IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

International Medical Device Regulators Forum

Title: Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC)

Authoring Group: Regulated Product Submissions Table of Contents Working Group

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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 is 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 premarket medical device submissions.

This document provides an internationally harmonized, modular, format for use when filing medical device submissions to regulatory authorities for market authorization. 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.

This ToC document has been developed with consideration of public comments and experience gained from the pilot testing of the draft ToC version.

The ToC documents are intended to work together with a separate document created for each participating jurisdiction – a classification matrix. The classification matrix defines whether for the given submissions type a heading is required, not required, optional, conditionally required, etc. The classification matrices are the published under the authority of participating authorities and are not products of IMDRF, please consult regional regulator websites for further information.

The release of the first version of the final ToC document makes available harmonized formats for use in filing nIVD medical device submissions for market authorization.

IMDRF will monitor the use of these structures and work to continually improve the documents at appropriate intervals based on sufficient use and experience. Comments or questions associated with these documents will be accepted in the prescribed format (Feedback form – excel spreadsheet) and can be submitted to imdrf.toc@gmail.com with the following subject line: IMDRF nIVD ToC MA Feedback.

SCOPE

This document was developed for non-In-vitro diagnostics device (nIVD) market authorization submissions. Market authorization submissions for combination products are out of scope; 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 can be used as a harmonized international electronic submission format while minimizing regional divergences and indicating where regional variation exists. This document is intended to provide guidance regarding the location of submission elements. This document is intended to work together with a separate document created for each participating jurisdiction – a classification matrix.

This document is not intended to introduce any new regulatory requirements; however, by virtue of being more transparent, it may appear to be introducing new requirements.

CLASSIFICATION MATRICES

As this document is comprehensive in nature, not all headings are required for all submission types and/or jurisdictions. This document is intended to work together with a separate document created for each participating jurisdiction – a classification matrix. The classification matrix defines whether for the given submissions type a heading is required, not required, optional, conditionally required, etc. The classification matrices are to be made available on regional regulators websites.

DEFINITIONS

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.

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 ± SD, confidence intervals, etc.).
The summary should specifically address:

1. Why the characteristic being evaluated is of interest;

2. 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;
3. How the stated acceptance and sample size are scientifically supported;
4. What device was tested and how it relates to the devices that will be marketed;
5. Why the tested components are representative of the range of devices that will be marketed;
6. 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
7. 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)

HEADING CLASS - Headings are classified as either **IMDRF; IMDRF, RF; or Regional**.

Heading classification is provided in this document to provide an indication of the relevance of any given heading to a particular jurisdiction. The classification matrices provide further requirement classification by jurisdiction and submission type and should be used as the final reference for information of this type.

IMDRF headings are used by most regulators and are therefore considered an IMDRF heading. Content of IMDRF heading contain common elements and may contain regional elements in addition to the common elements.

- **Regional Focus (IMDRF, RF)** – content needs to be considered with the specific region in mind and will likely need to be adapted for that region (e.g. regional approval numbers or regulatory history, regional variation in approved or requested intended use/indications for use)

- In cases where not all regulators use the heading, the applicable jurisdictions are listed following the heading classification **(e.g. IMDRF (USFDA, HC, JP)).**

Regional headings are those that contain no common elements. In this case the heading name is consistent amongst IMDRF members, but the content will be specific and different for each region. Headings are also classified as Regional if they are required by only one jurisdiction.

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.

NUMBERING OF HEADINGS

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.

QUALITY MANAGEMENT SYSTEM CHAPTERS (6A & 6B)

Chapter 6A & B of the ToC is written in terms of the quality management system language employed in ISO 13485. **Chapter 6A** is where the company places the standard operating procedures (SOPs) the company utilizes to implement its overall high level quality management system. **Chapter 6B** is where the company places the documents and records the company utilizes to implement the quality management system SOPs described in Chapter 6A.

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 include 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 MDUFA IV 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:

1. Refuse to Accept Policy for 510(k)s: Guidance for Industry and Food and Drug Administration Staff
2. Acceptance and Filing Reviews for Premarket Approval Applications (PMAs): Guidance for Industry and Food and Drug Administration Staff
3. eCopy Program for Medical Device Submissions: Guidance for Industry and Food and Drug Administration Staff

For the EU, the latest EN ISO version and related Annex Z should be taken as reference to verify the correct presumption of conformity with the essential requirement of medical Devices Directives.

ACRONYMS

ANVISA	National Health Surveillance Agency – Brazil
CAPA	Corrective Action and Preventive Action
EU	European Union
GMDN	Global Medical Device Nomenclature
HC	Health Canada
HSA	Health Sciences Authority – Singapore
IMDRF	International Medical Device Regulators Forum
JP	Japan
MDUFA	Medical Device User Fee Amendments
NB	Notified Body
NMPA	National Medical Products Administration – China
PMDA	Pharmaceuticals and Medical Devices Agency – Japan
RCT	Randomized Controlled Trial
RF	Regional Focus
SUD	Single Use Device
TGA	Therapeutic Goods Administration – Australia
ToC	Table of Contents
USFDA	United States Food and Drug Administration

HIERARCHY PRESENTATION

The following is a hierarchical presentation of the submission structure. More detailed guidance regarding where elements belong is provided following this table.

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3.07.02.01	[Study description, study identifier, date of initiation]
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6B.08	Purchasing information
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6B.10	Control of monitoring and measuring devices information
6B.11	QMS measurement, analysis and improvement information
6B.12	Other Device Specific Quality Management System Information

CHAPTER 1 – REGIONAL ADMINISTRATIVE

Row ID	Heading Class & Level	Heading	Common Content	Regional Content
1.01	IMDRF, RF 1	Cover Letter	a) The cover letter should state applicant or sponsor name and/or their authorized representative, the type of submission, the common name of the device (if applicable), device trade name or proprietary name (both of the base device and a new name if one is given to the new version/model of the device) and include the purpose of the application, including any changes being made to existing approvals. b) If applicable and accepted by the regulator, it should include information pertaining to any Master Files referenced by the submission. c) If applicable, acknowledgement that a device sample has been submitted or offered alternatives to allow the regulator to view or access the device (when the regulator requests a sample). d) If the submission is requesting approval of a change that is the result of CAPA due to a recall, this should be stated. e) If the submission is in response to a request for information from the regulator this should be stated and the date of that letter should be included as well as any reference number(s). f) If the submission is unsolicited information (where accepted), this should be stated and any related reference number(s) provided. **NOTE:** The cover letter should not contain any detailed scientific information.	**NMPA** Attached documents should be signed or sealed by applicants and/or authorized representatives. **USFDA PMA and 510(k)** a) mailing address, b) official correspondent(s), c) phone/fax number(s), d) email address(s 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) **(PMA Only)** f) Device class and panel or classification regulation or statement that the device has not been classified with rationale for that conclusion **(510(k) only)** **TGA** The covering letter of application needs to be prepared on company letterhead and to also include; a) Submission ID that is generated electronically when completing the application form in eBusiness b) Contact details of the person authorised to liaise with TGA during the evaluation process c) Signed by the authorised person for the company
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. **NOTE:** 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	Regional (ANVISA, NMPA, EU, HC, JP, TGA, USFDA) 1	Application Form/Administrative Information		**ANVISA** ANVISA´s "Manufacturer or Importer Form" (form available at www.anvisa.gov.br), containing general information related to the application. **NMPA** Application form shall be filled out and submitted on line (http://125.35.24.156/) **EU** Notified Bodies (NBs) will each have their own application form and company information form, including details on the submission type (new, renew, changes), administrative data of the manufacturer, overview of subcontractors and their QMS certification documentation, underlying CE certificates in case of Own Brand labelling, general information of the product, including sterilisation method where applicable, nature of selected starting materials (e.g. drugs, animal tissue), applicable directive and classification. Consult relevant NB. N.B. Under EU legislation, the Own Brand Labeller is to be considered as the legal manufacturer and bears the regulatory responsibility of a manufacturer including the need to dispose of the entire

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
					technical documentation (see the EU Guideline on OBL: http://ec.europa.eu/health/medical-devices/files/guide-stds-directives/interpretative_fiche_obl_en.pdf) **HC** Health Canada application forms should be included here. **JP** PMDA's "Application form" – from http://www.pmda.go.jp/ **TGA** Application forms to include administrative data of the applicant, application scope (including applicable conformity assessment procedure and type of application (new, change or recertification)), current certification details, manufacturer details, critical supplier details and device details including classification. Refer to www.tga.gov.au for the most up to date information. **USFDA PMA and 510(k)** CDRH Coversheet Form 3514
1.05	IMDRF, RF (ANVISA, NMPA, EU, HC, HSA, TGA, USFDA)	I	Listing of Device(s)	A table listing each variant/model/configuration/component/accessory that is the subject of the submission and the following information for each variant/model: a) the identifier (e.g. bar code, catalogue, model or part number, UDI) b) a statement of its name/description that provides (e.g. Trade name, size, material) **NOTE:** i. A model/variant/configuration/component/accessory of a device has common specifications, performance and composition, within limits set by the applicant. ii. Typically each item listed should be available for sale. For example, if everything is sold as part of a kit, then this list would only include the kit. You do not need to list all components that may be sold within a kit/set, unless the component is available for sale independently of the kit. iii. This is classified as RF in recognition that identification numbers may vary from jurisdiction to jurisdiction.	**ANVISA** The grouping (family, set and systems) of medical devices shall be in compliance with ANVISA´s requirements which specify the conditions to establish grouping of medical devices. **EU** The listing should include the relevant Global Medical Device Nomenclature (GMDN) Code and Term **HSA** 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 www.hsa.gov.sg **Russia NOTE:** 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. **TGA** For all classes of devices the applicant needs to include: a) The Global Medical Device Nomenclature (GMDN) Code and Term b) The classification and the applicable classification rule For class III and AIMDs this table should also identify the following: c) Unique Product Identifiers (see the Therapeutic Goods (Medical Devices) Regulations 2002) d) Variants (as defined in the Therapeutic Goods (Medical Devices) Regulations 2002)
1.06	Regional (ANVISA, NMPA, EU, HC,	I	Quality Management System, Full Quality System or		**ANVISA** Good Manufacturing Practice Certificate (GMPC) issued by ANVISA, covering the scope of products. NOTES:

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
	HSA, TGA)		Other Regulatory Certificates		a) Device registration or amendment request to change/include manufacturer of Class III or IV devices requires a valid GMP Certificate issued by ANVISA. However, submission review may be initiated prior to GMP certification. In these cases, the document proving that the application for the GMP Certification has been submitted to ANVISA should be presented, identifying the manufacturer name, the address of the site to be certified and the identification number of the GMP Cert application to ANVISA. The registration or amendment will only be approved after the GMP certificate has been issued. b) Device registration renewal submissions of Class III or IV devices, also requires a valid GMP Certificate issued by ANVISA. The document proving that the GMP Certification was requested from ANVISA will be accepted if the GMP Certificate has not yet been issued. However, if the final result of the GMP certification process leads to a refusal, the device registration will be canceled. **NMPA** a) Domestic applicant shall provide: i. Copies of business license and organization code certificate. ii. When applying for registration of domestic medical devices according to Special Procedure of Approval and Evaluation for Innovative Medical Devices, applicant shall provide a notice of application for reviewing "Special procedure of approval and evaluation for innovative medical devices", and if the sample products are produced by entrusted manufacturers, manufacturing license of the entrusted manufacturer and consignment agreement shall be provided. The scope of manufacturing license shall cover the category of the submitted products. **EU** EN ISO 13485 certificate in case it is issued by another Notified Body or registrar. CE full quality system certificates (QMS and annex II.3 MDD) covering the scope of products when issued by another Notified Body. **HC** This subsection includes a copy of the quality management system certificate certifying that the quality management system under which the device is designed and manufactured satisfies CAN/CSA ISO 13485, Medical devices - Quality management systems - Requirements for regulatory purposes. Health Canada will only accept quality system certificates that have been issued by special third party auditing organizations recognized by the Minister in accordance with Section 32.1 of the *Medical Devices Regulations*. **TGA** Copies of any current TGA or other regulatory authority certification referenced within the submission or required for the submission type. The reference certificates requirements will vary based on the submission type, refer to TGA guidance for these requirements. **HSA** ISO 13485 certificates are to be provided for manufacturing and sterilisation sites of finished 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	Regional (ANVISA,	1	Free Sale Certificate/ Certificate of		**ANVISA** Document/certificate issued by the Regulatory Authority where the medical device is marketable, attesting that the device is marketable, without any restriction at their jurisdiction.

Row ID	Heading Class & Level	Heading	Common Content	Regional Content
	NMPA, HSA)	Marketing authorization		**NMPA** a) Imported Medical Device applicant shall provide: i. Supporting documents of marketing authorization or certificate of the product issued by authority of the country (or region) where the applicant's headquarter or manufacturing site is located, and the authorization/qualification documents of the enterprise ii. If the product is not managed as a medical device by authority of the country (or region) where the Imported medical device applicant is located, applicant shall provide relevant supporting documents, quantification certificate of manufacturer issued by authority of the country (or region) where the registration office or manufacturing site is located(for registration). b) Applications for extension renewal and change registration shall include: i. Copies of the original registration certificate of medical device and its appendices, and copies of all documents on the change of registration of medical device in China (for). ii. For Imported Medical Device, the relevant documents if the new market clearance issued by the medical device authority of the country (or region) where the overseas applicant's registration office or manufacturing site is located is required for change items; or description if the change items need not to be approved by the medical device authority of the country (or region) where the overseas applicant's registration office or manufacturing site is located. **HSA** 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.
1.08	Regional (HSA)	Expedited Review Documentation		**HSA** For applications with approvals from HSA's reference regulatory agencies and applying for faster evaluation routes, following information is required: a) Declaration of no safety issues globally (refer to GN-15 for the template) 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) Refer to GN-15 available at www.hsa.gov.sg for more information
1.09	Regional (ANVISA, EU, HC, USFDA)	User Fees		**ANVISA** a) Receipt of the User Fee payment. Information about User Fee available at: http://portal.anvisa.gov.br/taxas1 **EU** Signed quote and agreement for dossier review/audits **HC** Health Canada user fee forms should be included here. **USFDA PMA and 510(k)** FDA User Fee Form
1.10	IMDRF, RF	Pre-Submission Correspondence and Previous	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	**NMPA NOTE:** For example, innovative medical device communication record. **EU**

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
			Regulator Interactions	addressed in other areas of the submission. If applicable, the following elements should be provided: i. List prior submission or pre-submissions where regulator feedback was provided ii. Prior submissions should include identification of submission # iii. For any pre-submission activities that have not previously been assigned any tracking/reference number, include the information package that is submitted prior to pre-submission meetings, the meeting agenda, any presentation slides, final meeting minutes, responses to any action items arising from the meetings, and any email correspondence related to specific aspects of the application. iv. Issues identified by the regulator in prior submissions (i.e., clinical study applications, withdrawn/deleted/denied marketing submission) for the subject device v. Issues identified and advice provided by the regulator in pre-submission interactions between the regulator and the applicant/sponsor. vi. Explain how and where the prior advice was addressed within the submission **OR** b) Affirmatively state there has been no prior submissions and/or pre-submission interactions for the specific device that is the subject of the current submission. **NOTE** The scope of this section is limited to the particular regulator to which the submission is being submitted (i.e. Health Canada does not need pre-submission information relating to interactions with ANVISA).	a) A statement is required that the product to be reviewed is not under application with another Notified Body, and has not previously been refused or cancelled by another notified body. b) For "borderline products", where applicable, any rationale, supportive documentation and key documentation on communication with an EU Competent Authority and/or COM services, relating to the qualification/classification decision on such product. c) In case of transfer from another Notified Body, that status, including any open Non-conformity, and the associated dossier review reports, the latest audit report and for QMS transfer all audit reports from the existing certification cycle, will need to be submitted along with a letter of access from the new notified body to contact the old notified body to confirm any open issue. This will allow a specific date of transfer of application and CE marking.
1.11	Regional (TGA, USFDA)	1	Acceptance for Review Checklist		**USFDA PMA** 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 ***Acceptance and Filing Reviews for Premarket Approval Applications (PMAs): Guidance for Industry and Food and Drug Administration Staff Guidance*** **USFDA 510(k)** Optionally, you may complete the checklist by answering the preliminary questions and providing the pages numbers indicating the locations of each item on the check is addressed in the submission See the Acceptance Checklist for Traditional 510(k)s in ***Refuse to Accept Policy for 510(k)s : Guidance for Industry and Food and Drug Administration Staff*** **TGA** Includes the Supporting data checklists
1.12	Regional (ANVISA, EU, HC, HSA, TGA, USFDA)	1	Statements/Certifications/Declarations of Conformity	NO CONTENT AT THIS LEVEL	NO CONTENT AT THIS LEVEL
1.12.01	Regional (USFDA)	2	Performance and Voluntary Standard		**USFDA** **Note to RPS Team:** USFDA wants this information displayed here in the admin section but will request it in Chapter 3 where standards information other IMDRF members request (List of Standards)
1.12.02	Regional (USFDA)	2	Environmental Assessment		**USFDA PMA** a) If claiming categorical exclusion, information to justify the exclusion

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
					OR b) Provide the environmental assessment (only required for devices that present new environmental concerns
1.12.03	Regional (USFDA)	2	Clinical Trial Certifications		**USFDA PMA and 510(k)** 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)
1.12.04	Regional (USFDA)	2	Indications for Use Statement with Rx and/or OTC designation Enclosure		**USFDA 510(k)** Use Form FDA 3881
1.12.05	Regional (ANVISA, NMPA, HC, TGA, USFDA)	2	Truthful and Accurate Statement		**ANVISA** a) A declaration (per text below), dated and signed by the legal representative and technical manager of the company: "We declare that the information provided at this submission are truthful and accurate, and can be proven by documental evidence and that no material fact has been omitted. We also declare that: i. The device will be marketed observing all requirements established by the Brazilian Legislation; ii. The labelling (e.g. labels, instructions of use, promotional material) of the device complies with the Brazilian regulatory requirements, and will be maintained up to date during all the period that it will be available on the Brazilian market; iii. The device and accessories that accompany the device were designed and are manufactured attending the Essential Requirements of Safety and Efficacy and the Good Manufacturing Practices established by ANVISA; iv. All the reasonably foreseeable risks were identified and mitigated. The residual risk is acceptable in relation to the benefits obtained by the use of the devices; v. The devices delivered to the market will be continuously monitored in order to identify new risks that have not been already addressed, according to the Risk Management Plan established by the manufacturer. The company is aware that if the Brazilian regulatory requirements were not fulfilled, administrative sanctions established on federal law (Lei nº 6437/1977) shall be applied. The legal representative and technical manager of the company are aware that they are answerable to the court by any infraction indicated on art. 273 – Decreto Lei nº 2848/1940 (Criminal Code – Chapter III: Crime against Public Health)." **NMPA** The self-assurance declaration of the authenticity of submitted data (the ones of domestic products shall be issued by applicants and the ones of imported products shall be issued respectively by applications and agents.) **HC** 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. Consult current Health Canada guidance for specific language.

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
					TGA Conformity Assessment - Manufacturer's statutory declaration 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. http://www.tga.gov.au/industry/manuf-statutory-declarations.htm#forms Statements of undertaking by the manufacturer as required by conformity assessment procedures set in the Therapeutic Goods (Medical Devices) Regulations 2002 **USFDA 510(k)** a) Truthful and Accurate statement per 21 CFR 807.87(k). Text: *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.* **NOTE:** Signed by a responsible person of the firm (not a consultant)
1.12.06	Regional (USFDA)	2	USFDA Class III Summary and Certification		**USFDA 510(k)** Class III Certification and Summary per 21 CFR 807.94. Text: *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 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.* *(Attach the summary of problem data, bibliography or other citations upon which the summary is based.)*
1.12.07	IMDRF (NMPA, EU, HSA, JP, TGA)	2	Declaration of Conformity	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: a) the applicable provisions of the Essential Principles/Requirements b) the classification rules c) an appropriate conformity assessment procedure	**NMPA** a) For registration: i. A declaration that the product complies with the classification requirements of the Medical Device Classification Rules b) For registration, change and extension renewal: i. A declaration that the product complies with the relevant requirements of the Provisions for Medical Device Registration and the relevant regulations ii. A declaration that the product complies with the current national standards, industrial standards, and provides an up-to-standard list **JP** Declaration and/or certificate that the relevant product is manufactured to conform to the essential principles and/or the quality management system. **NOTE:** 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." **TGA**

Row ID	Heading Class & Level	Heading	Common Content	Regional Content
				The wording of the Declaration of Conformity will depend on the conformity assessment procedure chosen by the manufacturer. Templates for each of the six possible types of Declarations of Conformity under Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002 are available at <http://www.tga.gov.au>. **HSA** 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 www.hsa.gov.sg, 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.
1.13	IMDRF 1	Letters of Reference for Master Files	Letter from any Master File owner granting access to the information in the master file. The letter should specify the scope of access granted.	
1.14	Regional (ANVISA, NMPA, HSA) 1	Letter of Authorization		**ANVISA** When applicable, an authorization letter issued by the device manufacturer allowing the importer/authorized legal agent to market the device in the subject jurisdiction, according to requirement on RDC 36/2015. **NMPA** a) Evidence of power of attorney of the foreign applicant for designating agent in China. b) Copies of the letter of commitment and business license or copy of organization registration certificate of agent. **HSA** 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 www.hsa.gov.sg **HSA NOTE:** 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.
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. **NOTE:** To ensure all elements of your submission are adequately reviewed, please be sure that any content placed here does not belong under any heading described above.	

CHAPTER 2 – SUBMISSION CONTEXT

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
2.01	IMDRF	1	Chapter Table of Contents	a) Includes all headings and sub-headings for the chapter. b) Specifies the page number for each item referred to in the table.	
2.02	IMDRF, RF	1	General Summary of Submission	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). b) Summary of submission, including i. The type of submission (e.g. new, amendment, change of existing application, renewal); ii. if amendment/supplement, the reason of the amendment/supplement; iii. if a change to existing approval, description of the change requested (e.g., changes in design, performance, indications, changes to manufacturing processes, manufacturing facilities, suppliers); iv. any high-level background information or unusual details that the manufacturer wishes to highlight in relation to the device, its history or relation to other approved devices or previous submissions (provides context to submission).	**ANVISA:** If renewal, amendment or change, identification of the registration/notification number issued by ANVISA for the device, family, system or set of devices and the number of the original application must be informed. **NMPA** a) If product registration, the applicant shall describe the management category, criteria for determining the classification code b) If registration extension, the applicant shall provide the statement that no changes are made to the product. **EU** If renewal, amendment or change, identification of product (family) currently Marketed under CE mark and related certificate of MDD annex. **HC** If amendment or new submission based on currently licenced device(s), the Canadian Medical Device Licence Number(s) should be provided along with the description of the change requested. **TGA** If recertification or change to a conformity assessment certificate, identification of the affected TGA certificate numbers must be detailed. **USFDA 510(k)** Executive Summary **HSA** Executive summary as per GN-17 available at www.hsa.gov.sg
2.03	Regional (USFDA)	1	Summary and Certifications for Premarket Submissions		**USFDA PMA** a) Summary of the Content of the Whole PMA per 21 CFR 814.20(b)(3) **USFDA 510(k)** a) 510(k) Summary contains all elements per 21 CFR 807.92 **OR** b) 510(k) Statement contains all elements per 21 CFR 807.93
2.04	IMDRF	1	Device Description	**NO CONTENT AT THIS LEVEL**	
2.04.01	IMDRF, RF	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)	**ANVISA:** a) Some accessories may request independent submission at ANVISA. Especially when it is considered a medical device by itself and is not of exclusive use of the medical device to be used in combination. For this accessories shall be identified and their registration/notification number in ANVISA provided.

Row ID	Heading Class & Level	Heading	Common Content	Regional Content
			v. How it works? Including a description of the features/variants/operating modes that enable the device to be used for indications/intended use (principle of operation/mechanism of action) and if not readily apparent or typical for the device type, a brief description of the underlying science/technology, design concepts, and/or theoretical principles supporting the device's function. vi. If applicable, labelled pictorial representation (diagrams, photos, drawings). vii. If system, how the components relate? viii. If applicable, identify if the device incorporates software/firmware and its role b) Product specification, including: i. Physical characteristics or relevance to the end user (dimensions, weight) ii. Features and operating modes iii. Input specifications (e.g. electrical power requirements, settings and associated allowable ranges/limits) iv. Output and performance characteristics (e.g. range and type of energy delivered, resolution of images) v. If applicable, an indication of the variants/models of the devices and a summary of the differences in specifications of the variants (comparison table and/or pictures/diagrams with supporting text). c) List of accessories intended to be used in combination with the devices. d) Indication of any other medical devices or general product intended to be used in combination with the medical device (e.g. infusion sets and infusion pumps, bipolar electrode and RF equipment). e) Components or accessories that can be sold separately should be identified. f) If approved by the regulator, provide the approval number and identification for each component or accessory. g) If the device is to be sterilized, an indication of who is to perform the sterilization and by what method (e.g. EtO, gamma irradiation, dry heat) **OR** an affirmative statement that the device is non-sterile when used. **NOTE:** The validation report is not expected be presented at this point, only the device sterility condition shall be indicated here. If appropriate, for the validation report, see Chapter 3 – Non-Clinical Studies. h) Summary of the composition of the device including, at minimum, the material specification and/or chemical composition of the materials that have direct or indirect contact with the user and/or patient. When required, full details to support how these specifications are met are to be provided in 3.5.02 – Chemical/Material Characterization. **NOTE:** If applicable, chemicals may be identified using either the IUPAC (International Union of Pure and Applied Chemistry) or the CAS (Chemical Abstract Service) Registry number. Reference to applicable material standards may also be useful in this description. i) If applicable, indication of biological material or derivate used in the medical device, including: 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.	b) For invasive, inhaled, ingested product, a list of ingredients, including their quantity, purity and or other relevant information. **EU** For invasive, inhaled, ingested product, a list of ingredients, including their quantity, purity and or other relevant information to determine potential pharmaceutical supportive action. **JP:** Explain that the established product specifications are necessary and sufficient to ensure the efficacy, safety, and quality of the product. **TGA** In the case of products that incorporate a medicinal substance, a rationale of applicability of medical device regulations should be included. **USFDA PMA:** Color Additive information per item A 6.a.ii in Appendix A of the ***Acceptance and Filing Reviews for Premarket Approval Applications (PMAs): Guidance for Industry and Food and Drug Administration Staff Guidance***; 21CFR 814.20(f)

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
				j) If the device contains an active pharmaceutical ingredient (API) or drug, an indication of the substance, should be provided. This should include its identity and source, and the intended reason for its presence and its primary mode of action. k) Engineering diagrams/prints/schematics of the device (should be provided as a separate file within the submission). l) **NOTE**: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the comprehensive device description and principles of operations provided in this section regarding the subject device	
2.04.02	IMDRF (ANVISA, NMPA, EU, HC, HSA, TGA, USFDA)	2	Description of Device Packaging	a) Information regarding the packaging of the devices, including, when applicable, primary packaging, secondary and any other packaging associated; b) Specific packaging of accessories marketed together with the medical devices shall also be described; c) If the user needs to package the medical device or its accessories before they perform sterilization, information about the correct packaging (e.g. material, composition, dimension) should be provided.	
2.04.03	IMDRF	2	History of Development	For any device versions/prototypes referenced in the evidence presented in the submission, a table describing the version/name, with 4 columns (Device Name and/or Version; Description of changes from previous row; motivation for the change; list of verification/validation activities, including clinical studies, conducted using this version). For any design verification or validation activities presented in this submission (including clinical studies) performed on any earlier versions of the subject device, include a justification for why the changes do not impact the validity of the data collected under those activities in supporting the safety and effectiveness of the final device design.	**JP** 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. b) Describe work allocation in the development process (i.e. what commercial or non-commercial entities were involved at what stages of development). **USFDA 510(k)** It is highly recommended that the following be provided for a device that has received prior 510(k) clearance: either a description of all changes made to the device since the last 510(k) clearance or a statement that no changes have been made
2.04.04	IMDRF, RF	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 reviewed and refused by the subject regulator. b) Description of why they were selected. c) A key specification comparison, preferably in a table, between the references (similar and/or previous generation) considered and the device.	**HC** 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). 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. **HSA** 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.
2.04.05	Regional (USFDA)	2	Substantial Equivalence Discussion		**USFDA 510(k)** a) Identify the predicate device(s), and optionally reference devices i. 510(k) number, trade name and model number 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). 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).

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
					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.
2.05	IMDRF	1	Indications for Use and/or Intended Use and Contraindications	**NO CONTENT AT THIS LEVEL**	
2.05.01	IMDRF, RF	2	Intended Use; Intended Purpose; Intended User; Indications for Use	This section should include, as appropriate: a) **Intended Use:** The statement of intended use should specify the therapeutic or diagnostic function provided by the device and may describe the medical procedure in which the device is to be used (e.g. Diagnosis *in vivo* or *in vitro*, treatment monitoring rehabilitation, contraception, disinfection). b) **Intended Purpose:** What is expected with the use of this medical device? Which results are expected? c) **Intended user** and skills/knowledge/training that the user should have to operate or use the device. d) Identify if the device is intended for **single or multiple use** e) **Indications for Use:** i. Disease or medical condition that the device will diagnose, treat, prevent, mitigate, or cure, parameters to be monitored and other considerations related to indication for use. ii. If applicable, information about patient selection criteria. iii. If applicable, information about intended patient population (e.g. adults, pediatrics or newborn) or a statement that no subpopulations exist for the disease or condition for which the device is intended. f) For amendments/supplements or changes to existing approvals, identify any changes to the previously approved intended use/intended purpose/intended user/indications. If there are no changes, this should be stated and a reference should be made to the precise regional regulatory tracking number associated with the previous submission/approval. **NOTES:** i. The statements of intended use and purpose and the intended user and indications for use must be **as presented in the labelling**. ii. If more than one device is included, the information should be provided for each device	**ANVISA** Indications for use shall include in which part of the human body the device is intended to be used (e.g. central nervous system, central circulatory system, teeth, eye surface, injured skin).
2.05.02	IMDRF, RF	2	Intended Environment/Setting for use	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. b) If applicable, environmental conditions that can affect the device's safety and/or performance (e.g. temperature, humidity, power, pressure, movement).	**USFDA PMA and 510(k)** FDA includes this information in the indications for use and product labelling
2.05.03	Regional (USFDA)	2	Pediatric Use		**USFDA PMA** a) Description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose or cure, b) The number of affected pediatric patients, as a whole and within each pediatric subpopulation. **OR** c) Statement that no pediatric subpopulation exists for the disease or condition for which the device is intended.
2.05.04	IMDRF, RF	2	Contraindications For Use	If applicable, specify the disease or medical conditions that would make use of the device inadvisable due to unfavorable risk/benefit profile.	**USFDA PMA and 510(k)** FDA includes this information in the indications for use and product labelling

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
				NOTE: The statement if contraindications for the device must be as presented in the labelling.	
2.06	IMDRF	1	Global Market History	**NO CONTENT AT THIS LEVEL**	
2.06.01	IMDRF	2	Global Market History	a) Up to date indication of the markets (all countries or jurisdictions) where the device is approved for marketing, including any marketing under compassionate use regulations. b) Should include history of the marketing of the device by any other entity in as much detail as possible, acknowledging that detailed information may not be available in all cases. c) If the subject device is different in any way (e.g. design, labelling, specifications) from those approved or marketed in other jurisdiction, the differences should be described. d) 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. e) 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. f) State the date of data capture for the market history data g) 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.	**ANVISA and HC:** 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. **EU** The commercial names used by the Original Equipment Manufacturer in case of Own Brand Labelling should be identified. **HC** a) 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. **HC NOTE:** In this context, compassionate use includes **any** Special Access Authorizations. **TGA** Any notifications to foreign regulators of substantial change to the device
2.06.02	IMDRF, RF	2	Global Incident Reports and Recalls	a) List adverse events/incidents associated with the device and a statement of the period associated with this data. b) If the number of adverse events is voluminous, provide a summary by event type that state the number of reported events for each event type. c) List of the medical device recalls and/or advisory notice, and a discussion of the handling and solution given by the manufacturer in each case. d) A description of any analysis and/or corrective actions undertaken in response to items listed above. e) If there have been no adverse events/incidents, recalls and/or advisory notice to date, provide an attestation from device owner on company letterhead, that there have been no adverse events/incidents, recalls and/or advisory notice since commercial introduction of the device. **NOTES** i. It is acknowledged that the definition of recall may vary from one jurisdiction to another; hence this heading is labelled as regionally focused (RF).	**HC** a) The jurisdiction(s) associated with the incident should be clearly indicated. b) Incidents should include any Canadian incidents through SAP or other previous Canadian applications, if known. c) If marketing history is presented for a previously licensed device, then the associated recalls, and incident reports for that device should also be summarized here. **USFDA 510(k) NOTE** Include when submitting a 510(k) to implement a design change to address a recall of a device in the US **HSA** 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.
2.06.03	IMDRF, RF (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: i. Incident rate = # adverse events/incidents divided by # units sold, expressed as a percentage ii. Recall rate = # recalls divided by # units sold, expressed as a percentage Rates may be presented in other appropriate units such as per patient year of use or per use. In this case, methods for determining these rates should be presented and any assumptions supported.	

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
				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)?). **NOTES** i. It is acknowledged that the definition of recall may vary from one jurisdiction to another; hence this heading is labelled as regionally focused (RF). ii. Sales in this context should be reported as the number of units sold. iii. The summary of sales should be broken down by components when appropriate.	
2.06.04	Regional (TGA)	2	Evaluation/Inspection Reports		**TGA** Copies of Evaluation/Inspection Reports from other parties (e.g. Notified Body inspection reports).
2.07	IMDRF	1	Other Submission Context Information	Heading for other submission context information that may be important to the submission but that does not fit in any of the other headings of this chapter. **NOTE:** To ensure all elements of your submission are adequately reviewed, please be sure that any content placed here does not belong under any heading described above.	

CHAPTER 3 – NON-CLINICAL EVIDENCE

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
3.01	IMDRF	1	Chapter Table of Contents	a) Includes major headings for the chapter, to the level of the custom headings. b) Specifies the page number for each item referred to in the table.	
3.02	IMDRF	1	Risk Management	a) A summary of the risks identified during the risk analysis process and how these risks have been controlled to an acceptable level. b) The results of the risk analysis should provide a conclusion with evidence that remaining risks are acceptable when compared to the benefits. c) Where a standard is followed, identify the standard.	**EU** A formal signed statement accepting the residual risk upon completing the risk-benefit analysis before placing product on the EU market.
3.03	IMDRF (ANVISA, NMPA, EU, HSA, JP, TGA)	1	Essential Principles (EP) Checklist	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. 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. c) If any EP indicated in the checklist does not apply to the device: a documented rationale of the non-application of each EP that does not apply. **NOTE:** Methods used to demonstrate conformity may include one or more of the following: a) conformity with recognised or other standards; b) conformity with a commonly accepted industry test method(s); c) conformity with an in-house test method(s); d) the evaluation of pre-clinical and clinical evidence; e) comparison to a similar device already available on the market.	**HSA NOTE** The checklist of conformity to the Singapore Essential Principles is to be submitted – refer to GN-16 available at www.hsa.gov.sg. Alternatively, the checklist to EU or Australian Essential Requirements can be submitted.
3.04	IMDRF	1	Standards	**NO CONTENT AT THIS LEVEL**	
3.04.01	IMDRF, RF	2	List of Standards and Guidance Documents	This section should include: 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. i. At a minimum should include the standard organization, standard number, standard title, year/version, and if full or partial compliance. ii. If partial compliance, a list the sections of standard that • Are not applicable to the device, and/or • have been adapted, and/or • were deviated from for other reasons – discussion to accompany b) If applicable, a list of relevant guidance documents published by regulators and referenced in the design and/or manufacture of the device with the jurisdiction of publication, publication date and title identified. c) If applicable, a list of relevant clinical guidelines referenced in the design and/or manufacture of the device, the publisher, publication date and title identified.	**ANVISA** At a minimum all the essential requirements of safety and efficacy, established at ANVISA's regulations, shall be addressed by the standards referred at this list. **NMPA NOTE** When applicable, this should include reference to any relevant NMPA registration standards. **EU NOTE** An overview of used standards typically is added in the essential requirements checklist, including rationales for using standards that are non-harmonised or complied with only in part. This information needs only to be presented once in the application. **TGA** 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. **USFDA PMA and 510(k)**

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					If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (FDA Form 3654) **HSA NOTE** The list of standards complied to can be submitted together with the Essential Principles Checklist. This information needs only to be presented once.
3.04.02	Regional (ANVISA, NMPA, HC, USFDA)	2	Declaration and/or Certification of Conformity		**ANVISA** a) Conformity Assessment Certification according applicable standards, issued by a Third Part Organization (e.g. Notify Body) officially recognized by the Regulatory Authority. b) The certificate shall be issued under the SBAC - Sistema Brasileiro de Avaliação da Conformidade / Brazilian Conformity Assessment System - INMETRO. c) Certain types of devices (intra-uterine devices and blood bags) require pre-submission analyses 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. **NMPA** A declaration that the product complies with the current national standards, industrial standards. **HC** The applicant is advised to prepare the Declaration of Conformity to recognized standards using Health Canada's Declaration of Conformity form. Refer to the Guidance Document: Recognition and Use of Standards under the Medical Devices Regulations and the current list of recognized standards for medical devices. **USFDA** Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards
3.05	IMDRF	1	Non-clinical Studies	**NO CONTENT AT THIS LEVEL**	
3.05.01	IMDRF	2	Physical and Mechanical Characterization	Evidence that support the physical or mechanical properties of the subject device is to be included in this section. This should include: a) A summary of the non-clinical evidence that falls within this category b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) c) Discussion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of non-clinical laboratory study is not applicable to this case.	**EU** a) Where applicable, the accreditation status of laboratories used in physical and mechanical testing. b) Include evidence of accreditation, e.g. certificate of the lab (or reference to the certificate), which might be part of purchasing department/supplier documentation

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
				NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device	
3.05.01.01	IMDRF	3	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL.** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone. For example, the structure will look something like this Component A Fatigue Test, MT4203, 2010-10-10 Summary of MT4203 Full Report for MT4203 Assembly B Compatibility Test, MT4584, 2011-01-23 Summary of MT4584 Full Report for MT4584	
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.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.05.01.01.03	Regional (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. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
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) 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) c) Discussion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device	
3.05.02.01	IMDRF	3	[Study description, study	**NO CONTENT AT THIS LEVEL**	

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
			identifier, date of initiation]	This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
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.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.05.02.01.03	Regional (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. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
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 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) c) Discussion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device	
3.05.03.01	IMDRF	3	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.05.03.01.01	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	
3.05.03.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.05.03.01.03	Regional (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. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.05.04	IMDRF	2	Radiation Safety	Studies supporting radiation safety, where the device emits radiation or where the device is exposed to radiation are to be included in this section. This should include:	

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				a) A summary of the non-clinical evidence that falls within this category b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) c) Discussion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device	
3.05.04.01	IMDRF	3	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.05.04.01.01	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	
3.05.04.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.05.04.01.03	Regional (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. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.05.05	IMDRF	2	Software/Firmware	**NO CONTENT AT THIS LEVEL** Studies and supporting information on the software design, development process and evidence of the validation of the software, as used in the finished device, are to be included in this section and the associated sub-sections. It should also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling	
3.05.05.01	IMDRF	3	Software/Firmware Description	a) Specify the name of the software b) Specify the version of the software - The version tested must be clearly identified and should match the release version of the software, otherwise justification must be provided. c) Provide a description of the software including the 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. d) Provide a statement about software version naming rules; specify all fields and their meanings.	**USFDA 510(k) and HC** Identify the level of concern (minor, moderate, major) and include a description of the rationale for that level. **USFDA NOTE** For guidance on what specific software documentation to submit, refer to the Guidance For industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

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3.05.05.02	IMDRF	3	Hazard Analysis	The Hazard Analysis should take into account all device hazards associated with the device's intended use, including both hardware and software hazards. **NOTE:** i. This document can be in the form of an extract of the software-related items from comprehensive risk management documentation, described in ISO 14971. ii. Hazard analysis, should address all foreseeable hazards, including those resulting from intentional or inadvertent misuse of the device.	
3.05.05.03	IMDRF	3	Software Requirement Specification	The Software Requirements Specification (SRS) documents the requirements for the software. This typically includes functional, performance, interface, design, developmental, and other requirements for the software. In effect, this document describes what the Software Device is supposed to do. For example, hardware requirements, programming language requirement, interface requirements, performance and functional requirements,	
3.05.05.04	IMDRF (EU, HC, JP, USFDA)	3	Architecture Design Chart	Detailed depiction of functional units and software modules. May include state diagrams as well as flow charts.	
3.05.05.05	IMDRF (EU, HC, JP, USFDA)	3	Software Design Specification	The Software Design Specification (SDS) describes the implementation of the requirements for the Software Device. The SDS describes how the requirements in the SRS are implemented.	
3.05.05.06	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.	
3.05.05.07	IMDRF	3	Software Life Cycle Process Description	A summary describing the software development life cycle and the processes that are in place to manage the various life cycle activities.	
3.05.05.08	IMDRF	3	Software Verification and Validation	This heading should include: a) An overview of all verification, validation and testing performed prior to final release b) For each test presented, identify the testing environment (e.g. in-house, in a simulated or actual user environment). c) Discussion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE** i. Discussion should address all of the different hardware configurations and, where applicable, operating systems identified in the labelling. 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	
3.05.05.08.01	IMDRF	4	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created for each study under the parent heading. The sub headings below would be for this study alone.	
3.05.05.08.01.01	IMDRF	5	Summary	A summary of the specific study described in the custom heading above.	

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3.05.05.08.01.02	IMDRF	5	Full Report	The test report for the test described in the custom heading above.	
3.05.05.08.01.03	Regional (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. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.05.05.09	IMDRF	3	Revision Level History	Revision history log, including release version number and date.	
3.05.05.10	IMDRF	3	Unresolved Anomalies (Bugs or Defects)	All unresolved anomalies in the release version of the software should be summarized, along with a justification for acceptability (i.e. the problem, impact on safety and effectiveness, and any plans for correction of the problems).	
3.05.05.11	IMDRF (USFDA, HC, HSA)	3	Cybersecurity	Evidence to support the cybersecurity should be provided here. For example, but not limited to: a) Cybersecurity vulnerabilities and risks analysis b) Cybersecurity controls measures c) Traceability matrix linking cybersecurity controls to the cybersecurity vulnerabilities and risks	**USFDA** Guidance for Industry and Staff – "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices"
3.05.05.12	IMDRF (USFDA, HC, HSA)	3	Interoperability	If the device can communicate with other devices. Evidence to support the interoperability should be provided.	**USFDA** Guidance for Industry and Staff – "Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices"
3.05.06	IMDRF	2	Biocompatibility and Toxicology Evaluation	Studies supporting biocompatibility and assessing toxicology are to be included in this section. Studies to assess the immunological response to animal or human tissues, tissue components or derivatives are to be included in this section. This should include: a) A list of all materials in direct or indirect contact with the patient or user. b) State conducted tests, applied standards, test protocols, the analysis of data and the summary of results c) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) d) Discussion to support why the evidence presented is sufficient to support the application. **OR** e) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTES:** i. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device ii. Tests should be conducted on samples from the finished, sterilized (when supplied sterile) device.	
3.05.06.01	IMDRF	3	[Study description, study	**NO CONTENT AT THIS LEVEL**	

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
			identifier, date of initiation]	This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.05.06.01.01	IMDRF	4	**Summary**	A **summary** of the **specific study** described in the custom **heading** above.	
3.05.06.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.05.06.01.03	Regional (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. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.05.07	IMDRF	2	Non-Material-Mediated Pyrogenicity	Studies to support pyrogenicity evaluation of final release are to be included in this section. This should include: a) A summary of the non-clinical evidence that falls within this category b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) c) Discussion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the **subject device**	
3.05.07.01	IMDRF	3	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.05.07.01.01	IMDRF	4	Summary	A **summary** of the **specific study** described in the custom **heading** above.	
3.05.07.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.05.07.01.03	Regional (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. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.05.08	IMDRF	2	Safety of Materials of	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:	**ANVISA IMPORTANT NOTE:**

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			Biological Origin (human/animal)	a) A description of biological material or derivate b) State the harvesting, processing, preservation, testing and handling of tissues, cells and substances c) If applicable, discussion of infectious agents/transmissible agents known to infect the source animal d) Clarify the origin (including details of donor screening and source country), and describe the tests on validation of removal or inactivation methods of viruses and other pathogens in the manufacturing process. e) A brief summary of process validation should be included to substantiate that manufacturing and screening procedures are in place to minimize biological risks, in particular, with regard to viruses and other transmissible agents. f) The system for recordkeeping to allow traceability from sources to the finished device should be fully described g) Discussion to support why the evidence presented is sufficient to support the application. **OR** h) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device	The commercialization of any type of products of human origin is not allowed in Brazilian territory, according to the Brazilian Federal Constitution. **NMPA NOTE:** Medical devices that includes materials from animal origin that bear TSE risk are prohibited for sale in China **EU** 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. **TGA** Details of the QMS records of the assessment and control of the subcontractors that supply the manufacturer with materials
3.05.08.01	IMDRF (ANVISA, HC, HSA)	3	Certificates	Certificates that support the safety of materials of biological origin (e.g. certificate of abattoir inspection).	**HSA** If available, Certificate of Suitability (CEP) for biological material that bears TSE (Transmissible Spongiform Encephalopathy) risk.
3.05.08.02	IMDRF	3	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created for each study under the parent heading. The sub headings below would be for this study alone.	
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.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.05.08.02.03	Regional (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. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.05.09	IMDRF	2	Sterilization Validation	**NO CONTENT AT THIS LEVEL**	
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 sterilize the device. This should include: a) A description of the sterilization process (method, parameters) b) A summary of the non-clinical evidence that falls within this category	**NMPA NOTE:** For products that can tolerate sterilization at least twice, supporting materials of product's resistance to recommended sterilization methods shall be provided. **USFDA NOTE:**

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				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) d) If applicable, state the rationale on the durability of the product against two or more sterilization. e) Discussion to support why the evidence presented is sufficient to support the application. **OR** f) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device	Refer to Guidance for Industry and Staff - Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
3.05.09.01.01	IMDRF	4	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
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.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.05.09.01.01.03	Regional (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. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.05.09.02	IMDRF	3	Manufacturer Sterilization	Information and validation of manufacturer sterilization where the device is provided sterile. This should include: a) A description of the sterilization process (method, parameters) and Sterility Assurance Level (SAL) b) State if parametric release is used c) A summary of the non-clinical evidence that falls within this category d) Information on the ongoing revalidation of the process. Typically, this would consist of arrangements for, or evidence of, revalidation of the packaging and sterilization processes. e) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) f) Discussion to support why the evidence presented is sufficient to support the application. **OR**	**USFDA NOTE:** Refer to Guidance for Industry and Staff - Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile

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				g) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device	
3.05.09.02.01	IMDRF	4	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.05.09.02.01.01	IMDRF	5	Summary	A summary of the specific study described in the custom heading above.	
3.05.09.02.01.02	IMDRF	5	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.05.09.02.01.03	Regional (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. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.05.09.03	IMDRF	3	Residual Toxicity	Contain the information on the testing for sterilant residues, where the device is supplied sterile and sterilized using a method susceptible to residues. This should include: a) A summary of the non-clinical evidence that falls within this category b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) c) Discussion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.	
3.05.09.3.01	IMDRF	4	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.05.09.3.01.01	IMDRF	5	Summary	A summary of the specific study described in the custom heading above.	
3.05.09.3.01.02	IMDRF	5	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
3.05.09.3.01.03	Regional (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. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.05.09.04	IMDRF	3	Cleaning and Disinfection Validation	Contains information on the validation of cleaning and disinfection instructions for reusable devices. This should include: a) A summary of the non-clinical evidence that falls within this category b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) c) Discussion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.	
3.05.09.04.01	IMDRF	4	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created for each study under the parent heading. The sub headings below would be for this study alone.	
3.05.09.04.01.01	IMDRF	5	Summary	A summary of the specific study described in the custom heading above.	
3.05.09.04.01.02	IMDRF	5	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.05.09.04.01.03	Regional (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. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.05.09.05	IMDRF (ANVISA, HC, USFDA)	3	Reprocessing of Single Use Devices, Validation Data	The required validation data including cleaning and sterilization data, and functional performance data demonstrating that each single use device (SUD) will continue to meet specifications after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.	**ANVISA** a) For SUD which does not match ANVISA's requirements of "forbidden reprocessing", must be justified (with technical evidence) why the device should not be reprocessed; b) Labelling of SUD shall comply with specific ANVISA's requirements regarding reprocessing. **USFDA NOTE** Refer to the Guidance for Industry and FDA Staff – "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling." **USFDA 510(k) NOTE**

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
					Please see Appendix E of the Reprocessing Guidance for a list of devices which require data to validate reprocessing instructions.
3.05.09.05.01	IMDRF (ANVISA, HC, USFDA)	4	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.05.09.05.01.01	IMDRF (ANVISA, HC, USFDA)	5	Summary	A summary of the specific study described in the custom heading above.	
3.05.09.05.01.02	IMDRF (ANVISA, HC, USFDA)	5	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** Required for reprocessed single use devices. If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.05.09.05.01.03	Regional (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. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.05.10	IMDRF	2	Animal Testing	Contains information about any animal studies conducted to support the submission. This should include: a) A summary of the non-clinical evidence that falls within this category b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) c) Discussion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.	**USFDA** Requirements for reporting non-clinical data laboratory study results are outline in 21 CFR 58.185
3.05.10.01	IMDRF	3	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.05.10.01.01	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	
3.05.10.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
3.05.10.01.03	Regional (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. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
3.05.11	IMDRF	2	Usability/Human Factors	Studies specifically assessing the instructions and/or device design in terms of impact of human behaviour, abilities, limitations, and other characteristics on the ability of the device to perform as intended should be included here. This should include: a) A summary of the non-clinical evidence that falls within this category b) A statement of the test environment and relation to the intended use environment c) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) d) If a clinical study has been conducted that includes human factors/usability endpoints, reference to the studies and endpoints should be made, but full results do not need to be repeated. e) Discussion to support why the evidence presented is sufficient to support the application. **OR** f) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTES:** i. If a clinical study has been conducted that includes usability/human factors endpoints, **reference to the studies and endpoints should be made, but full results do not need to be repeated and should be included in Chapter 4 – Clinical Evidence.** ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.	
3.05.11.01	IMDRF	3	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
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.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.05.11.01.03	Regional (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. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
3.06	IMDRF, RF (ANVISA, HC, HSA, JP, USFDA)	1	Non-clinical Bibliography	This heading should include: a) A listing of published non-clinical studies involving this specific device (e.g. cadaveric evaluations, biomechanical assessments) b) A legible copies of key articles , including translation where applicable to meet the regulators language requirements c) Discussion to support why the evidence presented is sufficient to support the application. **OR** d) A statement that no literature related to the device was found.	
3.07	IMDRF	1	Expiration Period and Package Validation	This heading should include: a) An indication of environmental conditions for correct storage of the device (e.g. temperature, pressure, humidity, luminosity). b) A statement of the expiration period considering the materials and sterilization (when applicable), indicated as a period of time or any other means of appropriate quantification. **OR** c) A rationale that storage conditions could not affect device safety or effectiveness	**ANVISA and TGA and EU and JP and HSA** 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. **NMPA** For medical devices with re-use limitations, provide details relating to the number of times the device can be re-used and evidence to support in this and the sub-sections below.
3.07.01	IMDRF	2	Product Stability	Contains details relating to product stability under specified storage conditions and in final packaging or simulated conditions. This should include: a) A statement of the shelf-life (for each component if there are differences between components) b) A summary of the non-clinical evidence that falls within this category c) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) d) Discussion to support why the evidence presented is sufficient to support the application. **OR** e) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.	**ANVISA** If applicable, product stability shall also include: a) In use stability, containing details and evidence supporting the stability during actual routine use of the device (real or simulated); b) Shipping stability containing details and evidence supporting the tolerance of device components to the anticipated shipping conditions. **HSA** 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);
3.07.01.01	IMDRF	3	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created for each study under the parent heading. The sub headings below would be for this study alone.	
3.07.01.01.01	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	
3.07.01.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
3.07.01.01.03	Regional (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. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
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 that falls within this category b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed) c) Discussion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.	
3.07.02.01	IMDRF	3	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.07.02.01.01	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	
3.07.02.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.07.02.01.03	Regional (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. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**
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 **that are not delineated in the rest of the Chapter 3.** This should include a) A description of the purpose of the test, the risk/safety issue the test is addressing; the test methods and results of the test	

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
				NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device.	
3.08.01	IMDRF	2	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.	
3.08.01.01	IMDRF	3	Summary	A summary of the specific study described in the custom heading above.	
3.08.01.02	IMDRF	3	Full Report	The test report for the test described in the custom heading above.	**USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards.
3.08.01.03	Regional (USFDA)	3	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. **The applicant is advised to contact the specific review division for further guidance on the specific data format that is preferred.** **NOTE: Do not place PDFs here.**

CHAPTER 4 – CLINICAL EVIDENCE

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
4.01	IMDRF	1	Chapter Table of Contents	a) Includes all headings for the chapter. b) Specifies the page number for each item referred to in the table.	
4.02	IMDRF	1	Overall Clinical Evidence Summary	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) and provide a discussion of how this is considered sufficient to support request for marketing for the requested indications. A tabular listing of clinical studies may be included in this section. b) If any of the study devices differ from the devices to be marketed, including competitors devices, a description of these differences and their impact on the validity of the evidence in terms of support for the application. 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) d) Discussion to support why the evidence presented is sufficient to support the application. **NOTE:** Human factors testing that include patients should be included here.	**EU, TGA NOTE** Clinical evidence is always required, regardless of risk class. **NMPA NOTE** Class II and Class III devices should be submitted with clinical evaluation data. **HC** a) Provide the Investigational Testing Authorization reference number for any clinical trials conducted under an Investigational Testing Authorization in Canada. b) If applicable, provide the clinicaltrials.gov reference number for any clinical studies registered with clinicaltrials.gov. **USFDA PMA and 510(k)** Does not limit the page number for the summary of the clinical information submitted **USFDA, HC, ANVISA, JP and HSA** If no clinical evidence is being provided, discuss why this is acceptable. **HSA NOTE** 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.
4.02.01	IMDRF (EU, NMPA, HSA, 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 the clinical data submitted in relation to the device. b) A complete curriculum vitae, or similar documentation, to justify the manufacturer's choice of the clinical expert.	
4.02.02	IMDRF	2	Device Specific Clinical Trials	**NO CONTENT AT THIS LEVEL** Clinical trial information under this heading should be grouped by trial	
4.02.02.01	IMDRF	3	[Trial description, protocol #, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone. For example, the structure will look something like this Level 3: EU Pilot Study, CT4203, 2010-10-10 Level 4: Clinical Trial Summary Level 4: Clinical Trial Report Level 3: NA RCT Study, CT4584, 2011-01-23 Level 4: Clinical Trial Summary Level 4: Clinical Trial Report	
4.02.02.01.01	IMDRF	4	Clinical Trial Summary	a) A summary of the specific study described in the custom heading above. b) 2-3 page summary document that presents a summary of:	**USFDA PMA and 510(k)** Does not limit the page number for the summary of the clinical investigations

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
				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 ii. Summary of the results of the analysis iii. Summary of conclusions related to the endpoints **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the components of the clinical trial summary.	
4.02.02.01.02	IMDRF	4	Clinical Trial Report	a) A clinical trial report of the specific study described in the custom heading above. **NOTES:** i. The clinical study report should include elements such as the investigational plan/study protocol, protocol changes and deviations, description of patients, data quality assurance, analysis/results. ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the components of the clinical trial report.	**NMPA NOTE:** The clinical trial report should be in accordance with the Medical Device Registration Regulations, the Medical Device Clinical Trial Quality Management Specification, and relevant clinical guidelines. **USFDA PMA and 510(k)** http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046717.htm#sugforforidepro
4.02.02.01.03	Regional (USFDA)	4	Clinical Trial Data		**USFDA** 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. 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. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm136377.htm
4.02.03	IMDRF	2	Clinical Literature Review and Other Reasonable Known Information	a) Clinical literature review that critically reviews available information that is published, available, or reasonably known to the applicant/sponsor that describes safety and/or effectiveness of the device b) A legible copy of key articles, including translation where applicable to meet the regulators language requirements. **OR** c) A statement that no literature related to the device was found. **NOTE:** 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	
4.03	Regional (USFDA)	1	IRB Approved Informed Consent Forms		Copies of IRB approved informed consent forms are to be provided here.

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
4.04	Regional (USFDA)	1	Investigators Sites and IRB Contact Information		Investigators and study administrative structure information should be provided, including (as appropriate): a) Investigators (who signed the Investigator agreement)-name, address, telephone # (contact info), CV b) Sites-Site number as reflected in the study report in reference to the investigator, address if different from the above c) Sponsor-address and regulatory contact information d) Contract Research Organization (CRO), if applicable-name, address, and contact information 5. Laboratory facilities (central lab and/or local lab that participated in the study)-name, address, contact information
4.05	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.	

CHAPTER 5 – LABELLING AND PROMOTIONAL MATERIAL

Row ID	Heading Class & Level	Heading	Common Content	Regional Content
5.01	IMDRF	Chapter Table of Contents	a) Includes all headings for the chapter. b) Specifies the page number for each item referred to in the table.	
5.02	IMDRF, RF	Product/Package Labels	Samples of the primary and secondary packaging labels. **NOTES:** i. Do not include shipping labels. ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to labelling the subject IVD medical device.	**ANVISA** a) According to Brazilian Legislation all information associated with the device, including labelling, shall be in Brazilian-Portuguese. b) Specific requirements of labelling content are established by ANVISA´s regulation. c) (PDFs of) the artwork of the labels will need to be provided for device. d) In case the product is marketed with original labels, (PDFs of) stickers with local information will need to be provided. **NMPA NOTE** Provide label samples of minimum sales unit conform to Provisions on the Management of Instructions and Labels of Medical Devices (NMPA No. 6) **EU** a) (PDFs of) labels will need to be provided for device labels as well as labelling of primary and secondary packaging. b) For Own Brand labelling, packaging and IFU of both the OBL and the OEM will need to be provided. **HC NOTES** a) All labelling must be provided in English or French, both official languages are to be available upon request. b) Labelling for near-patient devices must also be provided in French and English **TGA NOTES** The labels and instructions for use (including any package inserts) must a) meet the requirements of Essential Principle 13 b) be in English and legible when viewed on screen and printed c) include the Australian sponsor's contact details to meet Regulation 10.2 If the applicant is including draft labels, artist impression or mock-up labels, the applicant needs to provide: a) the mock-up as full size suitable for A3 printing b) a statement as to where and how the batch/serial number/ date of manufacture/expiry date/ will be displayed **HSA NOTES** Refer to GN-23 – available at www.hsa.gov.sg for labelling requirements. a) Copies of device and packaging labels are to be provided in original color. 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.
5.03	IMDRF, RF	Package Insert/Instructions for Use	Package Insert/Instructions for Use included in the package, when required or provide support for why this element is not applicable.	**ANVISA** a) According to Brazilian Legislation all information associated with the device, including labelling, shall be in Brazilian-Portuguese. b) Specific requirements of labelling content are established by ANVISA´s regulation.

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
				NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to labelling the subject device	c) The current version of the instruction for use must be informed. d) (PDFs of) the artwork of the IFU will need to be provided for device. **NMPA** Provide IFU conform to Provisions on the Management of Instructions and Labels of Medical Devices (NMPA No. 6) **EU** a) At minimum the IFU in a relevant acceptable language, required by Notified Bodies following their national law, should be provided. Further language version will need to be available for verification during audits. b) (PDFs of) labels will need to be provided for device labels as well as labelling of primary and secondary packaging. c) For Own Brand labelling, packaging and IFU of both the OBL and the OEM will need to be provided. **HC NOTES** a) All labelling must be provided in English or French, both official languages are to be available upon request. b) Labelling for near-patient devices must also be provided in French and English c) The current version and date of the instruction for use must be stated. **TGA NOTES** The labels and instructions for use (including any package inserts) must d) meet the requirements of Essential Principle 13 e) be in English and legible when viewed on screen and printed f) include the Australian sponsor's contact details to meet Regulation 10.2 If the applicant is including draft labels, artist impression or mock-up labels, the applicant needs to provide: c) the mock-up as full size suitable for A3 printing d) a statement as to where and how the batch/serial number/ date of manufacture/expiry date/ will be displayed **USFDA PMA** a) Package inserts include a summary of clinical data **HSA NOTE** Refer to GN-23 – available at www.hsa.gov.sg for labelling requirements.
5.04	IMDRF, RF (ANVISA, EU, HSA)	I	e-labelling	The following should be provided: a) For eligible medical devices and stand-alone software, the applicant needs to identify which form of e-labelling is being used in case of e-labelling (e.g. electronic storage system or built-in system, website). b) Details of risk management in relation to e-labelling. If this is part of the overall risk management, refer to it here c) A description of the procedure and operations on providing IFU's when requested d) Written information for user Information on webpage where IFU and further information can be found in relevant languages. e) A description on how the requirements detailed for the website have been met.	**EU** For fixed installed medical devices provide text message / information which will be given on or with the device itself as well as description of place where it would be placed **HC NOTE:** If a video/App is available as described in f) above, the video should be available in both French and English. **HSA NOTE** Refer to GN-23 – available at www.hsa.gov.sg for e-labelling requirements.

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
				f) If a video/App is available to demonstrate how the test is to be performed and interpreted, provide a link as well as details about how it is maintained and updated throughout the life cycle of the device.	
5.05	IMDRF (ANVISA, HC, HSA, TGA, USFDA)	1	Physician Labelling	Labelling directed at the physician other than the package insert, such as the surgical manual	
5.06	IMDRF (ANVISA, 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	
5.07	IMDRF (ANVISA, HC, HSA, TGA, USFDA)	1	Technical/Operator Manual	Labelling directed the technical users and operators of medical devices focusing on the proper use and maintenance of the device	
5.08	Regional (ANVISA, HC)	1	Patient File Stickers/Cards and Implant Registration Cards		**ANVISA** 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. **HC** a) 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 c) The sponsor/applicant should explicitly address any existing regional regulatory guidance related to labelling the subject device
5.09	Regional (HC)	1	Product Brochures		**HC** a) Draft product brochures available at the time of application b) The sponsor/applicant should explicitly address any existing regional regulatory guidance related to labelling the subject device
5.10	IMDRF	1	Other Labelling and Promotional Material	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.	

CHAPTER 6A – QUALITY MANAGEMENT SYSTEM PROCEDURES

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
6A.01	Regional (USFDA)	1	Cover Letter		**USFDA PMA** Any modular PMA submission of quality system information would need a cover letter containing the information describe in Chapter 1 under the Cover Letter heading
6A.02	IMDRF (JP, TGA, USFDA)	1	Chapter Table of Contents	a) Includes all headings for the chapter. b) Specifies the page number for each item referred to in the table.	
6A.03	IMDRF (JP, TGA, USFDA)	1	Administrative	**NO CONTENT AT THIS LEVEL.** Administrative information needed to evaluate the premarket submission related to the QMS	
6A.03.01	IMDRF (JP, NMPA, TGA, USFDA)	2	Product Descriptive Information	Abbreviated description of the device, operating principles and overall manufacturing methods	**USFDA PMA** a) Item A7 Appendix A in the ***Acceptance and Filing Reviews for Premarket Approval Applications (PMAs): Guidance for Industry and Food and Drug Administration Staff Guidance*** b) The guidance document ***Quality System Information for Certain Premarket Application Reviews; Guidance for Industry and FDA Staff***
6A.03.02	IMDRF, RF (ANVISA, NMPA, HC, HSA, JP, TGA USFDA)	2	General Manufacturing Information	a) Address and contact information for all sites where the device or its components are manufactured. b) 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.	**NMPA** For change registration, if manufacturing site of the Imported Medical Device applicant changes, provide Comparative table and description. **USFDA PMA** a) Item A7 Appendix A in the ***Acceptance and Filing Reviews for Premarket Approval Applications (PMAs): Guidance for Industry and Food and Drug Administration Staff Guidance*** b) The guidance document ***Quality System Information for Certain Premarket Application Reviews; Guidance for Industry and FDA Staff***
6A.03.03	IMDRF, RF (TGA, USFDA)	2	Required Forms	Any regional specific forms to be completed associated with Quality management Systems in the premarket review process	
6A.04	IMDRF (TGA, USFDA)	1	Quality management system procedures	High level quality management system procedures for establishing and maintaining the quality management system such as the quality manual, quality policy, quality objectives, and control of documents and records ***ISO 13485 Elements– SOPs to satisfy clause 4***	**USFDA PMA** Outline of the Quality System Documentation Structure
6A.05	IMDRF (TGA, USFDA)	1	Management responsibilities procedures	Procedures that document the management commitment to the establishment and maintenance of the QMS by addressing quality policy, planning, responsibilities/authority/communication and management review. ***ISO 13485 Elements – SOPs implementing clause 5***	**USFDA PMA** Management review procedure(s)
6A.06	IMDRF (TGA, USFDA)	1	Resource management procedures	Procedures that document the adequate provision of resources to implement and maintain the QMS including human resources, infrastructure and work environment. ***ISO 13485 Elements – SOPs implementing clause 6***	
6A.07	IMDRF (TGA, USFDA)	1	Product realization procedures	High level product realization procedures such as those addressing planning and customer related processes ***ISO 13485 Elements – SOPs implementing sub clause 7.1 and 7.2***	

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
6A.08	IMDRF (TGA, USFDA)	1	Design and development procedures	Procedures that document the systematic and controlled development of the device design from initiation of the project to transfer to production. ***ISO 13485 Elements – SOPs for implementing sub clause 7.3***	**USFDA PMA** a) Design Control Procedure(s) b) Design & Development Planning Procedure(s) c) Design Input Procedure(s) d) Design Output - Procedure(s) e) Design Review Procedure(s) f) Design Verification Procedure(s) g) Design Validation Procedure(s) h) Risk Analysis Procedure(s) i) Design Transfer Procedure(s) j) Design Changes Procedure(s) k) Design History File Procedure(s)
6A.09	IMDRF (TGA, USFDA)	1	Purchasing procedures	Procedures that document that purchased products/services conform to established quality and/or product specifications. ***ISO 13485 Elements – SOPs to implement sub clause 7.4***	**USFDA PMA:** a) Purchasing Controls - Procedure(s) b) Receiving Acceptance Procedure(s) c) Discuss of How Receiving Acceptance are balanced with Purchasing Control activities
6A.10	IMDRF (TGA, USFDA)	1	Production and service controls procedures	Procedures that document the production and service activities are carried out under controlled conditions. These SOPS address issues such as cleanliness of product and contamination control; installation and servicing activities; process validation; identification and traceability; etc. ***ISO 13485 Elements – SOPs implementing sub clause 7.5***	**USFDA PMA** a) Servicing Procedures b) Final Acceptance Activities Procedure(s)
6A.11	IMDRF (TGA, USFDA)	1	Control of monitoring and measuring devices procedures	Procedure that document that monitoring and measuring equipment used in the QMS is controlled and continuously performing per the established requirements. ***ISO 13485 Element- SOPs for implementing sub clause 7.6***	**USFDA PMA** Inspection, Measuring & Test Equipment Procedure(s)
6A.12	IMDRF (TGA, USFDA)	1	QMS measurement, analysis and improvement procedures	Procedures that document how monitoring, measurement, analysis and improvement to ensure the conformity of the product and QMS, and to maintain the effectiveness of the QMS. ***ISO 13485 Element – SOPS for implementing clause 8***	**TGA** Note that the following should be included in this section: a) Procedures for the notification to TGA and other regulatory authorities of substantial changes to the QMS or to the kinds of medical devices manufactured b) Procedures for the issue of advisory notices, including the required notification to regulatory authorities for product recall c) Procedures for required notification to the TGA and other regulatory authorities of adverse events and changes to the QMS ***USFDA PMA:*** a) *Explain how complaint handling ties to MDR procedures* b) *Explain how risk management is tied to the CAPA activities* c) *CAPA Subsystem Procedures* d) *Nonconforming Product Procedure(s)* e) *Complaint Handling Procedures* f) *Quality Audit Procedures*
6A.13	IMDRF (TGA, USFDA)	1	Other Quality System Procedures Information	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.	

CHAPTER 6B – QUALITY MANAGEMENT SYSTEM DEVICE SPECIFIC INFORMATION

Row ID	Heading Class & Level	Heading	Common Content	Regional Content
6B.01	IMDRF (ANVISA, NMPA, EU, HC, TGA, USFDA) 1	Chapter Table of Contents	a) Includes all headings for the chapter. b) Specifies the page number for each item referred to in the table.	
6B.02	IMDRF (TGA, USFDA) 1	Quality management system information	Documentation and records specific to the subject device that results from the high level quality management system procedures for establishing and maintaining the quality management system such as the quality manual, quality policy, quality objectives, and control of documents, noted in Chapter 6A. ***ISO 13485 Elements – documentation specific to the subject device for the implementation of clause 4***	
6B.03	IMDRF (TGA, USFDA) 1	Management responsibilities information	Documentation and records specific to the subject device that result from the implementation the management responsibilities procedures noted in Chapter 6A. ***ISO 13485 Elements – documentation specific to the subject device for the implementation of clause 5***	
6B.04	IMDRF (TGA, USFDA) 1	Resource management information	Documentation and records specific to the subject device that result from the implementation the resource management procedures noted in Chapter 6A. ***ISO 13485 Elements – documentation specific to the subject device for the implementation of clause 6***	
6B.05	Regional (HC) 1	Device Specific Quality Plan		**HC** The review requirement for a quality plan are not met by the ISO 13485 certificate alone, instead refer to ISO 10005. A quality plan should specify "which processes, procedures and associated resources will be applied by whom and when to meet the requirements of a specific project, product, process or contract…". This information may be provided in an application in the form of a flow chart, process map, document matrix, table or text description. A quality plan specific for the subject device should link device requirements to the processes, resources and projects used by the manufacturer in producing that device.
6B.06	IMDRF (TGA, USFDA) 1	Product realization information	Documentation and records specific to the subject device that results from the implementation of the high level product realization procedures noted in Chapter 6A. ***ISO 13485 Elements – documentation specific to the subject device for the implementation of sub clause 7.1 and 7.2***	
6B.07	Regional (ANVISA, TGA, USFDA) 1	Design and development information	Documentation and records specific to the subject device that results from the implementation of the design and development procedures noted in Chapter 6A. **NOTE:** The source of this information is the Design and Development Records (e.g. DHF - Design History File). ***ISO 13485 Elements – documentation specific to the subject device for the implementation of sub clause 7.3***	**ANVISA and USFDA PMA** Design Control Information a) Design Outputs - List of Essential Design Outputs b) Design Validation- Justification for use of non-production units in validation testing, if applicable **ANVISA** a) Receiving and Acceptance Activities defined for critical row materials. "Critical raw materials" are those related with the "essential design outputs" indicated at the Design and Development Control. For example, if among the essential design outputs reference is made to specifications of raw material, this is considered a "critical raw material".

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
6B.08	IMDRF (TGA, USFDA)	1	Purchasing information	Documentation and records specific to the subject device that results from the implementation of purchasing procedures noted in Chapter 6A ***ISO 13485 Elements – documentation specific to the subject device for the implementation of sub clause 7.4***	**TGA** List of suppliers of goods or services that affect product conformity with requirements (critical suppliers) and a description of how purchasing requirements are fulfilled for these suppliers **USFDA PMA** a) List of Suppliers for the subject device b) Receiving and Acceptance activities for select suppliers
6B.09	Regional (ANVISA, HC, HSA, TGA USFDA)	1	Production and service controls information		**ANVISA, HC and TGA:** a) Detailed Manufacturing Flow Diagram b) Summary of in-process acceptance activities for subject device c) Process Validation Master Plan d) List of processes that have not been validated e) For each process validation considered critical to the safety and effectiveness of the device: i. Protocols/Procedures for the validated process ii. Process validation report iii. The procedures for monitoring and controlling the process parameters of a validated process should be fully described. iv. State the frequency of re-validation **HC and HSA NOTES:** a) Manufacturing flow diagram should a description is required of the methods used in, and quality controls used for, the manufacture, processing, packaging, storage and, where appropriate, the installation of the device. Sufficient detail must be provided to enable the judgement of the appropriateness of the quality controls in place. b) If multiple facilities are involved in the manufacture of a device, the applicable information for each facility must be submitted. If the information is identical for a number of sites, this should be stated. **USFDA PMA** a) Description of the use of standards in manufacturing the PMA device b) Detailed Manufacturing Flow Diagram c) Summary of in-process acceptance activities for subject device (optional) d) Process Validation Master Plan e) List of processes that will not be validated f) Protocols/Procedures for each validated process g) Completed process validation reports (optional/if available) ***ISO 13485 Elements – documentation specific to the subject device for the implementation of sub clause 7.5***
6B.10	IMDRF (TGA, USFDA)	1	Control of monitoring and measuring devices information	Documentation and records specific to the subject device that results from the implementation of the control of monitoring and measuring device procedures noted in Chapter 6A. ***ISO 13485 Elements – documentation specific to the subject device for the implementation of sub clause 7.6***	
6B.11	IMDRF (TGA, USFDA)	1	QMS measurement, analysis and	Documentation and records specific to the subject device that results from the implementation of the QMS measurement, analysis and improvement procedures noted in Chapter 6A.	

Row ID	Heading Class & Level		Heading	Common Content	Regional Content
			improvement information	***ISO 13485 Elements – documentation specific to the subject device for the implementation of clause 8***	
6B.12	IMDRF (TGA, HC, USFDA)	1	Other Device Specific Quality Management System Information	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.	