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance and EN 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements

Row ID	Regions & Level		Heading	Common Content	Regional Content
				<p>and support for their selection or omission from the verification and validation studies conducted in this category (i.e., what tests were considered and why they were or were not performed)</p> <p>c) Discussion to support why the evidence presented is sufficient to support the application.</p> <p><b>OR</b></p> <p>d) A statement of why this category of study is not applicable to this case.</p> <p><b>NOTE:</b> 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</p>	<p>and tests, and applicable collateral and particular standards.</p> <p><b><u>NMPA</u></b> Research materials on electrical safety, mechanical and environmental protection, and electromagnetic compatibility should be provided, explaining the applicable standards and the research carried out.</p>
<b>3.05.03.01</b>	IMDRF	3	[Study description, study identifier, date of initiation]	<p><b>NO CONTENT AT THIS LEVEL</b> This heading should be CUSTOM AND BASED ON STUDY DETAILS and created <b>for each study</b> under the parent heading. The sub headings below would be for this study alone.</p>	
<b>3.05.03.01.01</b>	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	

Row ID	Regions & Level		Heading	Common Content	Regional Content
3.05.03.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	<b>USFDA 510(k)</b> If referencing a standard, refer to <a href="#">Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</a> .
3.05.03.01.03	USFDA	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. <b>The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.</b>  <b>NOTE: Do not place PDFs here.</b>
3.05.04	IMDRF	2	Radiation Safety	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	<b>EU</b> For specific MDR requirements see MDR Annex I GSPRs 14.2 (b) and 16 and Annex II Section 6.1 (b). Guidance is also available in EN 60601-1-3 Medical electrical equipment - General requirements for basic safety and essential performance. Collateral Standard: Radiation protection in diagnostic X-ray equipment and relevant EN 60601-2-xx standards.  <b>TGA</b>

Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p>and support for their selection or omission from the verification and validation studies conducted in this category (i.e., what tests were considered and why they were or were not performed)</p> <p>c) Discussion to support why the evidence presented is sufficient to support the application.</p> <p><b>OR</b></p> <p>d) A statement of why this category of non-clinical laboratory study is not applicable to this case.</p> <p><b>NOTE:</b> 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</p>	<p>MR labelling claims to be supported by bench tests ensuring safety and performance of the device, including the below risks:</p> <p>Note: Testing may not be warranted if an adequate scientific rationale or validated computational modelling/simulation is provided.</p> <ul style="list-style-type: none"> <li>○ Magnetically Induced Displacement Force</li> <li>○ Magnetically Induced Torque</li> <li>○ Extent of Image Artifact</li> <li>○ RF induced heating or heating induced by time-varying magnetic field gradients, (dB/dt)</li> <li>○ Gradient Induced Vibration</li> <li>○ Gradient Induced Extrinsic Electrical Potential (Unintended Stimulation)</li> <li>○ Rectification of RF pulses from MR Exams (Unintended Stimulation)</li> </ul> <p><b><u>NMPA</u></b></p> <p>For products with radiation or potential radiation hazards (including ionizing radiation and non-ionizing radiation), radiation safety research materials should be provided, including:</p> <p>a) Explain the general and specific radiation safety standards that are in compliance, and the reasons for the inapplicable clauses in the standards should be explained in detail;</p> <p>b) Indicate the type of radiation and provide radiation safety verification data. It should be ensured that the radiation energy, radiation</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				distribution and other key radiation characteristics can be reasonably controlled and adjusted and can be estimated and monitored during use. (If applicable) c) Provide protective measures to reduce the radiation absorbed dose during transportation, storage, installation, and use by users, others, and patients, and methods to avoid misuse. For products that need to be installed, information about acceptance and performance testing, acceptance standards and maintenance procedures should be clear.
<b>3.05.04.01</b>	IMDRF	3 [Study description, study identifier, date of initiation]	<b>NO CONTENT AT THIS LEVEL</b> This heading should be CUSTOM AND BASED ON STUDY DETAILS and created <u>for each study</u> under the parent heading. The sub headings below would be for this study alone.	
<b>3.05.04.01.01</b>	IMDRF	4 Summary	A summary of the specific study described in the custom heading above.	
<b>3.05.04.01.02</b>	IMDRF	4 Full Report	The test report for the test described in the custom heading above.	<b>USFDA 510(k)</b> If referencing a standard, refer to <a href="#">Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</a> .
<b>3.05.04.01.03</b>	USFDA	4 Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata

Row ID	Regions & Level		Heading	Common Content	Regional Content
					and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. <b>The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.</b>  <b>NOTE: Do not place PDFs here.</b>
3.05.05	IMDRF	2	Software/Firmware /Programmed or programmable medical device	<b>NO CONTENT AT THIS LEVEL</b> 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 the different hardware configurations and, where applicable, operating systems identified in the labelling. Documentation should be organized according to software or hardware systems.	
3.05.05.01	IMDRF	3	Software/Firmware Description	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>ANVISA</b> For Medical Device or Independent Software, see the appropriate documentation required in ANVISA Resolutions RDC nº 751/2022 and RDC nº 657/2022; And Anvisa Guidance nº 38/2020 - Cybersecurity principles and practices in medical devices. If the Medical device adopts artificial intelligence technology, it should provide

Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p>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,</p> <p>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.</p> <p>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:</p> <ul style="list-style-type: none"> <li>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);</li> <li>ii. model selection and evaluation;</li> <li>iii. risk management activities;</li> <li>iv. materials/approaches used to provide transparency; and</li> </ul>	<p>algorithm description, including basic algorithm information, data collection, algorithm training, algorithm performance evaluation, validation, etc.</p> <p><b><u>EU</u></b> Appropriate documentation is required if the medical devices are either standalone software or rely upon software. See MDR Annex II Section 6.1 (b) for requirements. Guidance is also available in EN 62304 Medical device software – Software life-cycle processes and, if applicable, EN 82304-1 Health Software - General requirements for product safety.</p> <p><b><u>USFDA</u></b> Identify the Level of Documentation (Basic or Enhanced) and include a description of the rationale for that level.  For guidance on what specific software documentation to submit, refer to the <a href="#">Guidance for the Content of Premarket Submissions for Device Software Functions</a></p> <p><b><u>TGA</u></b> Refer to guidance on '<a href="#">Regulation of Software based medical devices</a>'.</p> <p><b><u>NMPA</u></b> a) Software</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
			v. post-market performance monitoring activities.	<p>For products and independent software that contain software components, software research materials should be provided, including basic information, implementation processes, core functions, conclusions, etc.</p> <p>The degree of detail depends on the software security level (severe, moderate, and minor). Among them, basic information includes software identification, security level, structural function, physical topology, operating environment, and registration history. The realization process includes development overview, risk management, requirement specification, life cycle, verification and confirmation, traceability analysis, defect management, update history, clarify the correspondence between core functions, core algorithms, and expected uses.</p> <p>b) Ready-made software</p> <p>If the product uses off-the-shelf software, corresponding software research data and network security research data should be provided based on the type and usage of the off-the-shelf software.</p> <p>c) Artificial intelligence</p>



Row ID	Regions & Level		Heading	Common Content	Regional Content
					<p>If the product adopts artificial intelligence technology such as deep learning to achieve the expected function and purpose, it should provide algorithm research materials, including basic algorithm information, data collection, algorithm training, algorithm performance evaluation, etc.</p> <p>d) Other</p> <p>If products adopt mobile computing, cloud computing, virtual reality and other information and communication technologies to achieve expected functions and uses, corresponding technical research materials should be provided, including basic information, requirements specifications, risk management, verification and confirmation, maintenance plans, etc.</p>
3.05.05.02	IMDRF	3	<p>Risk Management File (including Hazard Analysis)</p>	<p>The risk management file should be provided and include the risk management plan, risk assessment (e.g. hazard analysis), and risk management report.</p> <p>The risk assessment (e.g. hazard analysis) should take into account all device hazards associated with the device's intended use.</p> <p>For software that is part of a system, a risk assessment should be performed on the system comprising</p>	<p><b><u>EU</u></b> See EN 62304 and ISO 14971 for further guidance</p> <p><b><u>HC</u></b> The risk management file in this section should specifically relate to the software/hardware. Overall risk analysis should be placed in section 2.08.</p> <p><b><u>HC, USFDA</u></b> For the risk control measures in the risk assessment or hazard analysis, there should be verification of the implementation of the risk</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
				<p>the software and its whole hardware environment and noted in the software documentation with reference to the particular section of the premarket submission.</p>	<p>control measures and verification of the effectiveness of the implemented risk control measures (i.e. the implemented risk control measure reduces risk). This can be accomplished by tracing the identified hazard to the verified specific risk control measures (e.g. 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).</p>
3.05.05.03	IMDRF	3	Software Requirement Specifications (SRS)	<p>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 (e.g. risk management file, software design specification, system and software architecture design chart, software testing).</p> <p>The SRS documents the requirements for the software which typically specifies inputs and outputs, functions that the software will perform, hardware, performance, interfaces, user</p>	<p><b>EU</b> See MDR Annex I Section 14.2 (d) for requirements. Further guidance is also available in EN 62304.</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
			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.	
<b>3.05.05.04</b>	EU, HC, JP, TGA, USFDA	3 System and Software Architecture Design (SAD) Chart	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.	<b><u>EU</u></b> See EN 62304 for further guidance
<b>3.05.05.05</b>	EU, HC, JP, TGA, USFDA	3 Software Design Specification (SDS)	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	<b><u>EU</u></b> See EN 62304 for further guidance

Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p>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.</p> <p>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.</p>	
<b>3.05.05.06</b>	IMDRF	3 Traceability Analysis	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.	<b><u>USFDA, HC</u></b> The Traceability Analysis can be incorporated into the SRS documentation.
<b>3.05.05.07</b>	IMDRF	3 Software Life Cycle Process Description / Software Development, Configuration Management, and	The Software Life Cycle Process Description / Software Development, Configuration Management, and Maintenance Practices description should describe the software development	<b><u>EU</u></b> For specific MDR requirements see MDR Annex I GSPR 17.2 and Annex II Section 6.2 (b). See EN 62304 for further guidance.

Row ID	Regions & Level		Heading	Common Content	Regional Content
			Maintenance Practices	life cycle and the processes that are in place to manage the various life cycle activities.	
3.05.05.08	IMDRF	3	Software Testing as Part of Verification and Validation	<p>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.</p> <p><b>NOTE:</b> Discussion should address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.</p>	<p><b>EU</b> See EN 62304 and EN 82304-1, if applicable, for further guidance</p>
3.05.05.09	IMDRF	3	Software Version / Revision Level History	<p>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.</p> <p>The last entry in a line-item tabulation should be the final version to be incorporated in the</p>	<p><b>EU</b> See EN 62304 for further guidance</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
				released device. This entry should also include any differences between the tested version of software and the released version.	
3.05.05.10	IMDRF	3	Unresolved Software Anomalies	<p>Documentation should include a list of unresolved anomalies present in the software with the following items (e.g. in tabular format) for each unresolved anomaly:</p> <ul style="list-style-type: none"> <li>i) A description of what the anomaly is and what root cause(s) of the anomaly could be;</li> <li>ii) Identification of how the anomaly was discovered and, where possible, identification of the root cause(s) of the anomaly;</li> <li>iii) Evaluation of the impact of the anomaly on the device's safety and effectiveness, including operator usage and human factors considerations;</li> <li>iv) Outcome of the evaluation; and</li> <li>v) Risk-based rationale for not correcting or fixing the anomaly in alignment with the risk management plan or procedure(s).</li> </ul>	<p><b>EU</b> See EN 62304 for further guidance</p>
3.05.05.11	EU, USFDA,	3	Cybersecurity	For a description of the Cybersecurity Common Content,	<b>EU</b>

Row ID	Regions & Level	Heading	Common Content	Regional Content
	HC, HSA, TGA		please refer to <a href="#">IMDRF/CYBER WG/N60 FINAL:2020 “Principles and Practices for Medical Device Cybersecurity”</a>	<p>See MDR Annex I GSPR 14.5, 17 and Annex II Section 6.2 (g) for requirements.</p> <p><b>HC</b> Guidance Document: <a href="#">Pre-market Requirements for Medical Device Cybersecurity</a></p> <p><b>USFDA</b> Guidance for Industry and Staff – <a href="#">“Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions”</a></p> <p><b>TGA</b> Guidance for industry and consumers <a href="#">“Medical device cyber security guidance for industry”</a>.</p> <p><b>NMPA</b></p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
					<p>Independent software with electronic data exchange, remote control or user access functions and products containing software components shall provide network security research materials, including basic information, implementation process, vulnerability assessment, conclusions, etc. The degree of detail depends on the software security level . Among them, basic information includes software information, data architecture, network security capabilities, network security patches, and security software. The implementation process includes risk management, requirements specification, verification and confirmation, traceability analysis, update maintenance plans, and vulnerability assessments to identify known vulnerabilities. Related Information.</p> <p><b>HSA</b> Regulatory Guidelines for Software Medical Devices - A Life Cycle Approach – available at <a href="http://www.hsa.gov.sg">www.hsa.gov.sg</a></p>
3.05.05.12	EU, USFDA, HC, HSA	3	Interoperability	If the device can communicate with other devices. Evidence to support the interoperability should be provided.	<p><b>EU</b> See MDR Annex I GSPR 14.5 and Annex II Section 6.2 (g) for requirements.</p> <p><b>USFDA</b> Guidance for Industry and Staff – “Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices”</p>



Row ID	Regions & Level		Heading	Common Content	Regional Content
				<p><b><u>NMPA</u></b>            If products exchange and use information with other medical devices or non-medical devices through electronic interfaces, interoperability research materials should be provided, including basic information, requirements specifications, risk management, verification and confirmation, maintenance plans, etc.</p>	
3.05.06	IMDRF	2	<p>Biocompatibility and Toxicology Evaluation</p>	<p>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:</p> <ol style="list-style-type: none"> <li>a) A list of all materials in direct or indirect contact with the patient or user.</li> <li>b) State conducted tests, applied standards, test protocols, the analysis of data and the summary of results</li> <li>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 (i.e., what tests were considered and why they were or were not performed)</li> </ol>	<p><b><u>EU</u></b>            For specific MDR requirements see MDR Annex I GSPRs 10 and 13, and Annex II Sections 6.1 (b) and 6.2 (b). Guidance is also available in EN ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.</p> <p><b><u>TGA</u></b>            For each material that is in direct contact with the patient or user, provide:</p> <ul style="list-style-type: none"> <li>• details of the name of the material supplier</li> <li>• copies of certificate of analysis or certificate of conformance from the material supplier to support the quality of the material(s)</li> <li>• amount of each material present in the device and evidence to support its safety</li> </ul> <p>For medical devices containing a medicinal substance, the following information to be provided to support the quality and safety of the product in the device:</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p>d) Discussion to support why the evidence presented is sufficient to support the application.</p> <p><b>OR</b></p> <p>e) A statement of why this category of non-clinical laboratory study is not applicable to this case.</p> <p><b>NOTES:</b></p> <p>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</p> <p>ii. Tests should be conducted on samples from the finished, sterilized (when supplied sterile) device.</p>	<ul style="list-style-type: none"> <li>evidence to support its quality including <a href="#">European Directorate for the Quality of Medicines</a> (EDQM) certificate of suitability for the medicinal substance or if relevant, provide reference to the TGA Drug master file (DMF)</li> <li>an authorisation in the form of a 'Letter of Access' obtained from the medicinal substance manufacturer for the TGA to access to the EDQM certificate. The form template can be found in 'Module 1.6.3 - Proforma Letter of Access to DMF/PMF/CE' of the ARGPM (<a href="https://www.tga.gov.au/form/ctd-module-1-additional-forms-and-proformas#mod1-6">https://www.tga.gov.au/form/ctd-module-1-additional-forms-and-proformas#mod1-6</a>);</li> <li>In the absence of EDQM certificate, provide a TGA Drug Master File (DMF) or Plasma Master File (PMF) (reference number.</li> <li>An authorisation in the form of a 'Letter of Access' obtained from the manufacturer of medicinal substance for the TGA to access to the DMF or PMF in relation to the application. The form template can be found in 'Module 1.6.3 - Proforma Letter of Access to DMF/PMF/CE' of the Australian Regulatory Guidelines of Prescription Medicines (ARGPM) (<a href="https://www.tga.gov.au/form/ctd-module-1-additional-forms-and-proformas#mod1-6">https://www.tga.gov.au/form/ctd-module-1-additional-forms-and-proformas#mod1-6</a>);</li> <li>Device manufacturer declaration, which can also be found in '<a href="#">Module 1.6.2 Applicant declaration - Drug master files, plasma master files, and EDQM certificates</a></li> </ul>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				<p>of suitability' of the ARGPM (the same website as for the <i>Letter of Access</i> above)</p> <p><b><u>NMPA</u></b></p> <p>For devices that come into direct or indirect contact with the patient, biological evaluation should be carried out. Biological evaluation data should include:</p> <p>a) Describe the materials used in the product and the nature of contact with the human body, the pollutants and residues that may be introduced during the design and production process, the precipitates (including leachate and/or evaporate) and degradation that may be generated during the design and production process Related information about products, processing residues, and packaging materials in direct contact with medical devices.</p> <p>b) Describe the physical and/or chemical information of the declared product and consider the material characterization (if applicable). If the physical action of the device may cause a biological risk, it should be evaluated.</p> <p>c) Strategies, basis and methods of biological evaluation.</p> <p>d) Evaluation of existing data and results.</p> <p>e) Reasons and justifications for selecting or exempting biological experiments.</p> <p>f) Other data required to complete the biological evaluation.</p> <p>If medical device materials may release particles into patients and users, resulting in risks related to particle size and properties,</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				such as nanomaterials, relevant biological risk research data should be provided for all medical devices that contain, produce, or consist of them. If the declared product will be absorbed and metabolized by the human body according to its intended use, such as an absorbable product, research data on the compatibility of the materials/substances used with human tissues, cells and body fluids should be provided.
<b>3.05.06.01</b>	IMDRF	3 [Study description, study identifier, date of initiation]	<b>NO CONTENT AT THIS LEVEL</b> This heading should be CUSTOM AND BASED ON STUDY DETAILS and created <u>for each study</u> under the parent heading. The sub headings below would be for this study alone.	
<b>3.05.06.01.01</b>	IMDRF	4 Summary	A summary of the specific study described in the custom heading above.	
<b>3.05.06.01.02</b>	IMDRF	4 Full Report	The test report for the test described in the custom heading above.	<b>USFDA 510(k)</b> If referencing a standard, refer to <a href="#">Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</a> .

Row ID	Regions & Level		Heading	Common Content	Regional Content
3.05.06.01.03	USFDA	4	Statistical Data		<p>This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. <b>The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.</b></p> <p><b>NOTE: Do not place PDFs here.</b></p>
3.05.07	IMDRF	2	Non-Material-Mediated Pyrogenicity	<p>Studies to support pyrogenicity evaluation of final release, such as endotoxin levels, are to be included in this section. This should include:</p> <ol style="list-style-type: none"> <li>A summary of the non-clinical evidence that falls within this category</li> <li>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 (i.e., what tests were considered and why they were or were not performed)</li> <li>Discussion to support why the evidence presented is sufficient to support the application.</li> </ol>	<p><b>EU</b> For specific MDR requirements see MDR Annex II Section 6.2 (e)</p> <p><b>TGA</b> Minimisation of risks associated with endotoxin contaminants and residues in or on medical devices must be considered for certain kinds of medical devices. Refer to <a href="#">Medical Device Standards Order (Endotoxin Requirements for Medical Devices) 2018</a>.</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
				<p>OR</p> <p>d) A statement of why this category of non-clinical laboratory study is not applicable to this case.</p> <p><b>NOTE:</b> 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</p>	
<b>3.05.07.01</b>	IMDRF	3	[Study description, study identifier, date of initiation, date of completion]	<p><b>NO CONTENT AT THIS LEVEL</b> This heading should be CUSTOM AND BASED ON STUDY DETAILS and created <b>for each study</b> under the parent heading. The sub headings below would be for this study alone.</p>	
<b>3.05.07.01.01</b>	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	
<b>3.05.07.01.02</b>	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	<p><b>USFDA 510(k)</b> If referencing a standard, refer to <a href="#">Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.</a></p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
3.05.07.01.03	USFDA 4	Statistical Data		<p>This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. <b>The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.</b></p> <p><b>NOTE: Do not place PDFs here.</b></p>
3.05.08	IMDRF 2	Safety of Materials of Biological Origin (human/animal)	<p>Evaluations performed to demonstrate the safety of materials of biological origin (e.g. animal sourced, human sourced material) are to be included in this section. This should include:</p> <ol style="list-style-type: none"> <li>A description of biological material or derivate</li> <li>State the harvesting, processing, preservation, testing and handling of tissues, cells and substances</li> <li>If applicable, discussion of infectious agents/transmissible agents known to infect the source animal</li> <li>Clarify the origin (including details of donor screening and source country) and describe the tests on validation of removal or</li> </ol>	<p><b><u>ANVISA IMPORTANT NOTE:</u></b> The commercialization of any type of products of human origin is not allowed in Brazilian territory, according to the Brazilian Federal Constitution.</p> <p><b><u>NMPA</u></b> For products that contain biosafety risks such as allogeneic materials, animal-derived materials or biologically active substances, corresponding biosafety research materials shall be provided. Biosafety research materials should include: a) The situation of the corresponding materials or substances, the acquisition, processing, preservation, testing and handling of tissues, cells and materials. b) Explain the source and explain the process of inactivation and removal of viruses and/or infectious agents in the production process,</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p>inactivation methods of viruses and other pathogens in the manufacturing process.</p> <p>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.</p> <p>f) The system for recordkeeping to allow traceability from sources to the finished device should be fully described</p> <p>g) Discussion to support why the evidence presented is sufficient to support the application.</p> <p><b>OR</b></p> <p>h) A statement of why this category of non-clinical laboratory study is not applicable to this case.</p> <p><b>NOTE:</b> 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</p>	<p>and provide validity verification data or related materials.</p> <p>c) Explain the methods and/or technological processes for reducing immunogenic substances, and provide quality control indicators and confirmatory experimental data or related materials.</p> <p>d) Other materials supporting the safety of biological materials.</p> <p><b>EU</b> For specific MDR requirements see MDR Annex I GSPR 13 and Annex II Section 6.2 (b).</p> <ul style="list-style-type: none"> <li>• Compliance to Commission Regulation (EU) No 722/2012 is necessary when applicable. Compliance with the EN ISO 22442 series of harmonised standards may also be considered. There are possible exclusions (e.g. tallow species and processing method utilised) from the subcontractor. If in doubt, consult relevant NB before submitting technical documentation.</li> <li>• Devices which incorporate human or animal-derived substances may be subject to requirements of additional European Directives / Regulations. Additional review resources may be required, including external independent reviewers and/or Competent Authority consultation and/or a European Agency for the Evaluation of Medicinal Products (EMA).</li> </ul>



Row ID	Regions & Level	Heading	Common Content	Regional Content
				<p>NOTE: In case of materials from animal origin being utilised that bear TSE risk, the submission should clarify if an EDQM certificate is available for the starting material, and if so it will need to be provided.</p> <p><b>TGA</b> Details of the QMS records of the assessment and control of the subcontractors that supply the manufacturer with materials.</p> <p>For materials of animal origin</p> <ul style="list-style-type: none"> <li>○ Information on controls related to sourcing/collection/handling (ISO22442-2)</li> <li>○ Validation of the manufacturing process' capacity to clear viruses (ISO22442-3)</li> <li>○ Risk assessment that identifies the adventitious agents that are likely to be in the starting material, estimates the concentrations likely to be present and demonstrates that the control measures in place adequately controls these adventitious agents to an acceptable level in the final product (ISO22442-1)</li> </ul> <p>For human blood or human plasma derived material</p> <ul style="list-style-type: none"> <li>○ Information on donor selection and testing of individual donations, mini-pools and plasma pools (information can be submitted to the TGA in a Plasma Master File (PMF))</li> <li>○ Validation of the manufacturing process' capacity to clear viruses</li> </ul>

Row ID	Regions & Level		Heading	Common Content	Regional Content
					<ul style="list-style-type: none"> <li>○ Risk assessment that identifies the adventitious agents that are likely to be in the starting material, estimates the concentrations likely to be present and demonstrates that the control measures in place adequately controls these adventitious agents to an acceptable level in the final product</li> </ul> <p><b>HC</b> Refer to the <a href="#">guidance on the regulation of medical devices manufactured from or incorporating viable or non-viable animal tissue or their derivative(s)</a>.</p>
3.05.08.01	ANVISA, HSA, TGA	3	Certificates	Certificates that support the safety of materials of biological origin (e.g. certificate of abattoir inspection).	<p><b><u>ANVISA and HSA</u></b> If available, Certificate of Suitability (CEP) for biological material that bears TSE (Transmissible Spongiform Encephalopathy) risk.</p> <p><b><u>TGA</u></b> If available, EDQM certificate for animal origin material that bears TSE (Transmissible Spongiform Encephalopathy) risk. If available, European Medicines Agency PMF certificate for human blood or human plasma derived material contained in the device.</p>
3.05.08.02	IMDRF	3	[Study description, study identifier, date of initiation]	<b>NO CONTENT AT THIS LEVEL</b> This heading should be CUSTOM AND BASED ON STUDY DETAILS	

Row ID	Regions & Level	Heading	Common Content	Regional Content
			and created <b>for each study</b> under the parent heading. The sub headings below would be for this study alone.	
3.05.08.02.01	IMDRF	4 Summary	A summary of the specific study described in the custom heading above.	
3.05.08.02.02	IMDRF	4 Full Report	The test report for the test described in the custom heading above.	<b>USFDA 510(k)</b> If referencing a standard, refer to <a href="#">Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</a> .
3.05.08.02.03	USFDA	4 Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. <b>The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.</b>  <b>NOTE: Do not place PDFs here.</b>
3.05.09	IMDRF	2 Sterilization and Reprocessing Validation	<b>NO CONTENT AT THIS LEVEL</b>	
3.05.09.01	IMDRF	3 End-User Sterilization	Information and validation of end-user sterilization where it is necessary for the end-user to	<b>EU</b> For specific MDR requirements see MDR Annex I GSPR 23.4 (i) and (m). Guidance is also available in EN ISO 17664.

Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p>sterilize the device. This should include:</p> <ul style="list-style-type: none"> <li>a) A description of the sterilization process (method, parameters) and Sterility Assurance Level (SAL)</li> <li>b) A summary of the non-clinical evidence that falls within this category</li> <li>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 (i.e., what tests were considered and why they were or were not performed)</li> <li>d) If applicable, state the rationale on the durability of the product against two or more sterilization.</li> <li>e) Discussion to support why the evidence presented is sufficient to support the application.</li> </ul> <p><b>OR</b></p> <ul style="list-style-type: none"> <li>f) A statement of why this category of non-clinical laboratory study is not applicable to this case.</li> </ul> <p><b>NOTE:</b> The sponsor/applicant should explicitly address any existing regional regulatory</p>	<p><b><u>NMPA</u></b></p> <p>The recommended sterilization process (methods and parameters), the basis for the determination of the recommended sterilization process, and the relevant research data for verification should be clearly defined; for products that can withstand two or more sterilizations, The research data on the tolerance of the product's recommended sterilization process should be provided.</p> <p>For medical devices that are delivered in a non-sterile state and need to be sterilized before use, research materials that prove that the packaging can reduce the risk of microbial contamination of the product and are applicable to the sterilization method specified by the manufacturer shall be provided.</p> <p><b><u>USFDA</u></b></p> <p>Refer to Guidance for Industry and Staff - Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
				guidance related to the non-clinical study results provided in this section regarding the subject device	
3.05.09.01.01	IMDRF	4	[Study description, study identifier, date of initiation]	<b>NO CONTENT AT THIS LEVEL</b> This heading should be CUSTOM AND BASED ON STUDY DETAILS and created <u>for each study</u> under the parent heading. The sub headings below would be for this study alone.	
3.05.09.01.01.01	IMDRF	5	Summary	A summary of the specific study described in the custom heading above.	
3.05.09.01.01.02	IMDRF	5	Full Report	The test report for the test described in the custom heading above.	<b>USFDA 510(k)</b> If referencing a standard, refer to <a href="#">Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</a> .
3.05.09.01.01.03	USFDA	5	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. <b>The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.</b>

Row ID	Regions & Level		Heading	Common Content	Regional Content
					<b>NOTE: Do not place PDFs here.</b>
3.05.09.02	IMDRF	3	Manufacturer Sterilization Validation	<p>Information and validation of manufacturer sterilization where the device is provided sterile. This should include:</p> <ul style="list-style-type: none"> <li>a) A description of the sterilization process (method, parameters) and Sterility Assurance Level (SAL)</li> <li>b) State if parametric release is used</li> <li>c) A summary of the non-clinical evidence that falls within this category</li> <li>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.</li> <li>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 (i.e., what tests were considered and why they were or were not performed)</li> <li>f) Discussion to support why the evidence presented is sufficient to support the application.</li> </ul>	<p><b><u>EU</u></b> For specific MDR requirements see MDR Annex II Section 6.2 (e). Guidance is also available in EN ISO 11137 series, EN ISO 11135, EN ISO 17665, EN ISO 13408 series, EN ISO 20857, EN ISO 14937.</p> <p><b><u>USFDA</u></b> Refer to Guidance for Industry and Staff - Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile</p> <p><b><u>NMPA</u></b> The sterilization process (methods and parameters) and the sterility assurance level (SAL) should be clarified, and relevant research materials for sterilization verification and confirmation should be provided.</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
				<p>OR</p> <p>g) A statement of why this category of non-clinical laboratory study is not applicable to this case.</p> <p><b>NOTE:</b> 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</p>	
<b>3.05.09.02.01</b>	IMDRF	4	[Study description, study identifier, date of initiation]	<p><b>NO CONTENT AT THIS LEVEL</b> This heading should be CUSTOM AND BASED ON STUDY DETAILS and created <b>for each study</b> under the parent heading. The sub headings below would be for this study alone.</p>	
<b>3.05.09.02.01.01</b>	IMDRF	5	Summary	A summary of the specific study described in the custom heading above.	
<b>3.05.09.02.01.02</b>	IMDRF	5	Full Report	The test report for the test described in the custom heading above.	<p><b>USFDA 510(k)</b> If referencing a standard, refer to <a href="#">Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</a>.</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
3.05.09.02.01.03	USFDA	5	Statistical Data		<p>This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. <b>The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.</b></p> <p><b>NOTE: Do not place PDFs here.</b></p>
3.05.09.03	IMDRF	3	Residual Toxicity	<p>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:</p> <ol style="list-style-type: none"> <li>A summary of the non-clinical evidence that falls within this category</li> <li>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 (i.e., what tests were considered and why they were or were not performed)</li> <li>Discussion to support why the evidence presented is sufficient</li> </ol>	<p><b><u>EU</u></b> See MDR Annex II Section 6.2 (e) for requirements.</p> <p><b><u>NMPA</u></b> If the product may produce residual substances after sterilization or disinfection, a residual toxicity study should be carried out on the sterilized or disinfected product, the residual information and the treatment method adopted should be clarified, and relevant research materials should be provided.</p>



Row ID	Regions & Level		Heading	Common Content	Regional Content
				<p>to support the application.</p> <p><b>OR</b></p> <p>d) A statement of why this category of non-clinical laboratory study is not applicable to this case.</p> <p><b>NOTE:</b> 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.</p>	
<b>3.05.09.03.01</b>	IMDRF	4	[Study description, study identifier, date of initiation]	<p><b>NO CONTENT AT THIS LEVEL</b> This heading should be CUSTOM AND BASED ON STUDY DETAILS and created <b>for each study</b> under the parent heading. The sub headings below would be for this study alone.</p>	
<b>3.05.09.03.01.01</b>	IMDRF	5	Summary	A summary of the specific study described in the custom heading above.	
<b>3.05.09.03.01.02</b>	IMDRF	5	Full Report	The test report for the test described in the custom heading above.	<p><b>USFDA 510(k)</b> If referencing a standard, refer to <a href="#">Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.</a></p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
3.05.09.03.01.03	USFDA	5	Statistical Data		<p>This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. <b>The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.</b></p> <p><b>NOTE: Do not place PDFs here.</b></p>
3.05.09.04	IMDRF	3	Cleaning and Disinfection Validation	<p>Contains information on the validation of cleaning and disinfection instructions for reusable devices. This should include:</p> <ul style="list-style-type: none"> <li>a) A summary of the non-clinical evidence that falls within this category</li> <li>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 (i.e., what tests were considered and why they were or were not performed)</li> <li>c) Discussion to support why the evidence presented is sufficient to support the application.</li> </ul>	<p><b>EU</b> For specific MDR requirements see MDR Annex I GSPR 23.4 (n).</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p><b>OR</b></p> <p>d) A statement of why this category of non-clinical laboratory study is not applicable to this case.</p> <p><b>NOTE:</b> 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.</p>	
<b>3.05.09.04.01</b>	IMDRF	4 [Study description, study identifier, date of initiation]	<p><b>NO CONTENT AT THIS LEVEL</b> This heading should be CUSTOM AND BASED ON STUDY DETAILS and created <b>for each study</b> under the parent heading. The sub headings below would be for this study alone.</p>	
<b>3.05.09.04.01.01</b>	IMDRF	5 Summary	A summary of the specific study described in the custom heading above.	
<b>3.05.09.04.01.02</b>	IMDRF	5 Full Report	The test report for the test described in the custom heading above.	<p><b>USFDA 510(k)</b> If referencing a standard, refer to <a href="#">Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</a>.</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
3.05.09.04.01.03	USFDA	5 Statistical Data		<p>This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. <b>The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.</b></p> <p><b>NOTE: Do not place PDFs here.</b></p>
3.05.09.05	ANVISA, EU, HC, USFDA, JP	3 Reprocessing of Single Use Devices, Validation Data	<p>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.</p> <p><b>NOTE:</b> 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.</p>	<p><b>ANVISA</b> ANVISA's specific requirements for SUD and reprocessing must be considered.</p> <p><b>EU</b> For specific MDR requirements see MDR Article 17 and Commission Implementing Regulation (EU) 2020/1207 on common specifications for the reprocessing of single-use devices.</p> <p><b>USFDA</b> Refer to the Guidance for Industry and FDA Staff – “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.”</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				<p><b>USFDA 510(k)</b> Please see Appendix E of the Reprocessing Guidance for a list of devices which require data to validate reprocessing instructions.</p> <p><b>JP</b> Refer to the Guidance for Industry – “Cleaning guideline.” and “Pick up from hospitals, transport, and acceptance process at the manufacturing plant.”</p>
<b>3.05.09.05.01</b>	ANVISA, HC, USFDA	4 [Study description, study identifier, date of initiation]	<b>NO CONTENT AT THIS LEVEL</b> This heading should be CUSTOM AND BASED ON STUDY DETAILS and created <u>for each study</u> under the parent heading. The sub headings below would be for this study alone.	
<b>3.05.09.05.01.01</b>	ANVISA, HC, USFDA	5 Summary	A summary of the specific study described in the custom heading above.	
<b>3.05.09.05.01.02</b>	ANVISA, HC, USFDA	5 Full Report	The test report for the test described in the custom heading above.	<p><b>USFDA 510(k)</b> Required for reprocessed single use devices.</p> <p>If referencing a standard, refer to <a href="#">Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</a>.</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
3.05.09.05.01.03	USFDA	5	Statistical Data		<p>This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. <b>The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.</b></p> <p><b>NOTE: Do not place PDFs here.</b></p>
3.05.10	IMDRF	2	Animal Testing	<p>Contains information about any animal studies conducted to support the submission. This should include:</p> <ul style="list-style-type: none"> <li>a) A summary of the non-clinical evidence that falls within this category</li> <li>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 (i.e., what tests were considered and why they were or were not performed)</li> <li>c) Discussion to support why the evidence presented is sufficient to support the application.</li> </ul> <p><b>OR</b></p>	<p><b><u>EU</u></b> For specific MDR requirements see MDR Annex II Section 6.1 (a).</p> <p><b><u>USFDA</u></b> Requirements for reporting non-clinical data laboratory study results are outline in 21 CFR 58.185</p> <p><b><u>TGA</u></b> Specify if the animal studies have been conducted under Good Laboratory Practices conditions.</p> <p><b><u>NMPA</u></b> In order to avoid unnecessary animal experiments, scientific decisions should be made on whether or not to carry out animal experiments on medical devices, and demonstration/explanatory materials should be</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p>d) A statement of why this category of non-clinical laboratory study is not applicable to this case.</p> <p><b>NOTE:</b> 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.</p>	<p>provided. If the decision is made to verify/confirm the effectiveness of product risk control measures through animal test research, animal test research materials shall be provided, and the research materials shall include test purpose, laboratory animal information, test equipment and control information, number of animals, evaluation indicators, and test The results, the basis for determining the design elements of animal experiments, etc.</p>
<b>3.05.10.01</b>	IMDRF	3 [Study description, study identifier, date of initiation, date of completion]	<p><b>NO CONTENT AT THIS LEVEL</b> This heading should be CUSTOM AND BASED ON STUDY DETAILS and created <u>for each study</u> under the parent heading. The sub headings below would be for this study alone.</p>	
<b>3.05.10.01.01</b>	IMDRF	4 Summary	<p>A summary of the specific study described in the custom heading above.</p>	
<b>3.05.10.01.02</b>	IMDRF	4 Full Report	<p>The test report for the test described in the custom heading above.</p>	<p><b>USFDA 510(k)</b> If referencing a standard, refer to <a href="#">Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</a>.</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
3.05.10.01.03	USFDA	4	Statistical Data		<p>This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. <b>The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.</b></p> <p><b>NOTE: Do not place PDFs here.</b></p>
3.05.11	IMDRF	2	Usability/Human Factors	<p>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:</p> <ol style="list-style-type: none"> <li>A summary of the non-clinical evidence that falls within this category</li> <li>A statement of the test environment and relation to the intended use environment</li> <li>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 (i.e., what tests</li> </ol>	<p><b>EU</b> For specific MDR requirements see MDR Annex II Section 6.1 (a). Guidance is also available in EN 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices.</p> <p><b>USFDA</b> Please consult the “<a href="#">Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Medical Devices</a>”</p>



Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p>were considered and why they were or were not performed)</p> <p>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.</p> <p>e) Discussion to support why the evidence presented is sufficient to support the application.</p> <p><b>OR</b></p> <p>f) A statement of why this category of non-clinical laboratory study is not applicable to this case.</p> <p><b>NOTES:</b></p> <p>i. If a clinical study has been conducted that includes usability/human factors endpoints, <b>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.</b></p>	

Row ID	Regions & Level	Heading	Common Content	Regional Content
			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.	
3.05.11.01	IMDRF	3 [Study description, study identifier, date of initiation]	<b>NO CONTENT AT THIS LEVEL</b> This heading should be CUSTOM AND BASED ON STUDY DETAILS and created <b>for each study</b> under the parent heading. The sub headings below would be for this study alone.	
3.05.11.01.01	IMDRF	4 Summary	A summary of the specific study described in the custom heading above.	
3.05.11.01.02	IMDRF	4 Full Report	The test report for the test described in the custom heading above.	<b>USFDA 510(k)</b> If referencing a standard, refer to <a href="#">Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</a> .
3.05.11.01.03	USFDA	4 Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. <b>The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.</b>

Row ID	Regions & Level		Heading	Common Content	Regional Content
					<b>NOTE: Do not place PDFs here.</b>
3.05.12	TGA	2	Evidence for devices with preservatives or antimicrobial claims	<p>Applications for:</p> <ul style="list-style-type: none"> <li>• multi-use products such as eye lubricants and contact lens care products that contain a preservative, evidence to support its preservation efficacy must be provided.</li> <li>• products such as sterile dressings with antimicrobial claims, evidence to support its antimicrobial efficacy must be provided.</li> </ul>	
3.06	ANVISA, HC, HSA, JP, USFDA	1	Non-clinical Bibliography	<p>This heading should include:</p> <ol style="list-style-type: none"> <li>A listing of published non-clinical studies involving this specific device (e.g. cadaveric evaluations, biomechanical assessments)</li> <li>Legible copies of key articles, including translation where applicable to meet the regulators language requirements</li> <li>Discussion to support why the evidence presented is sufficient to support the application.</li> </ol> <p><b>OR</b></p>	

Row ID	Regions & Level		Heading	Common Content	Regional Content
				d) A statement that no literature related to the device was found.	
3.07	IMDRF	1	Expiration Period and Packaging Validation	<p>This heading should include:</p> <p>a) An indication of environmental conditions for correct storage of the device (e.g. temperature, pressure, humidity, luminosity).</p> <p>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.</p> <p><b>OR</b></p> <p>c) A rationale that storage conditions could not affect device safety or effectiveness</p>	<p><b><u>ANVISA, EU, HC, HSA, JP, and TGA</u></b> For devices that do not have an expiration period (e.g. 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.</p> <p><b><u>EU</u></b> For specific MDR requirements see MDR Annex I GSPRs 6, 23.2 (i), (j) and (k), 23.3 (i) and 23.4 (a).</p> <p><b><u>NMPA</u></b> If applicable, shelf life and packaging research materials should be provided to prove that during the shelf life, under the transportation and storage conditions specified by the manufacturer, the product can maintain performance and function to meet the use requirements, and products with microbial limit requirements should also meet the microbial limit requirements. Products delivered in a sterile state should also be kept sterile.</p>
3.07.01	IMDRF	2	Product Stability	Contains details relating to product stability under specified storage conditions and in final packaging or	<p><b><u>ANVISA</u></b> If applicable, product stability shall also include:</p> <p>a) In use stability, containing details and evidence supporting the stability during</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p>simulated conditions. This should include:</p> <ul style="list-style-type: none"> <li>a) A statement of the shelf-life (for each component if there are differences between components) and the proposed storage condition for the device</li> <li>b) A summary of the non-clinical evidence, covering shelf-life period when stored at the proposed storage condition, that falls within this category</li> <li>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 (i.e., what tests were considered and why they were or were not performed)</li> <li>d) Discussion to support why the evidence presented is sufficient to support the application.</li> <li>e) Evidence to support stability of the medicinal substance contained in the device at the proposed storage condition</li> <li>f) Evidence of in-use stability supporting the stability during actual routine use of the device (real or simulated);</li> </ul> <p><b>OR</b></p>	<p>actual routine use of the device (real or simulated);</p> <ul style="list-style-type: none"> <li>b) Shipping stability containing details and evidence supporting the tolerance of device components to the anticipated shipping conditions.</li> </ul> <p><b><u>EU</u></b> For specific MDR requirements see MDR Annex I GSPRs 6, 11.7 and Annex II Section 6.1(b).</p> <p><b><u>HSA</u></b> If applicable, product stability shall also include in use stability, containing details and evidence supporting the stability during actual routine use of the device (real or simulated);</p> <p><b><u>TGA</u></b> If applicable, product stability shall also include:</p> <ul style="list-style-type: none"> <li>c) In use stability, containing details and evidence supporting the stability during actual routine use of the device (real or simulated)</li> <li>d) Shipping stability containing details and evidence supporting the tolerance of device components to the anticipated shipping conditions.</li> </ul> <p><b><u>NMPA</u></b> a) In use stability, if applicable, use stability/reliability research materials should be</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
				<p>g) A statement of why this category of non-clinical laboratory study is not applicable to this case.</p> <p><b>NOTE:</b> 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.</p>	<p>provided to prove that the product's performance and functions meet the use requirements under normal use, maintenance and calibration (if applicable) within the use period/number of use specified by the manufacturer.</p> <p>b) Shipping stability, Shipping stability and packaging research data should be provided to prove that under the transportation conditions specified by the manufacturer, the environmental conditions during transportation (such as vibration, vibration, temperature and humidity fluctuations) will not affect the characteristics and performance of the medical device, including Integrity and cleanliness are adversely affected.</p> <p><b>USFDA</b> "Medicinal substances" includes biologics and drug in the context of combination products.</p>
<b>3.07.01.01</b>	IMDRF	3	[Study description, study identifier, date of initiation]	<p><b>NO CONTENT AT THIS LEVEL</b> This heading should be CUSTOM AND BASED ON STUDY DETAILS and created <u>for each study</u> under the parent heading. The sub headings below would be for this study alone.</p>	
<b>3.07.01.01.01</b>	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	

Row ID	Regions & Level		Heading	Common Content	Regional Content
3.07.01.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	<b>USFDA 510(k)</b> If referencing a standard, refer to <a href="#">Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</a> .
3.07.01.01.03	USFDA	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. <b>The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.</b>  <b>NOTE: Do not place PDFs here.</b>
3.07.02	IMDRF	2	Package Validation	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	<b>EU</b> For specific MDR requirements see MDR Annex I GSPRs 6, 11.7 and Annex II Section 6.2 (e).

Row ID	Regions & Level		Heading	Common Content	Regional Content
				<p>and support for their selection or omission from the verification and validation studies conducted in this category (i.e., what tests were considered and why they were or were not performed)</p> <p>c) Discussion to support why the evidence presented is sufficient to support the application.</p> <p><b>OR</b></p> <p>d) A statement of why this category of non-clinical laboratory study is not applicable to this case.</p> <p><b>NOTE:</b> 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.</p>	
<b>3.07.02.01</b>	IMDRF	3	[Study description, study identifier, date of initiation]	<p><b>NO CONTENT AT THIS LEVEL</b> This heading should be CUSTOM AND BASED ON STUDY DETAILS and created <b>for each study</b> under the parent heading. The sub headings below would be for this study alone.</p>	
<b>3.07.02.01.01</b>	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	



Row ID	Regions & Level		Heading	Common Content	Regional Content
3.07.02.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	<b>USFDA 510(k)</b> If referencing a standard, refer to <a href="#">Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</a> .
3.07.02.01.03	USFDA	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. <b>The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.</b>  <b>NOTE: Do not place PDFs here.</b>
3.08	IMDRF	1	Other non-clinical Evidence	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 <b>that are not delineated in the rest of the Chapter 3.</b> This should include a) A description of the purpose of the test, the risk/safety issue the	<b>EU</b> See MDR Annex I and Annex II Sections 6.1 (a) and 6.2 (a), (c), (d), (f), (g) for additional information required in specific cases: <ul style="list-style-type: none"> <li>• Devices incorporating medicinal substances</li> <li>• Devices composed of substances that are absorbed by or locally dispersed in the human body (Annex VIII Rule 21 devices): see GSPR 12.2</li> <li>• Devices containing CMR or endocrine-disrupting substances referred to in GSPR</li> </ul>

Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p>test is addressing; the test methods and results of the test</p> <p><b>NOTE:</b> 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.</p>	<p>10.4.1 of MDR Annex I: see GSPRs 10.4.1 - 10.4.5</p> <ul style="list-style-type: none"> <li>• Devices with a measuring or diagnostic function</li> <li>• Magnetic resonance imaging safety of implants</li> </ul> <p><b><u>NMPA</u></b></p> <p>a) Risk of explosion For medical devices that are exposed to flammable and explosive substances or used in combination with other combustibles or combustibles, the explosion risk research data shall be provided to prove that the explosion risk is acceptable under normal conditions and single fault conditions.</p> <p>b) Joint use If the declared product is expected to be used in combination with other medical devices, drugs, and non-medical device products to achieve the same intended use, research materials that prove the safety and effectiveness of the combined use should be provided, including basic interconnection information (connection type, interface, protocol, minimum performance), joint Use risks and control measures, restrictions on joint use, compatibility studies, etc. In the case of combined drug use, the drug compatibility research materials shall be provided to prove that the performance of the</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				combined drug and device meets its indications and intended use. c) Dose-effect relationship and energy safety For medical devices that provide energy or material therapy to patients, research data on the dose-effect relationship and energy safety should be provided, and the safety, effectiveness, and rationality of the treatment parameter settings should be provided. Research data on unacceptable harm caused by normal tissues.
<b>3.08.01</b>	IMDRF	2 [Study description, study identifier, date of initiation]	<b>NO CONTENT AT THIS LEVEL</b> This heading should be CUSTOM AND BASED ON STUDY DETAILS and created <b>for each study</b> under the parent heading. The sub headings below would be for this study alone.	
<b>3.08.01.01</b>	IMDRF	3 Summary	A summary of the specific study described in the custom heading above.	
<b>3.08.01.02</b>	IMDRF	3 Full Report	The test report for the test described in the custom heading above.	<b>USFDA 510(k)</b> If referencing a standard, refer to <a href="#">Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices</a> .

Row ID	Regions & Level		Heading	Common Content	Regional Content
3.08.01.03	USFDA	3	Statistical Data		<p>This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. <b>The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.</b></p> <p><b>NOTE: Do not place PDFs here.</b></p>

## 4. Chapter 4 – Clinical evidence

Row ID	Regions & Level		Heading	Common Content	Regional Content
4.01	IMDRF	1	Chapter Table of Contents	<ul style="list-style-type: none"> <li>a) Includes all headings for the chapter.</li> <li>b) Specifies the page number for each item referred to in the table.</li> </ul>	
4.02	IMDRF	1	Overall Clinical Evidence Summary	<ul style="list-style-type: none"> <li>a) This should be a brief (1-2 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.</li> <li>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</li> </ul>	<p><b><u>EU</u></b> Clinical evidence is always required, regardless of risk class. For Class III and implantable devices other than custom-made or investigational devices, a summary of safety and clinical performance (SSCP) per MDR Article 32 must be provided.</p> <p><b><u>TGA</u></b> Every medical device requires clinical evidence, appropriate for its intended use and classification of the device, demonstrating that the device complies with the applicable provisions of the Essential Principles, Schedule 2 <i>Therapeutic Goods (Medical Devices) Regulations 2002</i>. Follow the guidance on <a href="#">‘Clinical Evidence Guidelines: Medical Devices’</a> on expected data requirements for each application.”</p> <p><b><u>NMPA</u></b> Class II and Class III devices should be submitted with clinical evaluation data.</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
				<p>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.</p> <p>c) A discussion of the clinical evidence considered for the device and support for their selection (i.e., what type of evidence was considered and why they were or were not used)</p> <p>d) Discussion to support why the evidence presented is sufficient to support the application.</p> <p><b>NOTE:</b> Human factors testing that include patients should be included here.</p>	<p><b>HC</b></p> <p>a) Provide the Investigational Testing Authorization reference number for any clinical trials conducted under an Investigational Testing Authorization in Canada.</p> <p>b) If applicable, provide the clinicaltrials.gov reference number for any clinical studies registered with clinicaltrials.gov.</p> <p>c) Consult the <a href="#">guidance on clinical evidence requirements for medical devices</a> for additional requirements.</p> <p><b>USFDA PMA and 510(k)</b> Does not limit the page number for the summary of the clinical information submitted</p> <p><b>USFDA, HC, ANVISA, JP and HSA</b> If no clinical evidence is being provided, discuss why this is acceptable.</p> <p><b>HSA</b> Regardless of risk class, for medical devices with labelled use beyond the inherent performance of the device, clinical data should be provided to substantiate the proposed labelled use.</p>
4.02.01	EU, HC, HSA, NMPA, JP, TGA	2	Clinical Evaluation Report	a) A clinical evaluation report reviewed and signed by an expert in the relevant field that contains an objective critical evaluation of all of	<p><b>EU</b> For specific MDR requirements see MDR Article 61, Annex II Section 6.1 (c) and Annex XIV PART A for requirements. Provide also the</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p>the clinical data submitted in relation to the device.</p> <p>b) A complete curriculum vitae, or similar documentation, to justify the manufacturer's choice of the clinical expert.</p>	<p>clinical evaluation plan documented and used for the device.</p> <p><b>NMPA</b></p> <p>a) Product description and R&amp;D background: including the basic information of the proposed product, the scope of application, the existing diagnostic or therapeutic methods and the clinical application of the involved device, the relationship between the proposed product and the existing diagnostic or therapeutic methods, and the intended clinical efficacy, etc.</p> <p>b) Clarify the scope of clinical evaluation, and describe the structural composition and reasons for exemption from clinical evaluation if any part of the proposed product can be exempt from clinical evaluation.</p> <p>c) Clinical evaluation pathway: select the appropriate clinical evaluation pathway according to the scope of application, technical features, existing clinical data and other specific conditions of the proposed product, including the clinical evaluation pathway of the predicate medical device and/or clinical trial pathway.</p> <p>d) For the clinical evaluation conducted through the clinical evaluation pathway of the predicate medical device, the comparative data of the proposed product and the predicate medical device in terms of the application scope, technical features and biological properties shall be submitted; clinical data of the predicate medical device shall be collected, evaluated and analyzed to form clinical evidence. Where</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
					applicable, the differences between the proposed product and the predicate medical device shall be described, and sufficient scientific evidence shall be submitted to prove that they have the equivalent safety and effectiveness.
4.02.02	IMDRF	2	Device Specific Clinical Trials	<b>NO CONTENT AT THIS LEVEL</b> Clinical trial information under this heading should be grouped by trial	
4.02.02.01	IMDRF	3	[Trial description, protocol #, date of initiation]	<b>NO CONTENT AT THIS LEVEL</b> This heading should be CUSTOM AND BASED ON STUDY DETAILS and created <b>for each study</b> 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	
4.02.02.01.01	IMDRF	4	Clinical Trial Summary	a) A summary of the specific study described in the custom heading above that includes:	<b>HC</b> <a href="#">Guidance on Clinical Evidence Requirements for Medical Devices</a>  <b>USFDA</b>



Row ID	Regions & Level		Heading	Common Content	Regional Content
				<ul style="list-style-type: none"> <li>i. The key characteristics of the study (e.g. title of study, investigators, sites, study period (date of enrollment/date of last completed), objectives, methods, # patients, inclusion/exclusion criteria) and</li> <li>ii. Summary of the results of the analysis</li> <li>iii. Summary of conclusions related to the endpoints</li> </ul> <p><b>NOTES:</b></p> <ul style="list-style-type: none"> <li>i. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the components of the clinical trial summary.</li> <li>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.</li> </ul>	<a href="#">Collection of Race and Ethnicity Data in Clinical Trials</a>
4.02.02.01.0 2	IMDRF	4	Clinical Trial Report	<ul style="list-style-type: none"> <li>a) A clinical trial report of the specific study described in the custom heading above.</li> </ul> <p><b>NOTES:</b></p>	<p><b>EU</b> For specific MDR requirements see MDR Articles 61-82 and Annex XV. Guidance is also available in EN ISO 14155 Clinical investigation of medical devices for human subjects – Good clinical practice.</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
				<p>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.</p> <p>ii. The sponsor/applicant should explicitly address any relevant existing regional regulatory guidance related to the components of the clinical trial report.</p>	<p>For devices without suitable equivalents and / or insufficient data in the literature, pre-market clinical investigation may be required. In addition, for Class III devices and Class IIb implantable devices, pre-market clinical investigation will be required except in the cases listed in MDR Article 61 (4) and (6).</p> <p><b><u>TGA</u></b> Clinical trials must comply with:</p> <p>a) NHMRC National Statement of Ethical Conduct in Human Research if the study is conducted in Australia (clause 8.4(4) of Part 8 of Schedule 3 of the MD Regs); or the Declaration of Helsinki if the study is conducted outside of Australia (clause 8.4(5) of Part 8 of Schedule 3 of the MD Regs)</p>
<p><b>4.02.02.01.03</b></p>	<p>USFDA</p>	<p>4</p>	<p>Clinical Trial Data</p>		<p><b><u>USFDA</u></b></p> <p>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. In this instance regional regulatory guidance refers to Special Controls in a device specific regulation, device-specific guidance document, special controls guidance, special controls guideline, and Statutory or Regulatory criteria.</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
					<p>The Center for Devices and Radiological Health (CDRH) accepts and encourages the inclusion of clinical data in electronic (non-PDF) form as supporting material to a premarket (PMA or 510(k)) submission.</p> <p><a href="http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm136377.htm">http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm136377.htm</a></p>
4.02.03	IMDRF	2	Clinical Literature Review and Other Reasonable Known Information	<p>a) A critical evaluation of the relevant scientific literature currently available relating to the safety and/or effectiveness of the device. This should incorporate:</p> <ol style="list-style-type: none"> <li>i. A documented search protocol to a level of detail that allows the search to be reproduced;</li> <li>ii. A selection strategy (inclusion/exclusion criteria);</li> <li>iii. Criteria for appraising the data (both favourable and unfavourable) to determine the contribution of each data set to support the conclusions;</li> <li>iv. Results of the literature search; and</li> <li>v. A documentation of the appraisal to the extent that it can be critically reviewed by others.</li> </ol> <p>b) A legible copy of key articles, including translation where</p>	<p><b>EU</b></p> <p>For specific MDR requirements see MDR Article 61 (3) and Annex XIV Section 3.</p> <ul style="list-style-type: none"> <li>• A copy of all literature articles selected and analysed within the clinical evaluation report should be included in the technical documentation.</li> <li>• A full list of retrieved articles and of excluded articles provided, with reasons for exclusion, should also be provided.</li> </ul>

Row ID	Regions & Level		Heading	Common Content	Regional Content
				<p>applicable to meet the regulators language requirements.</p> <p><b>OR</b></p> <p>c) A statement that no literature related to the device was found.</p> <p><b>NOTES:</b></p> <ul style="list-style-type: none"> <li>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</li> <li>ii) Please see Chapter 2.07 for Post-Market Study plans.</li> </ul>	
4.03	NMPA, USFDA	1	Informed Consent Information		<p><b><u>NMPA</u></b> Clinical trial protocol, written opinions on the approval of the clinical trial from the Ethics Committee of the clinical trial institution, clinical trial report, and sample Informed Consent Form shall be provided.</p> <p><b><u>USFDA</u></b> Any information related to informed consent in the collection of the clinical information used to support the submission, such as copies of Institutional Review Board-approved informed consent forms, is to be provided here.</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
4.04	USFDA	1	Investigators Sites and IRB Contact Information		<p><b>USFDA</b> Investigators and study administrative structure information should be provided, including (as appropriate):</p> <ul style="list-style-type: none"> <li>a) Investigators (who signed the Investigator agreement)-name, address, telephone # (contact info), CV</li> <li>b) Sites-Site number as reflected in the study report in reference to the investigator, address if different from the above</li> <li>c) Sponsor-address and regulatory contact information</li> <li>d) Contract Research Organization (CRO), if applicable-name, address, and contact information</li> </ul> <p>5. Laboratory facilities (central lab and/or local lab that participated in the study)-name, address, contact information</p>
4.05	HC, HSA, TGA, USFDA	1	Real World Data (RWD)	Where applicable, other clinical experience data/real world data (including device registries, post-market studies conducted in other jurisdictions)	
4.06	EU, HC, HSA, TGA, USFDA	1	Post-Market Surveillance Data		<p><b>EU</b> See MDR Chapter VII and Annex III on post-market surveillance as well as Annex XIV for requirements relating to post-market clinical follow-up (PMCF); procedures to be in section 6.09.</p>
4.07	IMDRF	1	Other Clinical Evidence	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.	<p><b>NMPA</b> Where applicable, summary, reports and data of the corresponding project evaluation materials shall be provided.</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content

# 5. Chapter 5 – Labelling and promotional material

Row ID	Regions & Level		Heading	Common Content	Regional Content
5.01	IMDRF	1	Chapter Table of Contents	<ul style="list-style-type: none"><li>a) Includes all headings for the chapter.</li><li>b) Specifies the page number for each item referred to in the table.</li></ul>	

Row ID	Regions & Level		Heading	Common Content	Regional Content
5.02	IMDRF	1	Product/Package Labels	<p>Samples of the primary and secondary packaging labels.</p> <p><b>NOTES:</b></p> <ul style="list-style-type: none"> <li>i. Do not include shipping labels.</li> <li>ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to labelling the subject nIVD medical device.</li> </ul>	<p><b><u>ANVISA</u></b></p> <ul style="list-style-type: none"> <li>a) According to Brazilian Legislation all information associated with the device, including labelling, shall be in Brazilian-Portuguese.</li> <li>b) Specific requirements of labelling content are established by ANVISA’s regulatory framework.</li> <li>c) In case the product is marketed with original labels, (PDFs of) stickers with local information will need to be provided.</li> </ul> <p><b><u>EU</u></b></p> <p>For specific MDR requirements see MDR Annex I GSPRs 23.1, 23.2, 23.3 and Annex II Section 2.</p> <p><b><u>HC</u></b></p> <ul style="list-style-type: none"> <li>a) All labelling must comply with sections 21 to 23 of the <i>Medical Devices Regulations</i>.</li> <li>b) Consult the <a href="#">guidance for the labelling of medical devices, not including in vitro diagnostic devices</a>.</li> </ul> <p><b><u>NMPA</u></b></p> <p>Product instructions for use shall be submitted, with the contents conforming to the Provisions on the Administration of Instructions for Use and Labels of Medical Devices, relevant laws,</p>



Row ID	Regions & Level	Heading	Common Content	Regional Content
				<p>regulations, normative documents and mandatory standards.</p> <p><b><u>TGA</u></b>  The labels and instructions for use (including any package inserts) must</p> <ol style="list-style-type: none"> <li>a) meet the requirements of Essential Principle 13</li> <li>b) be in English and legible when viewed on screen and printed</li> <li>c) include the Australian sponsor’s contact details to meet Regulation 10.2</li> <li>d) meet the requirements of the Standard for the Uniform Scheduling of Medicines and Poisons, if the device contains a substance listed in Schedule 4</li> </ol> <p>If the applicant is including draft labels, artist impression or mock-up labels, the applicant needs to provide:</p> <ol style="list-style-type: none"> <li>a) the mock-up as full size suitable for A3 printing</li> <li>b) a statement as to where and how the batch/serial number/ date of manufacture/expiry date/ will be displayed</li> </ol> <p>For a medical device that is software, or that incorporates software, the current version number and current build number of the software must</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				<p>a) meet the requirements of Essential principle 13B</p> <p>b) be accessible by, and identifiable to, users of the device</p> <p>c) be in English</p> <p>MRI Safety Labelling of the devices (IFU, PIL) covering:</p> <p>a) MR conditional label claims to be included per standard requirements</p> <p>b) The safety and conditions of use of a medical device for each magnetic field strength (e.g. 0.25 T, 1.2 T, 1.5 T, 3.0 T, 7.0 T) MR system, radiofrequency (RF) transmit coil type (e.g. whole-body transmit coil, head RF transmit-receive coil) and RF excitation (e.g. Circularly Polarized (CP), Multichannel-2 (MC-2)) to which the medical device is anticipated to be exposed.</p> <p>Specific labelling requirements for IVF media:</p> <p>a) Labelling should indicate whether the product has been tested for reproductive or developmental toxicity</p> <p>b) Labelling should indicate results of the mouse embryo assay (one-cell or two-cell MEA)</p> <p>c) Labelling should indicate results for endotoxin test performed on the product</p> <p><b><u>HSA</u></b></p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
					<p>Refer to GN-23 – available at <a href="http://www.hsa.gov.sg">www.hsa.gov.sg</a> for labelling requirements.</p> <p>a) Copies of device and packaging labels are to be provided in original color.</p> <p>b) If representative labels are provided, variable fields on the artwork must be highlighted, and ranges of values for the variable fields should be indicated.</p> <p><b>USFDA</b> Follow device labelling regulations found in 21 CFR Part 801.</p>
5.03	IMDRF	1	<p>Package Insert/Instructions for Use</p> <p>Package Insert/Instructions for Use</p>	<p>Package Insert/Instructions for Use included in the package, when required or provide support for why this element is not applicable.</p> <p><b>NOTE:</b> The sponsor/applicant should explicitly address any existing regional regulatory guidance related to labelling the subject device</p>	<p><b>ANVISA</b></p> <p>a) According to Brazilian Legislation all information associated with the device, including labelling, shall be in Brazilian-Portuguese.</p> <p>b) Specific requirements of labelling content are established by ANVISA’s regulatory framework.</p> <p>c) The current version of the instruction for use must be informed.</p> <p><b>EU</b> See MDR Annex I GSPRs 23.1, 23.3, 23.4 and Annex II Section 2 for detailed requirements</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				<p><b>HC</b></p> <ul style="list-style-type: none"> <li>a) All labelling must comply with sections 21 to 23 of the <i>Medical Devices Regulations</i>.</li> <li>b) Consult the <a href="#">guidance for the labelling of medical devices, not including in vitro diagnostic devices</a>.</li> <li>c) The current version and date of the instructions for use must be stated.</li> </ul> <p><b>NMPA</b></p> <ul style="list-style-type: none"> <li>a) Product instructions for use shall be submitted, with the contents conforming to the Provisions on the Administration of Instructions for Use and Labels of Medical Devices, relevant laws, regulations, normative documents and mandatory standards.</li> <li>b) Overseas applicants shall submit the product instructions for use in original language.</li> </ul> <p><b>TGA</b></p> <p>The labels and instructions for use (including any package inserts) must</p> <ul style="list-style-type: none"> <li>a) meet the requirements of Essential Principle</li> <li>b) be in English and legible when viewed on screen and printed</li> <li>c) include the Australian sponsor's contact details to meet Regulation 10.2</li> </ul>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				<p>If the applicant is including draft labels, artist impression or mock-up labels, the applicant needs to provide:</p> <ol style="list-style-type: none"> <li>the mock-up as full size suitable for A3 printing</li> <li>a statement as to where and how the batch/serial number/ date of manufacture/expiry date/ will be displayed</li> </ol> <p><b>USFDA PMA</b> Package inserts include a summary of clinical data</p> <p><b>HSA</b> Refer to GN-23 – available at <a href="http://www.hsa.gov.sg">www.hsa.gov.sg</a> for labelling requirements.</p>
5.04	ANVISA, EU, HC, HSA, USFDA	1 e-labelling	<p>In addition to the e-labelling itself, the following should be provided:</p> <ol style="list-style-type: none"> <li>For eligible medical devices and Software as a Medical Device, the applicant needs to identify which form of e-labelling is being used (e.g. electronic storage system or built-in system, website).</li> <li>Details of risk management in relation to e-labelling. If this is part of the overall risk management, refer to it here</li> <li>When IFUs are requested, a description of the procedure and</li> </ol>	<p><b>EU</b></p> <ul style="list-style-type: none"> <li>Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in Commission Implementing Regulation (EU) 2021/2226, as per GSPR 23.1(f)</li> <li>If the manufacturer has a website, the instructions for use shall be made available and kept up to date on the website and comply with Article 9 of Commission Implementing Regulation (EU) 2021/2226. The URL of the website where such information will be made available should be included.</li> </ul>

Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p>operations on providing IFU's when requested</p> <p>d) Written information for users on the webpage identifying where the IFU and further information can be found in relevant languages.</p> <p>e) A description on how the e-labeling requirements for the website have been met.</p> <p>f) If a video/App is available to demonstrate how the device is intended to function, provide a link as well as details about how it is maintained and updated throughout the life cycle of the device.</p>	<p><b>HC</b> 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, e.g. 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 <a href="#">guidance for the labelling of medical devices, not including in vitro diagnostic devices</a>, for additional information.</p> <p>If a video/App is available as described in f) above, the video should be available in both French and English.</p> <p><b>HSA</b> Refer to GN-23 – available at <a href="http://www.hsa.gov.sg">www.hsa.gov.sg</a> for e-labeling requirements.</p>
5.05	ANVISA, EU, HC, HSA, TGA, USFDA	1 Healthcare Professional Labelling	Labelling directed at the healthcare professional other than the package insert, such as the surgical manual	<p><b>TGA</b> The requirements under Poison Standard for certain types of Class III implantable devices, refer to <a href="#">The poison standard and medical devices</a></p>
5.06	ANVISA, EU, HC, HSA, USFDA	1 Patient Labelling	Labelling directed at the patient other than the package insert, such as informational material written to be comprehended by the patient or lay caregiver	

Row ID	Regions & Level	Heading	Common Content	Regional Content
5.07	ANVISA, EU, HC, HSA, TGA, USFDA	1 Technical and/or Operator Manual	Labelling directed the technical users and operators of medical devices focusing on the proper use and maintenance of the device and surgical technique instructions	
5.08	ANVISA, EU, HC, TGA	1 Patient File Stickers/Cards and Implant Registration Cards		<p><b><u>ANVISA</u></b> Traceability labels for permanent implantable devices: Extra labels, according ANVISA's requirements, shall be included in the package, informing at the minimum: commercial trade name of the device, manufacturer and importer (if applicable) identification, catalog number of product, lot/serial number and the device authorization number issued by ANVISA.</p> <p><b><u>EU</u></b> If applicable, the implant card and other information per MDR Article 18 shall be included.</p> <p><b><u>HC</u></b> a) If applicable, stickers/cards intended to be place in the patient's chart identifying the implant (e.g. serial #, lot#, make, model) b) If applicable, implant registration cards</p> <p><b><u>TGA</u></b> For an implantable medical device or an active implantable medical device, a patient implant card and patient information leaflet must: a) meet the requirements of Essential Principle 13A b) be in English</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
5.09	EU, HC	1	Product Brochures		<p><b>EU</b></p> <ul style="list-style-type: none"> <li>Product brochures, catalogues containing devices (including claims) available for the user within the EU.</li> <li>The identification number of the NB shall also be indicated in any promotional material which mentions that a device fulfils the requirements for CE marking as per MDR Article 20.5.</li> </ul> <p><b>HC</b> Draft product brochures available at the time of application</p>
5.10	IMDRF	1	Other Labelling and Promotional Material	<p>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.</p> <p>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.</p>	<p><b>NMPA</b> Where applicable, other documents supplementing the product information shall be provided.</p> <p><b>TGA</b> Labelling elements or advertising and promotional materials must also comply with the requirements of the <a href="#">Therapeutic Goods Advertising Code</a>.</p>



## 6. Chapter 6 – Quality management system

Row ID	Regions & Level	Heading	Common Content	Regional Content
6.01	TGA, USFDA, NMPA	1 Cover Letter	A Cover Letter is only required under this chapter when the submission only includes quality system information.	<p><b><u>USFDA PMA</u></b> Any modular PMA submission of quality system information requires a cover letter containing the information describe in Chapter 1 under the Cover Letter heading.</p> <p><b><u>NMPA</u></b> The applicant shall undertake to have established a corresponding quality management system in accordance with the requirements of relevant laws and regulations and accept the inspection by the quality management system at any time.</p>
6.02	NMPA, USFDA	1 Chapter Table of Contents	<p>a) Includes all headings for the chapter.</p> <p>b) Specifies the page number for each item referred to in the table.</p>	
6.03	EU, NMPA, TGA, USFDA	1 Product Descriptive Information	<p>Abbreviated description of the device, operating principles and overall manufacturing methods. This section includes general information such as:</p> <ul style="list-style-type: none"> <li>• A description of the device, including pictures, and where possible, the proprietary name, common name, model number(s), product code, and intended use; and</li> <li>• A description of how the device works</li> </ul>	<p><b><u>USFDA</u></b> Any modular PMA submission of quality system information requires the contents of this subchapter.</p> <p><b><u>EU</u></b> MDR Article 53 (4) The notified body may require any information or data from the manufacturer, which is necessary in order to properly conduct the chosen conformity</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
			Product Descriptive Information is only provided under this chapter when the submission includes quality system information and Chapter 2.04 "Device Description" is not provided as part of the submission.	assessment procedure. However, such information (i.e., Risk Management, Clinical Evaluation related procedures, etc.) should be incorporated in the relevant chapters / subchapters.
6.04	ANVISA, EU, HSA, NMPA, USFDA, TGA	1 General Manufacturing Information	<p>a) Name, address, scope/role, and contact information for all sites where the device or its components are manufactured.</p> <p>b) Description of any relationship between the facilities to the applicant when there is more than one involved in the manufacturing process for the applicable device.</p> <p>c) Where applicable, addresses for all critical subcontractors, such as outsourced production, critical component, or raw material production (e.g. animal tissue, drugs), and sterilisation, will need to be provided.</p>	<p><b><u>EU</u></b> For specific MDR requirements see MDR Annex IX Section 2.1 and Annex II Section 3 (c). See also MDR Annex IX Section 2.1 for additional requirements related to the legal manufacturer, additional manufacturing sites and authorised representative.</p> <p><b><u>USFDA PMA</u></b> Any modular PMA submission of quality system information requires the contents of this subchapter. Please consult the guidance document <b><i>Quality System Information for Certain Premarket Application Reviews, Guidance for Industry and FDA Staff</i></b>. In this QS PMA guidance, please refer to section A.2 (Cover Letter) and provide the following information:</p> <ul style="list-style-type: none"> <li>• Full name and street address (no P.O. Box number),</li> <li>• Telephone number (with area code),</li> <li>• FDA Facility Establishment Identifier (FEI) or registration number,</li> <li>• Relationship of (each) manufacturing facility to applicant.</li> </ul>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				<ul style="list-style-type: none"> <li>• Contact person (and alternates) and their telephone number(s).</li> <li>• The date the facility site(s) will be ready for inspection.</li> </ul> <p><b><u>NMPA</u></b> For change registration, if manufacturing site of the Imported Medical Device applicant changes, provide Comparative table and description.</p> <p><b><u>TGA</u></b></p> <ul style="list-style-type: none"> <li>• For the manufacturer (as specified on device labelling), specify manufacturer name or trading name (if applicable), Australian Business number (ABN) / Australian Company number (ACN) (if applicable), TGA Client ID, manufacturer's physical address, manufacturer's postal address, scope of manufacturing facility (design, key production steps, labelling, final release, warehousing and dispatch).</li> <li>• For each manufacturing facility, specify facility name, physical address, scope of facility (design, key production steps (specify), labelling, final release, warehousing and dispatch)</li> <li>• For all manufacturing facilities include contact information (including full name of contact person, position of contact person, telephone number and email address)</li> </ul>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				<ul style="list-style-type: none"> <li>Where applicable, for each critical supplier such as outsourced production, critical component, or raw material production (e.g. animal tissue/recombinant origin material, medicinal substance) and sterilisation, specify supplier's name, physical address, scope (for each relevant device, manufacturing stages performed at this site or services provided)</li> </ul>
6.05	USFDA	1	Required Forms	<p>Any regional specific forms to be completed associated with Quality management Systems in the premarket review process</p> <p><b>USFDA</b> Any forms needed related to Quality Management.</p>
6.06	NMPA, TGA, USFDA	1	Quality Management System	<p>High level quality management system documents, including procedures for establishing and maintaining the quality management system such as the quality manual, quality policy, quality objectives, and control of documents and records, as well as records providing evidence of conformance to requirements, and of the effective operation of the quality management system (when applicable).</p> <ul style="list-style-type: none"> <li>ISO 13485 Elements– SOPs and device specific documentation to satisfy clause 4</li> </ul> <p><b>USFDA PMA</b> Please provide documentation according to QS PMA Guidance, Section II. Manufacturing Information, Item (1) Quality System Procedures 820.20(e)</p> <p><b>NMPA</b> According to the above procedures of the quality management system, applicants shall form documents and records related to the quality management system. The following materials shall be submitted for inspection during the inspection on the quality management system.</p> <ol style="list-style-type: none"> <li>Basic information form of applicant.</li> <li>Organizational chart of the applicant.</li> <li>General layout of the enterprise and the distribution map of production areas.</li> </ol>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				<p>4. Where there are requirements for purification in the production process, a copy of the environmental testing report (with the layout plan attached) issued by a qualified testing institution shall be provided.</p> <p>5. The flow chart of the product production process, which shall indicate the main control points and items, main raw materials and sources of purchased parts and the quality control methods.</p> <p>6. Catalogue of main production equipment and inspection equipment (including the equipment required for incoming inspection, process inspection and final factory inspection; environmental monitoring equipment shall also be provided for the production conducted under the purification conditions).</p> <p>7. Self-inspection report of the quality management system.</p> <p>8. Where applicable, the explanation on the comparison of the product to be inspected and products previously passing the inspection in terms of production conditions and production process shall be provided.</p> <p><b><u>TGA</u></b>  <b>New certificate application (initial)</b></p> <ul style="list-style-type: none"> <li>• Overview of manufacturing stages for each device Details of the manufacturing steps, or services provided by the responsible party</li> </ul>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				<ul style="list-style-type: none"> <li>• Latest version of the Quality Manual This must at a minimum include a reference to documented procedures.</li> <li>• List of validated processes. For each process validation considered critical to the safety and performance of the device, e.g. drug coating process, sterilisation. Protocols/procedures for the validated process. Process validation report. The procedures for monitoring and controlling the process parameters of a validated process should be fully described. The frequency of re-validation</li> </ul> <p><b>Substantial change application</b></p> <ul style="list-style-type: none"> <li>• Details of the changes relating to the scope of a Schedule 3, Part 1, 4 or 5 TGA conformity assessment certificate. e.g. If the change relates to the device category, critical suppliers or manufacturer facilities listed on the certificate.</li> <li>• Details of changes to Quality Manual. Note: At minimum, this must include a reference to documented procedures.</li> <li>• Details of changes to manufacturing process. This must include details of the changed manufacturing process, or services provided and the party responsible.</li> <li>• Details of changes to protocols and reports for the validated processes.</li> </ul>

Row ID	Regions & Level	Heading	Common Content	Regional Content
6.07	NMPA, TGA, USFDA	1 Management Responsibilities	<p>Documents, including procedures that provide evidence of the management commitment to the establishment and maintenance of the QMS by addressing quality policy, planning, responsibilities/authority/communication and management review, as well as records providing evidence of conformance to requirements, and of the effective operation of the quality management system (when applicable).</p> <ul style="list-style-type: none"> <li>• ISO 13485 Elements – SOPs and device specific documentation to satisfy clause 5</li> </ul>	<p><b><u>USFDA PMA</u></b> Please provide documentation according to QS PMA Guidance, Section II. Manufacturing Information, Item (1):</p> <ul style="list-style-type: none"> <li>• Management review SOPs</li> </ul> <p><b><u>TGA</u></b></p> <ul style="list-style-type: none"> <li>• An undertaking (in writing) by the manufacturer to continue to comply with the requirements of the quality management system after assessment.</li> <li>• An undertaking (in writing) by the manufacturer to ensure that the quality management system is at all times is adequate and efficacious.</li> <li>• An undertaking (in writing) by the manufacturer to notify the TGA, or the Australian sponsor, of any information of the kind mentioned in subparagraphs 1.4(3)(c), 4.4(3)(c), or 5.4(3)(c) (for Parts 1, 4 or 5 CA procedures respectively), that the manufacturer becomes aware of in relation to the kind of medical device.</li> </ul>
6.08	NMPA, USFDA	1 Resource Management	<p>Documents, including procedures that provide evidence of the adequate provision of resources to implement and maintain the QMS , as referenced in regulator’s guidance or regulation, including human resources, infrastructure, and work environment, as well as records providing evidence of</p>	<p><b><u>USFDA PMA</u></b> Please provide documentation according to QS PMA Guidance, Section II. Manufacturing Information, Item:</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p>conformance to requirements, and of the effective operation of the quality management system (when applicable).</p> <ul style="list-style-type: none"> <li>• ISO 13485 Elements – SOPs and device specific documentation to satisfy clause 6</li> </ul>	<ul style="list-style-type: none"> <li>• (5) Production and Process Controls, 820.70 – SOPs for environmental and contamination controls</li> </ul>
6.09	EU, NMPA, TGA	1 Planning of Product Realization and Customer Related Processes	<p>High level product realization documents, including procedures such as those addressing planning and customer related processes, as well as records providing evidence of conformance to requirements, and of the effective operation of the quality management system (when applicable).</p> <p>Records demonstrating conformance to requirements are only provided under this chapter when the submission includes quality system information, and these records were not provided within the submission as part of a previous subchapter (e.g. as part of “Biocompatibility and Toxicology Evaluation” Chapter 3.05.06).</p> <ul style="list-style-type: none"> <li>• ISO 13485 Elements – SOPs and device specific documentation implementing sub clause 7.1 and 7.2</li> </ul>	<p><b>EU</b> Annex II 3. DESIGN AND MANUFACTURING INFORMATION (b) complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. Data shall be fully included in the technical documentation</p> <p><b>Note:</b> Information provided in this subchapter should be concerning the relevant ISO 13485 clauses in the left column and should not cover manufacturing processes.</p> <ul style="list-style-type: none"> <li>• Design and Development information should be provided as per information in 6.10.</li> <li>• Manufacturing process related information should be provided as per information in 6.12.</li> </ul> <p>Annex III Technical Documentation on Post-Market Surveillance Please provide relevant Procedures describing the preparation and implementation of Post Market Activities</p>



Row ID	Regions & Level		Heading	Common Content	Regional Content
					<p>and how these activities are linked to other activities such as Risk Management, Clinical Evaluation, Periodic Safety Update Report, Summary on Safety and Clinical Performance.</p> <p>Do not provide the records or outputs of the processes here.</p>
6.10	EU, NMPA, TGA, USFDA	1	Design and Development	<p>Documents, including procedures that provide evidence of the systematic and controlled development of the device design from initiation of the project to transfer to production, as well as records providing evidence of conformance to requirements, and of the effective operation of the quality management system (when applicable).</p> <p>Records demonstrating conformance to requirements are only provided under this chapter when the submission includes quality system information, and these records were not provided within the submission as part of a previous subchapter (e.g. as part of “Biocompatibility and Toxicology Evaluation” Chapter 3.05.06).</p> <ul style="list-style-type: none"> <li>• ISO 13485 Elements – SOPs and device specific documentation implementing sub clause 7.3</li> </ul>	<p><b><u>EU</u></b> For specific MDR requirements see MDR Annex II Section 3 (a). See also MDR Annex IX Section 2.2 (c) for additional requirements related to design and development procedures.</p> <p><b><u>USFDA PMA</u></b> Any modular PMA submission of quality system information requires records providing evidence of conformance to requirements with respect to this subchapter. Please provide documentation according to the QS PMA Guidance, Section I. Design Control Information, Items:</p> <p>(1) Design Controls, General, 820.30(a) – Explanation of where in your design and development process the device became subject to your design control program.  (2) Design and Development Planning, 820.30(b) SOPs  (3) Design Input, 820.30(c) SOPs  (4) Design Output, 820.30(d) SOPs</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
					<p>(5) Design Review, 820.30(e) SOPs  (6) Design Verification, 820.30(f) SOPs  (7) Design Validation, 820.30(g) SOPs  (8) Design Transfer, 820.30(h) SOPs  (9) Design Changes, 820.30(i) SOPs  (10) Design History File, 820.30(j) SOPs</p> <p>Please also include:  (2) Design and Development Planning, 820.30(b) – Provide the design development plan for the subject device  – Risk Analysis Procedure(s)  (4) Design Output, 820.30(d) – Provide a list of the design outputs you consider essential for the proper functioning of the device for the device under review.  (7) Design Validation, 820.30(g) – Summarize the scientific method or process used to prove the equivalence of the units used in validation testing to production units.  – Summarize how the clinical evaluations of the device ensure the device meets user needs and the intended uses.  – Explain how you have (or will) complete your software validation, and include any system integration testing</p>
6.11	EU, NMPA, TGA, USFDA	1	Purchasing	Documents, including procedures that provide evidence that purchased products/services conform to established relevant quality and/or product specifications, as well as records providing evidence of conformance to requirements, and of the	<p><b>USFDA PMA</b>  Please provide documentation according to QS PMA Guidance, Section II. Manufacturing Information, Items:  (4) Purchasing Controls, 820.50 – SOPs</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
			<p>effective operation of the quality management system (when applicable).</p> <ul style="list-style-type: none"> <li>• ISO 13485 Elements – SOPs and device specific documentation implementing sub clause 7.4</li> </ul>	<p>– List of suppliers and controls for suppliers of outsourced design and manufacturing function  (9) Receiving Acceptance Activities, 820.80(b) – SOPs  – Discussion of how Receiving Acceptance is balanced with Purchasing Control activities</p> <p><b><u>EU</u></b>  Detailed information on elements of Annex II 3. DESIGN AND MANUFACTURING INFORMATION  (b) complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. Data shall be fully included in the technical documentation  (c) identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed.</p> <p>Please provide here only information on components and products provided by suppliers &amp; subcontractors focusing on controls relevant for those components and products (Purchasing, Incoming Inspection, Final Product Testing)</p> <p><b><u>TGA</u></b>  A description of how purchasing requirements are fulfilled for the suppliers</p>

Row ID	Regions & Level		Heading	Common Content	Regional Content
					<p>identified. This must include the supporting procedures and records of supplier evaluations by the manufacturer or suitable third party; and any agreement between the manufacturer and supplier defining responsibilities and authorities.</p>
6.12	ANVISA, EU, HC, HSA, NMPA, TGA, USFDA	1	Production and Service Controls	<ul style="list-style-type: none"> <li>• ISO 13485 Elements – SOPs and device specific documentation implementing sub clause 7.5</li> </ul>	<p><b><u>USFDA PMA</u></b> Please submit documentation according to QS PMA Guidance II. Manufacturing Information, Items:</p> <p>(2) Production Flow and summary of in-process acceptance activities  (3) Use of Standards  (7) Process Validation 820.75 (Master Plan), and list of process that will not be validated but verified by inspection and test instead,  (8) Process Validation 820.75(a) – process validation protocols and validation reports  (10) Final Acceptance Activities, 820.80(d) SOPs  (14) Servicing, 820.200 SOPs</p> <p><b><u>HC</u></b></p> <ul style="list-style-type: none"> <li>a) Detailed Manufacturing Flow Diagram</li> <li>b) Summary of in-process acceptance activities for subject device</li> <li>c) Process Validation Master Plan</li> <li>d) List of processes that have not been validated</li> </ul>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				<p>e) For each process validation considered critical to the safety and effectiveness of the device:</p> <ul style="list-style-type: none"> <li>i. Protocols/Procedures for the validated process</li> <li>ii. Process validation report</li> <li>iii. The procedures for monitoring and controlling the process parameters of a validated process should be fully described.</li> <li>iv. State the frequency of re-validation</li> </ul> <p><b>HC Note:</b></p> <p>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.</p> <p>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.</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				<p><b>EU</b>  Detailed information on elements of Annex II 3. DESIGN AND MANUFACTURING INFORMATION  (b) complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous monitoring and the final product testing. Data shall be fully included in the technical documentation.</p> <p>Note: Please provide only information on processes and their validation that are not covered in other chapters and subchapters. Information about the following topics should be provided in the relevant subchapters of Chapter 3:</p> <ul style="list-style-type: none"> <li>- Software/Firmware</li> <li>- Biocompatibility and Toxicology Evaluation</li> <li>- Non-Material-Mediated Pyrogenicity</li> <li>- Safety of Materials of Biological Origin (human/animal)</li> <li>- Sterilization Validation</li> <li>- Animal Testing</li> <li>- Usability/Human Factors</li> <li>- Expiration Period and Package Validation</li> </ul> <p>(c) Identification of all sites where design and manufacturing activities are performed.</p> <p>Note: Information on suppliers and subcontractors see 6.11</p>

Row ID	Regions & Level	Heading	Common Content	Regional Content
				<p><b><u>HSA and ANVISA</u></b></p> <p>Manufacturing process for the medical device should be provided in the form of a list of resources and activities that transform inputs to the desired output.</p> <ul style="list-style-type: none"> <li>- Information should include the appropriate manufacturing methods and procedures, manufacturing environment or condition, and the facilities and controls used for the manufacturing, processing, packaging, labeling, and storage.</li> <li>- Information on the manufacturing process should be provided in sufficient detail to allow a general understanding of the manufacturing processes and enable judgement of the appropriateness of the controls in place. Detailed proprietary information on the manufacturing process is not required. The information may be presented in the form of a process flow chart showing an overview of production, controls, assembly, final product testing and packaging of the finished medical device.</li> <li>- If multiple facilities are involved in the manufacture of medical device, <ul style="list-style-type: none"> <li>o Applicable information for each facility must be submitted</li> <li>o Manufacturing activities carried out at each site should be clearly identified</li> </ul> </li> </ul>

Row ID	Regions & Level	Heading	Common Content	Regional Content
6.13	NMPA, TGA, USFDA	1 Control of Monitoring and Measuring Equipment	Documents, including procedures that provide evidence of monitoring and measuring equipment used in the QMS is controlled and continuously performing per the established requirements, as well as records providing evidence of conformance to requirements, and of the effective operation of the quality management system (when applicable).  • ISO 13485 Element- SOPs and device specific documentation for implementing sub clause 7.6	<b>USFDA PMA</b> Please submit documentation according to QS PMA Guidance II. Manufacturing Information, Item:  (6) Inspection, Measuring, and Test Equipment, 820.72
6.14	NMPA, TGA, USFDA	1 QMS Measurement, Analysis and Improvement	Documents, including procedures that provide evidence of how monitoring, measurement, analysis and improvement to ensure the conformity of the product and QMS, and to maintain the effectiveness of the QMS, as well as records providing evidence of conformance to requirements, and of the effective operation of the quality management system (when applicable).  • ISO 13485 Element – SOPs and device specific documentation for implementing clause 8	<b>USFDA PMA</b> Please submit the following documentation according to QS PMA Guidance II. Manufacturing Information, Items: (1) Quality System SOPs – Quality audit (820.22) or internal audit procedure(s) (11) Nonconforming Products, 820.90 (12) Corrective and Preventive Action (CAPA), 820.100 (13) Complaint Files, 820.198  Please also explain: – How complaint handling ties to Adverse Event Report procedures – How risk management is tied to the CAPA activities
6.15	HC	1 Device Specific Quality Plan		The review requirement for a quality plan is not met by the ISO 13485 certificate alone, instead refer to ISO 10005. A quality plan



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					<p>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 may, 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.</p>
6.16	NMPA	1	Quality management system verification document		<p>According to the above procedures of the quality management system, applicants shall form documents and records related to the quality management system. The following materials shall be submitted for inspection during the inspection on the quality management system.</p> <ol style="list-style-type: none"> <li>1. Basic information form of applicant.</li> <li>2. Organizational chart of the applicant.</li> <li>3. General layout of the enterprise and the distribution map of production areas.</li> <li>4. Where there are requirements for purification in the production process, a copy of the environmental testing report (with the layout plan attached) issued by a qualified testing institution shall be provided.</li> <li>5. The flow chart of the product production process, which shall indicate the main control points and items, main raw</li> </ol>

Row ID	Regions & Level		Heading	Common Content	Regional Content
					<p>materials and sources of purchased parts and the quality control methods.</p> <p>6. Catalogue of main production equipment and inspection equipment (including the equipment required for incoming inspection, process inspection and final factory inspection; environmental monitoring equipment shall also be provided for the production conducted under the purification conditions).</p> <p>7. Self-inspection report of the quality management system.</p> <p>8. Where applicable, the explanation on the comparison of the product to be inspected and products previously passing the inspection in terms of production conditions and production process shall be provided.</p>
6.17	ANVISA, HC, NMPA, USFDA	1	Other Quality System Information	Heading for other information that may be important to the submission but that does not fit in any of the other headings.	

# Document revision history

Version	Description of Changes	Author	Date
PD1	Version for Public Consultation	B. Dowling & IMDRF's RPS ToC WG Members	22 February 2013
R1	Final Version following public consultation and piloting	B. Dowling & IMDRF's RPS ToC WG Members	27 May 2014
R2	Revisions for NMPA requirements, addition of "Cybersecurity" and "Interoperability" headings to software section, other minor revisions based on review and experience	B. Dowling & IMDRF's RPS ToC WG Members	27 March 2018
R3	Addition of Singapore (HSA) requirements, revised summary definition, other minor editorial changes.	B. Dowling & IMDRF's RPS ToC WG Members	21 March 2019
R4	Significant revisions based on policy changes in regions since last update	P. Axtell, D. Yoon, & IMDRF's RPS ToC WG Members	25 June 2024



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