IMDRF International Medical Device Regulators Forum

Final

IMDRF/RPS WG/N13 FINAL:2024 (Edition 4)

In Vitro Diagnostic Device Regulatory Submission Table of Contents (IVD ToC)

AUTHORING GROUP

Regulated Product Submissions Table of Contents Working Group

25 June 2024

Preface

This document was produced by the International Medical Device Regulators Forum. There are no restrictions on the reproduction or use of this document; however, incorporation of this document, in part or in whole, into another 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.

Andrzej Rys, IMDRF Chair

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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 to continue to monitor use of this structure and work to continually improve the documents.

Introduction

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

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

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

Revisions to this document since its initial release reflect input from the public and experience gained from use of the initial version.

Scope

This document was developed for in-vitro diagnostics medical device (IVD) regulatory submissions. Submissions to request approval to conduct clinical trials are not within the scope of this document. Companion Diagnostics are in scope for this document.

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

Purpose

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

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

Definitions

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

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

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

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

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

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

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

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

Language requirements

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

Other general notes

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

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

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

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

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

For the EU, manufacturers are required to draw up and keep up to date technical documentation for their devices (see Art. 10 (4) of Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), i.e., the "technical documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed. The technical documentation shall include the elements set out in Annexes II and III". Implementing and delegated acts published under the IVDR as well as guidance documents endorsed by the Medical Device Coordination Group (MDCG) in accordance with Article 99 of the IVDR should be taken into account . The latest EN ISO version and related Annex Z of harmonised standards should be taken as reference to verify the correct presumption of conformity with the general safety and performance requirement of (GSPRs) of the IVDR.

Acronyms

ANVISA	National Health Surveillance Agency – Brazil
CAPA	Corrective Action and Preventive Action
EMDN	European Medical Device Nomenclature
EU	European Union
GMDN	Global Medical Device Nomenclature
HC	Health Canada
HSA	Health Sciences Authority – Singapore
IMDRF	International Medical Device Regulators Forum
JP	Japan
MDSAP	Medical Device Single Audit Program
MFDS	Ministry of Food and Drug Safety - Korea
MHRA	Medicines and Healthcare products Regulatory Agency - UK
NB	Notified Body
NMPA	National Medical Products Administration – China
PMDA	Pharmaceuticals and Medical Devices Agency – Japan
TGA	Therapeutic Goods Administration – Australia
ToC	Table of Contents
UK	United Kingdom
USFDA	United States Food and Drug Administration
WHO PQ	World Health Organization Prequalification Team – Diagnostics Assessment

Hierarchy presentation

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

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3.06.05.03.01.02	Full Report
3.06.05.03.01.03	Statistical Data
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6.14	QMS measurement, analysis and improvement
6.15	Device Specific Quality Plan
6.16	Quality management system verification document
6.17	Other Quality System Information

1. Chapter 1 – Regional Administrative

Row ID	Regions & Level		Heading	Common Content	Regional Content
1.01	IMDRF	1	Cover Letter	a) The cover letter should state applicant or sponsor name and/or their authorized representative/s, 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).	**EU** Consult relevant Notified Body (NB). **USFDA PMA and 510(k)** a) mailing address, b) official correspondent(s), c) phone/fax number(s), d) email address 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 should be prepared on company letterhead and include; a) Submission or Application ID that is generated electronically when completing the application form in TGA Business services portal. b) Contact details of the person authorised to liaise with TGA during the evaluation process c) Signed by the authorised person for the company

Row ID	Regions & Level		Heading	Common Content	Regional Content
				f) If the submission is unsolicited information (where accepted), this should be stated and any related reference number(s) provided. g) Identification of the regulatory jurisdiction(s) in which marketing is sought. NOTE: The cover letter should not contain any detailed scientific information.	d) Where applicable, details about the similarities and differences between the new device and the predicate device in a tabular format with respect to their design, construction, materials (including formulation), intended purpose, administration, packaging materials, sterilisation process and shelf-life e) Where a reduction of assessment fees is sought, a written request for reduced fees must be provided detailing each of the relevant application ID numbers to be considered for abridged assessment fees; and an explanation on why and how the assessment can be abridged. Refer to guidance on the TGA website: https://www.tga.gov.au/publication/reduction-assessment-fees-medical-devices
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	ANVISA, NMPA,	1	Application Form/Administr		**ANVISA**

Row ID	Regions & Level		Heading	Common Content	Regional Content
	EU, HC, JP, TGA, USFDA, WHO PQ		ative Information		ANVISA's Online Application Form containing general information related to the application shall be filled out by the authorized representative. **EU** NBs will each have their application form, including details of manufacturer (per IVDR Article 2 (23)), manufacturer's SRN (per IVDR Article 28), details of authorised representative if manufacturer not resident in EU (per IVDR Article 2 (25)), route to conformity (refer to IVDR Article 48), device details including classification (per IVDR Annex VIII) and European Medical Device Nomenclature (EMDN) code (per IVDR Article 23), details of design and manufacturing sites and subcontractor/supplier sites and copies of certificates. The application form should be signed by the manufacturer or an authorised representative. Content of technical documentation is determined by IVDR Annexes II and III. See also section "Other general notes" on page 7. Consult relevant NB for guidance on documentation submissions. **HC** Health Canada application forms should be included here. **JP** PMDA's "Application form" – from https://www.pmda.go.jp **NMPA** Application form shall be filled out and submitted on line

Row ID	Regions & Level		Heading	Common Content	Regional Content
					TGA Application forms to include administrative data of the applicant, application scope (including applicable conformity assessment procedure and type of application (initial, substantial change notification and application or recertification)), current certification details, manufacturer details, critical supplier details and device details including device classification. Refer to www.tga.gov.au for the most up to date information. **WHO PQ** WHO PQ applications refer to: http://www.who.int/diagnostics_laboratory/evaluations/Application/en/
1.05	ANVISA, NMPA, HC, HSA, TGA, USFDA	1	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: a) the identifier (e.g. bar code, catalogue, model or part number, UDI) b) a statement of its name/description (e.g. Trade name, size, intended use) **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	**ANVISA** The grouping (family) of in vitro medical devices may apply and shall be in compliance with the requirements set in the specific regulation. **Russia** 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

Row ID	Regions & Level		Heading	Common Content	Regional Content
				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.	b) The classification and the applicable classification rule For Class 4 IVDs (other than Class 4 Immunohematology reagents) and Companion diagnostics this table should also identify the following: c) Unique Product Identifiers (see the Therapeutic Goods (Medical Devices) Regulations 2002). For Class 4 IVDs that are IHRs, the name of each individual product included in the application. **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. **JP** For devices that fit the definition of a JMDN code, the applicant needs to include the Japanese Medical Device Nomenclature (JMDN) Code and Term. For medical devices that do not fit the definition of a JMDN code, the applicant needs to include a Dummy Code and Term JMDN information is available at https://www.std.pmda.go.jp/stdDB/index_en.html.

Row ID	Regions & Level		Heading	Common Content	Regional Content
1.06	ANVISA, NMPA, EU, HC, HSA, TGA, WHO PQ	1	Quality Management System, Full Quality System or other Regulatory Certificates		**ANVISA** Good Manufacturing Practice Certificate (GMPC) issued by ANVISA covering the product range. This document or the requirement protocol number must be provided by the authorized representative at the time of application. a) A product registration or a submission for change/inclusion of the manufacturer of products in classes III or IV requires a valid GMP certificate issued by ANVISA. However, review of the submission may be initiated prior to GMP certification. In such cases, the document proving that the application for GMP certification has been submitted to ANVISA must be provided, indicating the name of the manufacturer, the address of the site to be certified and the identification number of the GMP certification application to ANVISA. The registration or amendment shall be approved only after the GMP certificate has been issued. b) A valid GMP certificate issued by ANVISA is also required for renewal of product registration of products in classes III or IV. The document proving that the GMP certificate has been applied to ANVISA will be accepted if the GMP certificate has not been issued yet. However, if the outcome of the GMP certification process results in a rejection, the registration of the product will be canceled. **NMPA** a) Domestic applicant shall provide:

Row ID	Regions & Level		Heading	Common Content	Regional Content
					i) Copies of the duplicate of Enterprise Business License or the Legal Person Certificate of Public Institution. ii) Where production is entrusted to another enterprise, the qualification document of the entrusted enterprise (a copy of the duplicate of Enterprise Business License), the entrustment contract and the quality assurance agreement shall be provided. b) Imported Medical Device applicant shall provide: iii) Enterprise qualification certificate: the certificate that is issued by the competent authority for enterprise registration or the competent authority for medical devices in the country (region) where the overseas applicant is registered, and can prove that the overseas applicant exists and has the corresponding medical device production qualification; or the certificate that is issued by a third-party certification authority and can prove that the overseas applicant has the corresponding medical device production qualification. iv) Where production is entrusted to another enterprise, the qualification document of the entrusted enterprise, the entrustment contract and the quality assurance agreement shall be provided. **EU** • If manufacturer holds IVDD or IVDR certificate(s) issued by another NB covering the products in the application.

Row ID	Regions & Level		Heading	Common Content	Regional Content
					• If manufacturer does not hold EN ISO 13485 with the NB, the EN ISO 13485 certificate/s will need to be provided. • Where submission relates to eg application for Type Testing where the Product Quality System is issued by another NB, the IVDR certificate(s) covering the product/s in the application will also be provided. **HC** Health Canada will only accept MDSAP certificates that have been issued by recognized auditing organizations. **TGA** Copies of any current TGA or other regulatory authority certification, including full audit or surveillance reports, technical reports ((e.g. IVDR certification report, details of MDSAP certification held), referenced within the submission or required for the submission type. The referenced certificate requirements will vary based on the submission type and device classification - refer to TGA guidance for these requirements. **WHO PQ** Copy of the quality management system certificate certifying that the quality management system under which the device is designed and manufactured satisfies ISO 13485, Medical devices - Quality management systems - ISO 13485 certificates that are provided must state the scope of products it covers.

Row ID	Regions & Level		Heading	Common Content	Regional Content
					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	NMPA, HSA	1	Free Sale Certificate/ Certificate of Marketing authorization	a) List of the Regulatory Authorities that have provided current regulatory approval for the supply of this product in their country/region of authority b) Details of the type of regulatory approval obtained from each Regulatory Authority c) Current evidence of the regulatory approval, such as certificates provided by the Regulatory Authority Copies can be certified by a notary public or by the manufacturer. The manufacturer may be asked to present the original copy at any time. Information relating to export-only regulatory approvals should be clearly identifiable as export-only approvals.	**NMPA** a) Imported Medical Device applicant shall provide: The certificate issued by the competent authority for medical devices of the country (region) where the overseas applicant is registered or where the production address is located that permits the marketing of the product, and the innovative medical device that has not been marketed in the country (region) where the overseas applicant is registered or the production address is located may not be submitted. If the country (region) where the overseas applicant is registered or the production address is located does not manage this product as medical device, the applicant needs to provide the relevant certificates, including the certificate issued by the said country (region) permitting the marketing of this product. Innovative medical devices that have not been marketed in the country (region) where the overseas applicant is registered or the production address is located may not be submitted. **HSA** Where available, approval letters or certificates of marketing authorisation from our reference

Row ID	Regions & Level		Heading	Common Content	Regional Content
					regulatory agencies (Health Canada, Japan MHLW, US FDA, TGA, and EU NB) can be submitted.
1.08	HSA NMPA, TGA	1	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 **NMPA** a)For the registration application of medical devices reviewed and approved in accordance with the Special Review Procedure for Innovative Medical Devices, relevant explanations on passing the review for innovative medical devices shall be submitted. b) For the registration application of medical devices reviewed and approved in accordance with the Emergency Review and Approval Procedure for Medical Devices, relevant explanations on passing the emergency review and approval of medical devices shall be submitted. **TGA** Where a priority applicant determination has been made for an application for a conformity

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					assessment certificate issued by the TGA, the following information is required: • Notification of the delegate's decision of priority applicant determination More information is available at: https://www.tga.gov.au/resource/priority-applicant-guidelines-medical-devices-including-ivds
1.09	ANVISA, HC, USFDA, WHO PQ	1	User Fees		**ANVISA** User fee form must be obtained by the authorized representative at the time of application. It will not be available in advance to include here. **HC** Health Canada user fee forms should be included here. **USFDA PMA and 510(k)** FDA User Fee Form 3601 **WHO PQ** Attestation of fee payment. **JP** Attach a copy of receipt of the user fee payment to the application form. Information about user fee available at; https://www.pmda.go.jp/review-services/drug-reviews/user-fees/0001.html
1.10	IMDRF	1	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	

Row ID	Regions & Level		Heading	Common Content	Regional Content
			Regulator Interactions	applicant. Further, the specific subject device may have been subject to previous regulatory submissions to the regulator. The contents should be limited to the subject device as similar devices are addressed in other areas of the submission. If applicable, the following elements should be provided: i. List prior submissions or pre-submissions where regulator feedback was provided ii. For previous regulatory submission, include identification of applicable submission reference number. iii. For any pre-submission activities that have not previously been assigned any tracking/reference number, include the information package that is submitted prior to pre-submission meetings, the meeting agenda, any presentation slides, final meeting minutes, responses to any action items arising from the meetings, and any email correspondence related to specific aspects of the application. iv. Issues identified by the regulator in prior submissions (i.e., clinical study applications, withdrawn/deleted/denied regulatory submission) for the subject device. v. Issues identified and advice provided by the regulator in pre-submission	

Row ID	Regions & Level		Heading	Common Content	Regional Content
				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 (e.g. Health Canada does not need pre-submission information relating to interactions with ANVISA).	
1.11	TGA, USFDA, WHO PQ	1	Acceptance for Review Checklist		**USFDA PMA** 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*** **TGA** Includes the Supporting data checklists. **WHO PQ**

Row ID	Regions & Level		Heading	Common Content	Regional Content
					WHO requests submission of a Product Dossier Checklist to be completed by the manufacturer which provides dossier sections and page numbers indicating where every item on the checklist is addressed in the submission. Refer to: http://www.who.int/diagnostics_laboratory/evaluations/140701_pqdx_049_dossier_checklist_v2.pdf?ua=1 NOTE: This provides the reviewer with a quick guide to where evidence for one requirement may be found throughout the dossier.
1.12	ANVISA, HC, EU, TGA, USFDA	1	Statements/Certifications/Declarations of Conformity	**NO CONTENT AT THIS LEVEL**	**NO CONTENT AT THIS LEVEL**
1.12.01	USFDA	2	Chapter Retired	Content redundant with 2.10	
1.12.02	USFDA	2	Environmental Assessment		**USFDA PMA** a) If claiming categorical exclusion, information to justify the exclusion **OR** b) Provide the environmental assessment (only required for devices that present new environmental concerns)
1.12.03	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	USFDA	2	Indications for Use Statement with Rx and/or OTC designation Enclosure		**USFDA 510(k)** Use FDA Form 3881

Row ID	Regions & Level		Heading	Common Content	Regional Content
1.12.05	ANVISA, NMPA, HC, TGA, USFDA, WHO PQ	2	Truthful and Accurate Statement		**ANVISA** A dated statement signed by the legal representative and technical manager of the authorized representative must be submitted at the time of application. The statement must certify that the information provided in the application is true and that the information provided in the attached documents is correct and complete. **NMPA** The authenticity of the documents submitted (domestic product materials are issued by the applicant and imported product materials are issued by the applicant and the agent respectively) shall be guaranteed. **HC** The attestation that statements in the application are true and that the information provided in this application and in any attached documentation is accurate and complete is a component of the application form. Consult current Health Canada guidance for specific language. **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. Manufacturer Statutory Declarations

Row ID	Regions & Level		Heading	Common Content	Regional Content
					Statements of undertaking by the manufacturer as required by conformity assessment procedures set in the Therapeutic Goods (Medical Devices) Regulations 2002 **<u>USFDA 510(k)</u>** a) Truthful and Accurate statement per 21 CFR 807.97(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) **<u>WHO PQ</u>** a) A signed Manufacturer Declaration WHO Document PQDx_049 “Product Dossier Checklist” attesting that all the information provided in this product dossier is current and correct. b) A letter attesting that the content of the electronic version is an exact duplicate of the printed copy.

Row ID	Regions & Level		Heading	Common Content	Regional Content
1.12.06	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	**EU** See IVDR Annex IV and Article 17 for requirements. **NMPA** Applicants shall make statement on the following contents: a) The proposed product shall meet the requirements of the Measures for the Administration of Registration and Filing of Medical Devices and other relevant regulations. b) The proposed product shall meet the requirements related to the classification in the Rules for the Classification of Medical Devices. c) The proposed product conforms to the current national standards and industry standards. Also, a list of conforming to standards shall be provided. **JP** Declaration and/or certificate that the relevant product is manufactured to conform to the essential principles and/or the quality management system. The applicant is advised to prepare the declaration of conformity according to ISO 17050-1 “Conformity Assessment - Supplier’s Declaration of Conformity - Part 1: General Requirement.” **TGA** The wording of the Declaration of Conformity will depend on the conformity assessment procedure chosen by the manufacturer. Templates for each of the four possible types of Declarations of

Row ID	Regions & Level		Heading	Common Content	Regional Content
					Conformity under Schedule 3 of the Therapeutic Goods (Medical Devices) Regulations 2002 are available at Australian declaration of conformity templates (medical devices) | Therapeutic Goods Administration (TGA). **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	Where applicable, letter from the owner of any separate document referenced in the submission (e.g. Master File or previous regulatory submission), granting access to the information in the referenced document. The letter should include the information of the applicant who cited the separate document (e.g. Master File or previous regulatory submission), the product name, the document number that has been filed, and the page number/chapter information of the separate document authorized to be cited.	
1.14	ANVISA, NMPA, HSA	1	Letter of Authorization		**ANVISA** Letter of authorization from the manufacturer authorizing the local representative to submit the application to ANVISA and place its product on the

Row ID	Regions & Level		Heading	Common Content	Regional Content
					Brazilian market, according to the template available at www.anvisa.gov.br. **NMPA** a) When the imported medical device registrant applies for registration through its foreign-invested enterprise established within the territory of China in accordance with relevant provisions on the production of imported medical devices in enterprises within the territory of China, the applicant shall submit not only the letter of statement or authorization showing the consent of the imported medical device registrant for the registration application, but also the documents explaining the relationship (including legal liability) between the applicant and the imported medical device registrant, with relevant agreements, quality liability documents, equity certificates, etc. attached. b) Copies of the Power of Attorney and Letter of Commitment of the appointed agent within the territory of China and the duplicate of Business License. **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 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.

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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 .	

2. Chapter 2 – Submission Context

Row ID	Regions & 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	1	General Summary of Submission	a) Statement of the device type (e.g. Tacrolimus test system, blood specimen collection device, calibrator) 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). 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	**ANVISA** If renewal, amendment or change, identification of the registration/notification number issued by ANVISA. **NMPA** a) If product registration, the applicant shall describe the general name and the basis for its determination, b) If product registration, the applicant shall describe the management category, including the name of the category sub-category, the first-level product category, the second-level product category, the management category, and the classification code. c) If product registration, the applicant shall describe the scope. d) if applicable, any high-level background information or unusual details that the manufacturer wishes to highlight in relation to the device, its history or previous submissions or relation to other approved devices.

Row ID	Regions & Level		Heading	Common Content	Regional Content
				in relation to the device, its history or relation to other approved devices or previous submissions (provides context to submission).	**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. If amendment, there may be multiple sections where there is “no change”. These folders would thus be considered “Not applicable”. A list of these sections may be provided here, identified as “no change” and then the appropriate folders would be excluded from the submission. If amendment or new submission, if a report can fit into multiple sections, only one copy should be included and references to the single copy provided in other sections where the information might be applicable. If requesting priority review per Section 15 of the application form, the justification should be provided here. **TGA** If recertification or substantial change notification and application for a conformity assessment certificate, identification of the affected TGA certificate number(s) must be provided. **USFDA 510(k)** Executive Summary as described in the “Guidance for Industry and Food and Drug Administration Staff - Format for Traditional and Abbreviated 510(k)s” **HSA**

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					Executive summary as per GN-18 available at www.hsa.gov.sg
2.03	USFDA	1	Summary and Certifications for Regulatory 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	2	Comprehensive Device Description and Principle of Operation	a) A general description of the device, including: i. The device name. ii. What does it do? iii. Who uses it and for what? (high level statement) iv. Where to use it? (places/environment where the device is intended to be used) v. General description of the principle of the assay method or instrument principles of operation. vi. Description of the components (e.g. reagents, assay controls, calibrators, cassette, etc.) and where appropriate, a description of the	**EU** See IVDR Annex II Section 1.1 for requirements. The Basic UDI-DI assigned by the manufacturer should be provided. Refer to Annex VI Part C for definitions and requirements. **NMPA** Describe the preparation methods of quality control products and calibrators. For more detailed information, please find “Description of the devices and operating principles” in *Requirements for Registration Application Dossiers of Medical Devices and the Format of Approval Certificates (No.121 in 2021).*

Row ID	Regions & Level		Heading	Common Content	Regional Content
				reactive ingredients of relevant components (such as antibodies, antigens, nucleic acid primers, probes, etc.). vii. If applicable, labelled pictorial representation (diagrams, photos, drawings). viii. If system, how the components relate? ix. If applicable, identify if the device incorporates software/firmware and its role. x. If applicable, identify the instrument(s) required to perform the test. b) Product specification, including: i. Physical characteristics of relevance to the end user (dimensions, weight) ii. If applicable, technical features and operating modes iii. If applicable, operating specifications and performance characteristics (e.g. electrical power requirements, settings and associated allowable ranges/limits, units of measure, temperature and humidity limits, throughput (number of tests per hour), analytical and clinical sensitivity and specificity) iv. If applicable, a complete list of the configurations/models of the devices and a summary of the differences in specifications (comparison table	**HC** If the application is an amendment, this section should describe the up-to-date device as applied for in the amendment, i.e. including the modifications. Modifications (e.g. changes in design, performance and indications) should be further detailed in Section 2.04.04 below. Components or accessories that can be sold separately should be identified. **JP** Explain that the established product specifications are necessary and sufficient to ensure the efficacy, safety, and quality of the product. **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) **WHO PQ** a) With respect to **item a) vii.,** WHO PQ requires photographs of all kit components (packaged and individually). Not optional. b) With respect to biological safety (**item h**)), WHO PQ requires the following additional information: i. Details of the use of the biological component in the product ii. A description of steps taken for the reduction of transmission or infection risk

Row ID	Regions & Level		Heading	Common Content	Regional Content
				and/or pictures/diagrams with supporting text). c) Describe the different specimen types that can be used for this device (e.g. serum, plasma, urine, cerebrospinal fluid), including any additives that are required (e.g. anticoagulant). d) Describe the use of controls. If applicable, a list of compatible control materials or control material specifications. e) Description of the accessories, other IVD or non-IVD medical devices and other products, which are intended to be used in combination with the IVD medical device. f) If approved by the regulator, provide the approval number and identification for each of the accessories, other IVD or non-IVD medical devices and other products, which are intended to be used in combination with the IVD medical device. g) 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) and source (e.g. blood, bone, heart, any other tissue or cells). Where a significant risk is identified, a brief summary of evaluations performed to minimize biological risks, in	iii. A determination of the residual risk of transmission or infection to the user of the device from these biological agents after risk reduction methods have been applied. If there are no such methods that apply to the product, state that this is the case. iv. Information on how users of the device are informed of any residual risk

Row ID	Regions & Level		Heading	Common Content	Regional Content
				particular, with regard to viruses and other transmissible agents. h) Description of the collection and/or transport container(s) provided with the IVD medical device or a description of specifications or recommended collection and/or transport container(s). i) If applicable, a listing of assays that are compatible with the instrument. j) If applicable, a listing of compatible instruments. k) A list of any software to be used with the IVD medical device and a description of its role in the delivery of the intended purpose. l) If applicable, engineering diagrams/prints/schematics of the device (should be provided as a separate file within the submission). **NOTE**: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the comprehensive device description and principles of operations provided in this section regarding the subject device.	
2.04.02	EU, HC, HSA, JP, TGA	2	Material Specifications	**HC and JP** a) Details of relevant material identifications and specifications, including critical raw materials and components should be provided. Information should include complete chemical and physical	**EU** This shall include a description of the critical ingredients of the device such as antibodies, antigens, enzymes and nucleic acid primers provided or recommended for use with the device. See IVDR Annex II 3.1 for requirements.

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				characterization of all component materials. **NOTE:** If applicable, chemicals should 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.	**HSA and TGA** a) All components of the IVD medical device should be listed and chemically and biologically characterised, including antibodies, antigens, assay controls, substrates used to detect antigen-antibody complexes, and test reagents. Appropriate references should be cited. b) If synthetic peptides are used, the peptide sequence should be provided. c) If applicable, information is to be provided on irradiating components, non-ionizing or ionizing. d) if applicable, information to be provided on the poison or controlled substance (e.g. Buprenorphine in drug assay kit).
2.04.03	ANVISA, EU, HC, HSA, TGA, USFDA WHO PQ	2	Description of Device Packaging	a) A brief description of the packaging of the devices, including the packaging configuration and materials involved. This is not intended to include shipping/transport packaging. b) Specific packaging of accessories marketed together with the IVD medical devices shall also be described.	**EU** See IVDR Annex I GSPRs 11.2-11.5 for requirements. **NMPA** For sterile medical devices, the information on the sterile barrier system should be stated; for medical devices with microbial limit requirements, the packaging information for maintaining the microbial limit should be stated. Explain how to ensure that the end user can clearly identify the integrity of the package.
2.04.04	ANVISA, EU, HC, HSA, TGA, USFDA, WHO PQ	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	**EU** IVDR Annex II Section 3.1 requires the manufacturer to provide “information to allow the design stages applied to the device” to be understood. For initial applications under the IVDR, if the device has been previously marketed under

Row ID	Regions & Level		Heading	Common Content	Regional Content
				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 performance of the final IVD medical device design.	the IVDD, confirm whether any changes have been made in comparison to the IVDD-certified device. **USFDA 510(k)** It is highly recommended that a description of all changes made to the device since the last 510(k) clearance be provided for a device that has received prior 510(k) clearance. **NMPA** Explain the research and development background and purpose of the product applied for registration. If there are similar products or predecessor products for reference, the information of the similar products or predecessor products should be provided, and the reasons for choosing them as R&D reference should be explained. **WHO PQ** Provision of the date of design lock down. This is considered to the date that final documentation is signed off, including quality control and quality assurance specifications, and finalized method in the IFU. **HC** It is highly recommended that a description of all changes made to the device since the issuance of the last medical device licence or licence amendment be provided for a device that has had a previous version licensed in Canada.
2.04.05	IMDRF	2	Reference and Comparison to	a) A list of the similar devices (available on local and international market) and/or	**EU** See IVDR Annex II Section 1.2 for requirements.

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			Similar and/or Previous Generations of the Device	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. Include a comparison of indications for use and the technology between the comparison device and the subject device. 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. **NMPA** The comparison of the list shows the similarities and differences between the declared product and similar products and/or previous-generation products in terms of working principle, structural composition, manufacturing materials, performance indicators, mode of action (such as implantation, intervention), and scope of application.

Row ID	Regions & Level		Heading	Common Content	Regional Content
2.04.06	USFDA, NMPA	2	Substantial Equivalence Discussion		**<u>USFDA 510(k)</u>** a) Identify the predicate device(s) 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 510(k) 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). 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. **<u>NMPA</u>** For the class II and class III medical devices that are exempt from clinical evaluation, the applicant should follow the "Technical Guidelines for the Comparative Description of Products Listed in the Catalog of Medical Devices Exempt from Clinical Evaluation", in terms of basic principles, structural composition, performance, safety and scope of application, etc., to prove the safety and effectiveness of the product.

Row ID	Regions & Level		Heading	Common Content	Regional Content
2.05	IMDRF	1	Indications for Use and/or Intended Use	**NO CONTENT AT THIS LEVEL**	
2.05.01	IMDRF	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 what specific disorder, condition, or risk factor of interest (i.e. the analyte to be measured) is detected and the purpose provided by the device (e.g. screening, monitoring, diagnosis or aid to diagnosis). It should identify: i. Instruments on which the device can be used, ii. if the assay is automated or not, iii. is the IVD medical device qualitative or quantitative, iv. and the specimen types (e.g. serum, plasma, urine, cerebrospinal fluid), including any additives that are required (e.g. anticoagulant) b) **Intended user:** Lay person or professional? c) Identify if the device is intended for **single or multiple use** d) **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.	**EU** See IVDR Annex II Section 1.1 and Annex I section 20.4.1 for complete list of requirements. **USFDA** a) For Intended Use/Indication for Use see 21 CFR 809.10 **HC** The content of this section should be contained in a single body of text. **NMPA** Describe other products that can be used in combination with it to achieve the intended use.

Row ID	Regions & Level		Heading	Common Content	Regional Content
				iii. If applicable, when/where the use of the IVD medical device should be avoided. iv. 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. e) 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 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	
2.05.02	ANVISA, EU, HC, HSA, TGA, USFDA	2	Intended Environment/Setting for use	a) The setting where the device is intended to be used (e.g. home use, domestic use, self-testing, near-patient, point of care). Multiple options can be indicated. b) If applicable, environmental conditions that can affect the device's safety and/or	**USFDA PMA and 510(k)** FDA includes this information in the indications for use and product labelling.

Row ID	Regions & Level		Heading	Common Content	Regional Content
				performance (e.g. temperature, humidity, power, pressure, movement).	
2.05.03	NMPA, USFDA	2	Pediatric Use		**<u>USFDA PMA</u>** 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. **<u>NMPA</u>** If the target patient population of the declared product includes newborns, infants or children, the specific group of non-adults who are expected to use the declared product to treat, diagnose, prevent, alleviate or cure the disease or condition shall be described.
2.05.04	NMPA, TGA, USFDA	2	Limitations/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. **NOTE:** The statement of limitations/contraindications for the device must be as presented in the labelling.	**<u>EU</u>** IVDR Annex I, GSPR 20.1 (g) contains additional information. **<u>USFDA PMA and 510(k)</u>** FDA includes this information in the indications for use and product labelling **<u>NMPA</u>**

Row ID	Regions & Level		Heading	Common Content	Regional Content
					If applicable, specify the disease or conditions or specific populations (e.g. children, the elderly, pregnant and lactating women, and people with liver and kidney dysfunction) that would make use of the device inadvisable due to unfavorable risk/benefit profile.
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 already marketed, 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) Include a list of all countries in which the device has been removed from marketing for any reason related to the safety or effectiveness of the device.	**All Regions but USFDA:** a) If the subject device is different in any way (e.g. design, labelling, specifications, indications) from those approved or marketed in other jurisdiction, the differences should be described. b) The month and year of market approval in each country or jurisdiction where the device is marketed. If the device has been marketed for greater than 10 years, a statement of greater than 10 years can be made. c) For each of the markets listed in (a) above, and statement of the commercial names used in those markets OR a clear statement that the commercial names are the same in all jurisdictions. d) State the date of data capture for the market history data e) If the subject device has been the subject of any previous compassionate use and/or clinical trials this should be identified and, if applicable, relevant reference numbers provided. **EU**

Row ID	Regions & Level		Heading	Common Content	Regional Content
					Link to section 2.04.05; see also IVDR Annex II Section 1.2. **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 informed. a) If applicable, market history should include data for previous generations of the device. b) Information regarding any Canadian Investigational Testing Authorizations should be included. In this context, compassionate use includes **any** Special Access Authorizations. **TGA** Include any notifications to comparable overseas regulators of substantial change(s) to the device. Comparable overseas regulators are defined at: https://www.tga.gov.au/resources/resource/guidance/comparable-overseas-regulators-medical-device-applications
2.06.02	IMDRF	2	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 events is voluminous, provide a summary by event type that state the number of reported events for each event type.	**EU** Link to sections 6.09 for procedures and 2.07; see also IVDR CHAPTER VII Section 1 and Annex III for requirements relating to post-market surveillance. **USFDA 510(k)**

Row ID	Regions & Level		Heading	Common Content	Regional Content
				c) List of the IVD 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.	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. **NMPA** If applicable, List adverse events/incidents associated with the device and a statement of the period associated with this data. Provide the time of occurrence and a discussion of the handling and solution given by the manufacturer in each case, including measures to actively control product risks, reports to medical device adverse event monitoring technical institutions, and descriptions of investigations and handling by relevant departments. At the same time, the above-mentioned adverse events and recalls should be analyzed and evaluated, the reasons for the adverse events and recalls should be clarified, and the impact on their safety and effectiveness should be explained. If the number of adverse events or recalls is large, the number involved in each type should be summarized according to the type of event.
2.06.03	HC, EU, 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.	**EU** Link to sections 6.09 for procedures and 2.07; see also IVDR CHAPTER VII Section 1 and Annex III

Row ID	Regions & Level		Heading	Common Content	Regional Content
				b) Provide the rates calculated as follows for each country/region: i. Incident rate = # adverse events/incidents divided by # units sold expressed as a percentage ii. Recall rate = # recalls divided by # units sold expressed as a percentage Rates may be presented in other appropriate units such as per patient year of use or per use. In this case, methods for determining these rates should be presented and any assumptions supported. c) Critical analyses of the rates calculated (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. ii. Sales in this context should be reported as the number of units sold.	for requirements relating to post-market surveillance.
2.06.04	TGA, WHO PQ	2	Evaluation/Inspection Reports		**TGA** Copies of full audit reports and technical assessment reports issued by other parties (e.g.

Row ID	Regions & Level		Heading	Common Content	Regional Content
					Notified Body certification reports). • The audit reports provided should be from the most recent audit and if the most recent audit is not a full initial or recertification, then the most recent full or recertification should also be provided. • The technical assessment reports should be relevant to the subject device in the submission. **<u>WHO PQ</u>** Copies of the last 2 Evaluation/Inspection Reports from other parties (e.g. Notified Body inspection reports, MDSAP).
2.07	EU, HC, USFDA	1	Post-Market Study Plans	Post-Market Study Plans may include clinical or nonclinical study plans. The documentation provided here will not include final reports and analysis, and instead includes study plan information only. This may include: a) Study Objectives b) Study Design c) Subjects and Sites information d) Endpoints (primary and secondary) e) Summary of Data Analysis plan f) Length and frequency of follow-up Note: Post-Market Non-Clinical or Clinical Data from one region provided during the pre-market phase to a second region would be considered non-clinical or clinical data for the second region and would reside in Chapter 3 or Chapter 4, respectively.	**<u>EU</u>** See Part B of IVDR Annex XIII for requirements relating to post-market performance follow-up (PMPF); procedures to be in section 6.09, records or outputs to be provided in section 4.06.
2.08	IMDRF	1	Risk Management	a) A summary of the risks identified during the risk analysis process and how these	**<u>EU</u>**

Row ID	Regions & Level		Heading	Common Content	Regional Content
				risks have been controlled to an acceptable level. Plans can be considered part of the risk management documentation. b) The results of the risk analysis should provide a conclusion with evidence that remaining risks are acceptable when compared to the benefits. c) Where a standard is followed, identify the standard.	Risk management is addressed in IVDR Annex I GSPR 3; see also IVDR Annex I GSPRs 1, 2, 4, 8 and Annex II Section 5. Guidance is also available in EN ISO 14971 Medical devices – Application of risk management to medical devices. **NMPA** Product risk management data is the data formed by recording the product risk management process and the results of its review. The following content shall be provided and the traceability of the following processes for each identified hazard shall be explained. a) Risk analysis: including identification of the scope of medical devices and safety-related features, identification of hazards, and estimation of the risk of each hazardous situation. b) Risk assessment: For each identified hazard situation, evaluate and decide whether the risk needs to be reduced, and if necessary, describe how to carry out corresponding risk control. c) Risk control: describe the related content of risk control implemented to reduce risk. d) Evaluation of the acceptability of any one or more residual risks. e) Compared with the product benefit, the comprehensive evaluation product risk is acceptable. **TGA** For Class 1-3 IVDs, a summary (text format or as a reduced table) of the risk management activities

Row ID	Regions & Level		Heading	Common Content	Regional Content
					performed by the manufacturer of the device must be provided. The summary should include as a minimum: a) Details on how the risk acceptability criteria have been determined b) A list of possible hazards arising from false positive or false negative results, as well as IVD associated hazards, and user/operator hazards. Please ensure that all harms associated with adverse events reported in clinical investigations, literature reviews, and clinical experience are included in the risk analysis. c) The risk mitigation strategies that have been implemented to reduce unacceptable risks d) An assessment of the acceptability of one or more residual risks, and e) A risk vs benefit analysis to demonstrate that remaining risks are acceptable when compared to the benefits. Preferably, the risk analysis should be based on recognised standards such as ISO 14971 and be part of the manufacturer's risk management plan. For Class 4 IVDs, detailed information about the risk management plan including risk analysis, risk evaluation and risk control, must be provided. **<u>WHO PQ</u>** In addition, WHO PQ requires evidence that the risk analysis is part of the manufacturer's risk management plan.
2.09	ANVISA, NMPA,	1	Essential Principles (EP) of Safety and	a) An EP checklist established for the medical devices, information about method(s) used to demonstrate	**<u>EU</u>** See IVDR Annex I for the general safety and performance requirements (GSPRs) and IVDR

Row ID	Regions & Level		Heading	Common Content	Regional Content
	EU, HSA, JP, TGA		Performance Checklist	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; comparison to a similar device already available on the market.	Annex II Section 4 which explains how a manufacturer should document their assessment. • It is recommended that the above information is provided in the form of a checklist against the GSPRs to show how compliance with the individual GSPRs has been achieved. • Identify the precise identity of documents supporting compliance with each GSPR. **HSA** 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. **TGA** The checklist of conformity to the Australian Essential Principles is to be submitted – checklist available at https://www.tga.gov.au. **NMPA** For the documents included in the product registration application materials, the specific position in the application materials should be stated; for the documents not included in the product registration application materials, the name of the evidence file and its in the quality management system document should be indicated. Number for reference.
2.10	IMDRF	1	Standards	**NO CONTENT AT THIS LEVEL**	

Row ID	Regions & Level		Heading	Common Content	Regional Content
2.10.01	IMDRF	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. 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** The list of standards complied can be submitted together with the Essential Principles Checklist. **NMPA** When applicable, this should include reference to the device relevant NMPA registration compulsory standards. For compulsory industry standards, if the structural features, intended use, and use methods of the declared product are inconsistent with the scope of application of the compulsory standard, the applicant shall provide an explanation on the non-applicability of the compulsory standard and provide verified supporting materials. **EU** See IVDR Annex I and Annex II Section 4 for requirements. • Devices that are in conformity with the relevant harmonised standards are presumed to be in conformity with the requirements of the IVDR covered by those standards. • An overview of used standards, including versions, typically is added in the GSPR checklist. • The documentation should demonstrate that all relevant and available Common Specifications (CS) and relevant standards, both harmonised and other product specific standards, have been considered • The technical documentation should continue to demonstrate that the files meet the state of the

Row ID	Regions & Level		Heading	Common Content	Regional Content
					art, including consideration of revised or replaced standards or CS. • Indicate other EU legislation which applies. If a device is governed by multiple regulations or directives, all applicable regulations / directives should be identified. **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. **HSA** The list of standards complied to can be submitted together with the Essential Principles Checklist. This information needs only to be presented once.
2.10.02	ANVISA, NMPA, HC, USFDA	2	Declaration and/or Certification of Conformity		**ANVISA** a) Conformity Assessment Certification according to applicable standards, issued by a Third Party Organization (e.g. Notify Body) officially recognized by the Regulatory Authority. The

Row ID	Regions & Level		Heading	Common Content	Regional Content
					certificate shall be issued under the SBAC - Sistema Brasileiro de Avaliação da Conformidade / Brazilian Conformity Assessment System - INMETRO. b) Certain types of devices (intra-uterine devices and blood bags) require pre-submission performance testing conducted by an official laboratory (INCQS/FioCruz – Instituto Nacional de Controle de Qualidade em Saúde) in Brazil. The report of these analyses shall be part of the submission. **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** Consider Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices **NMPA** a) product technical requirements The technical requirements for medical device products shall be compiled in accordance with the relevant requirements.

Row ID	Regions & Level		Heading	Common Content	Regional Content
					b) Product inspection report An inspection report in any of the following forms can be submitted: i: self-inspection report issued by the applicant. ii: an inspection report issued by a qualified medical device inspection agency.
2.11	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.	**NMPA** If applicable, specify the detailed information of other products that are used in conjunction with the declared product to achieve the intended use. For approved parts or accessories used in conjunction, the registration certificate number and the registration certificate information published on the official website of the State Drug Administration shall be provided.

3. Chapter 3 – Analytical performance and other evidence

Row ID	Regions & 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			Chapter Retired		
3.03			Chapter Retired		
3.04			Chapter Retired		
3.04.01			Chapter Retired		
3.04.02			Chapter Retired		
3.05	IMDRF	1	Analytical Performance	**NO CONTENT AT THIS LEVEL**	
3.05.01	IMDRF	2	Stability of Specimen(s)	Information regarding and studies to support the stability, storage and where appropriate, transport, of all of the specimen type(s) identified in the labelling, including any and all recommended additives (e.g. anticoagulants) is to be provided in this section. This should include:	**EU** For specific IVDR requirements see IVDR Annex II Section 6.1.1.

				a) For each specimen type identified in the labelling, a description of the recommended storage parameters and when applicable, transport conditions (e.g. duration, temperatures and freeze/thaw cycles). b) A justification on the selection of the studies performed. c) Provide summary of the evidence that falls within this category. d) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR** e) A discussion 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 study results provided in this section regarding the subject device.	
3.05.01.01	IMDRF	3	[Study description, study identifier, date of initiation, date of completion]	**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: Storage of serum samples for 7 days at 2-8ºC or 4 days at -20ºC. Level 4: Summary Level 4: Full Report Level 3: Validation of 3 freeze/thaw cycles for serum samples Level 4: Summary Level 4: Full Report	
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 - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.
3.05.01.01.03	USFDA	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **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	Validation of Specimens	Studies to support the validity of specimen type(s) used in the analytical and clinical studies as representative of all of the sample type(s) identified in the labelling, including any and all recommended additives (e.g. anticoagulants), as well as contrived specimens used in certain analytical studies are to be included in this section. This should include: a) A list of the specimen type(s) used, including any additives (e.g. anticoagulants), in each of the analytical performance studies. If the same specimens are used for all analytical studies this can be stated and the specimen type identified. b) For any or all of the analytical and clinical studies, if a particular specimen type(s) including additives (e.g. anticoagulants), has been chosen as representative of other specimen types identified in the labelling, this should be described and supported. c) If the preparation of the specimen has not followed the protocol described in the current labelling, this should be identified and validated. d) A justification of the selection of the studies performed. e) Provide summary of the evidence that falls within this category. f) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR**	**EU** For specific IVDR requirements see IVDR Annex II Sections 6.1.1 and 6.1.2.5. **TGA** All claimed specimen types should be validated and taken through the entire process from the recommended sample preparation/handling through to the assay protocol to determine if specimens used in the kit will affect performance of the device. The study may include specimen equivalence studies and statistical analysis of the data depending on the device classification **WHO PQ** In addition, information should be provided on the relationship of specimens collected by different methods. (Note: this applies, for example, to specimens that can be collected by a swab or by other means).

				g) 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 study results provided in this section regarding the subject IVD medical device.	
3.05.02.01	IMDRF	3	[Study description, study identifier, date of initiation, date of completion]	**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.	
3.05.02.01.01	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 - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.
3.05.02.01.03	USFDA	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **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	Metrological traceability of calibrator and control material values	Evidence that supports the metrological traceability of values assigned to calibrators and trueness control materials. This should include: a) A description of all calibrators and trueness control materials associated with the system. b) A justification of the selection of the studies performed. c) Provide summary of the evidence that falls within this category, including for example, methods and acceptance criteria for the metrological traceability to reference materials and/or reference measurement procedures and a description of value assignment and validation. d) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR** e) A statement of why this category of study is not applicable to this case. **NOTES:** i. Precision control materials used during analytical studies to establish the reproducibility of a measurement procedure do not require the assessment of metrological traceability to a reference material or a reference method. ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the analytical performance study results provided in this	**EU** For specific IVDR requirements see IVDR Annex II Section 6.1.2.4.

				section regarding the subject IVD medical device	
3.05.03.01	ANVISA, EU, HC, HSA, TGA, USFDA	3	[Study description, study identifier, date of initiation, date of completion]	**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	ANVISA, EU, HC, HSA, TGA, USFDA	4	Summary	A summary of the specific study described in the custom heading above.	
3.05.03.01.02	ANVISA, EU, HC, HSA, TGA, USFDA	4	Full Report	The test report for the test described in the custom heading above.	**TGA** The study may include statistical analysis of the data depending on the device classification. **USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.
3.05.03.01.03	USFDA	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **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	Accuracy of Measurement	**NO CONTENT AT THIS LEVEL** **NOTE:** The general term measurement accuracy is currently used to cover both trueness and precision, whereas this term was used in the past to cover only the one component now named trueness. While measurement **trueness**, affected by systematic error, is normally expressed in terms of bias, measurement **precision**, affected by random error, is naturally expressed in terms of standard deviation. Accuracy is affected by a combination of systematic and random effects that contribute as individual components of the total error of measurement.	
3.05.04.01	IMDRF	3	Trueness	This section should provide a summary of information and evidence relating to the trueness of the measurement procedure. Trueness measures apply to both quantitative and qualitative assays only when a reference standard or method is available. This should include: a) A rationale for the reference standard or method(s) used b) A summary of the evidence that falls within this category c) A discussion and a conclusion 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.	**EU** For specific IVDR requirements see IVDR Annex II Section 6.1.2.1(a). **NMPA** If there are different applicable models contained in the registration application, the test data and summary of the evaluation of above projects conducted on different models shall be submitted. **USFDA 510(k)** This is equivalent to a “method comparison study”; 510(k)s can compare to a reference standard OR a predicate device. **JP** Provide comparison studies, if it is investigated by non-clinical samples.

				NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the analytical performance study results provided in this section regarding the subject IVD medical device	**TGA** Where an IVD medical device that is to be marketed differs from an approved predicate IVD medical device (i.e. a substantial change is involved) a method comparison study may be done to demonstrate the devices to be similar to such an extent that there would be no significant difference in safety or performance.
3.05.04.01.01	IMDRF	4	[Study description, study identifier, date of initiation, date of completion]	**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.	
3.05.04.01.01.01	IMDRF	5	Summary	A summary of the specific study described in the custom heading above.	
3.05.04.01.01.02	IMDRF	5	Full Report	The test report for the test described in the custom heading above.	**TGA** The study may include statistical analysis of the data depending on the device classification. **USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.

3.05.04.01.01.03	USFDA	5	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **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**.
3.05.04.02	IMDRF	3	Precision (Repeatability and Reproducibility)	A summary of evidence that supports the precision characteristics of the measurement of the subject IVD medical device is to be included in this section. This should include: a) A justification of the selection of the studies performed. b) A summary of the evidence that falls within this category, including: i. Repeatability estimates and a brief summary about the studies used to estimate, as appropriate, within-run variability. ii. Reproducibility estimates and a brief summary of the studies used to estimate, as appropriate, variability between days, runs, sites, lots, operators (intended users) and instruments. Such variability is also known as **"Intermediate Precision".** c) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR**	**<u>EU</u>** For specific IVDR requirements see IVDR Annex II Section 6.1.2.1(b). **<u>NMPA</u>** If there are different applicable models contained in the registration application, the test data and summary of the evaluation of above projects conducted on different models shall be submitted.

				d) A statement of why this category of study is not applicable to this case. **NOTE:** i. Studies should include the use of specimens that represent the full range of expected analyte (measured) concentrations that can be measured by the product, as claimed by the manufacturer. ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the analytical performance study results provided in this section regarding the subject IVD medical device.	
3.05.04.02.01	IMDRF	4	[Study description, study identifier, date of initiation, date of completion]	**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.	
3.05.04.02.01.01	IMDRF	5	Summary	A summary of the specific study described in the custom heading above.	
3.05.04.02.01.02	IMDRF	5	Full Report	The test report for the test described in the custom heading above.	**TGA** The study may include statistical analysis of the data depending on the device classification.

3.05.04.02.01.03	USFDA	5	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **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	Analytical Sensitivity	Evidence that supports the analytical sensitivity of the subject IVD medical device is to be included in this section. This may include studies to establish the limit of blank (LoB), limit of detection (LoD), and/or limit of quantitation (LoQ). This should include: a) A justification of the selection of the studies performed. b) A summary of the evidence that falls within this category c) A discussion and a conclusion 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 analytical performance study results provided in this section regarding the subject IVD medical device	**EU** For specific IVDR requirements see IVDR Annex II Section 6.1.2.2. **NMPA** If there are different applicable models contained in the registration application, the test data and summary of the evaluation of above projects conducted on different models shall be submitted.

3.05.05.01	IMDRF	3	[Study description, study identifier, date of initiation, date of completion]	**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.	
3.05.05.01.01	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	
3.05.05.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	**TGA** The study may include statistical analysis of the data depending on the device classification. **USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.
3.05.05.01.03	USFDA	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **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**.

3.05.06	IMDRF	2	Analytic Specificity	Evidence that supports the analytical specificity (interference, including as appropriate, selectivity, and cross reactivity) of the subject IVD medical device is to be included in this section. This should include: a) A justification of the selection of the studies performed. b) A summary of the evidence that falls within this category c) A discussion and a conclusion 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 analytical performance study results provided in this section regarding the subject IVD medical device	**EU** For specific IVDR requirements see IVDR Annex II Section 6.1.2.3. **NMPA** If there are different applicable models contained in the registration application, the test data and summary of the evaluation of above projects conducted on different models shall be submitted. **TGA** This may also include cross reactivity, microbial interference, potential interfering substances (endogenous and exogenous) and in-silico studies, as applicable.
3.05.06.01	IMDRF	3	[Study description, study identifier, date of initiation, date of completion]	**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.	
3.05.06.01.01	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.	**TGA** The study may include statistical analysis of the data depending on the device classification.

					USFDA 510(k) If referencing a standard, refer to Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.
3.05.06.01.03	USFDA	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **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	High Dose Hook Effect	Evidence that supports the absence of a high dose hook effect or prozone effect. This should include: a) A justification of the selection of the studies performed. b) A summary of the evidence that falls within this category c) A discussion and a conclusion 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.	**EU** For specific IVDR requirements see IVDR Annex II Section 6.1.2.5.

				NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the analytical performance study results provided in this section regarding the subject IVD medical device	
3.05.07.01	IMDRF	3	[Study description, study identifier, date of initiation, date of completion]	**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.	**TGA** The study may include statistical analysis of the data depending on the device classification **USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.
3.05.07.01.03	USFDA	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **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	Measuring Range of the Assay	Evidence that supports the measuring range (linear and non-linear measuring systems). This measuring range should include the lower limit of quantification. This should include: a) A justification of the selection of the studies performed. b) A summary of the evidence that falls within this category c) A discussion and a conclusion 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 analytical performance study results provided in this section regarding the subject IVD medical device	**EU** For specific IVDR requirements see IVDR Annex II Section 6.1.2.5. **NMPA** If there are different applicable models contained in the registration application, the test data and summary of the evaluation of above projects conducted on different models shall be submitted.
3.05.08.01	IMDRF	3	[Study description, study identifier, date of initiation, date of completion]	**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.	
3.05.08.01.01	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	
3.05.08.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	**TGA** The study may include statistical analysis of the data depending on the device classification

					USFDA 510(k) If referencing a standard, refer to Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.
3.05.08.01.03	USFDA	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **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	Validation of Assay Cut-off	Evidence that supports the determining assay cut-off is to be included here. This should include: a) A justification of the selection of the studies performed. b) A summary of the evidence that falls within this category c) A discussion and a conclusion 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.	**EU** For specific IVDR requirements see IVDR Annex II Section 6.1.2.6. **TGA** This evidence should support the interpretation of results to clearly demonstrate the cut-off and differentiate between a true result and background signal.

				NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the analytical performance study results provided in this section regarding the subject IVD medical device	
3.05.09.01	IMDRF	3	[Study description, study identifier, date of initiation, date of completion]	**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	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	
3.05.09.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	**TGA** The study may include statistical analysis of the data depending on the device classification. **USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.
3.05.09.01.03	USFDA	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **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	Validation of the Assay Procedure	This section should provide a summary of information and evidence supporting the validity of the assay procedure in terms of important reaction conditions (e.g. reaction time, reaction temperature, reagent volume, reading time). This should include: a) A justification of the selection of the studies performed. b) A summary of the evidence that falls within this category c) A discussion and a conclusion 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 analytical performance study results provided in this section regarding the subject IVD medical device	**EU** For specific IVDR requirements see IVDR Annex II Section 6.1.3 and Annex XIII Section 1.2.2. **TGA** This may also include whole system failure rate (the frequency of failures when the entire process is performed as recommended by the manufacturer).
3.05.10.01	IMDRF	3	[Study description, study identifier, date of initiation, date of completion]	**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.	**TGA** The study may include statistical analysis of the data depending on the device classification.
3.05.10.01.03	USFDA	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **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**.
3.06	IMDRF	1	Other Studies	**NO CONTENT AT THIS LEVEL**	
3.06.01	ANVISA, NMPA, EU, HC, HSA, TGA, USFDA	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 justification of the selection of the studies performed. b) A summary of the evidence that falls within this category c) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of laboratory study is not applicable to this case.	**EU** For specific IVDR requirements see IVDR Annex I GSPR 17. Guidance is also available in EN 61010-2-101 Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for in vitro diagnostic (IVD) medical equipment and EN 61326-2-6 Electrical equipment for measurement, control and laboratory use. EMC requirements. Particular requirements. In vitro diagnostic (IVD) medical equipment. **NMPA** Research materials on electrical safety, mechanical and environmental protection, and electromagnetic compatibility should be provided, explaining the applicable standards and the research carried out.

				NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject IVD medical device	
3.06.01.01	ANVISA, EU, HC, HSA, TGA, USFDA	3	[Study description, study identifier, date of initiation, date of completion]	**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.	
3.06.01.01.01	ANVISA, EU, HC, HSA, TGA, USFDA	4	Summary	A summary of the specific study described in the custom heading above.	
3.06.01.01.02	ANVISA, EU, HC, HSA, TGA, USFDA	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 - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.
3.06.01.01.03	USFDA	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **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.
3.06.02	IMDRF	2	Software/Firmware/Programmed or programmable medical	**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 IVD medical device, are to be included in this section and the associated sub-sections. It should also address all the different hardware configurations and, where applicable, operating systems identified in the labelling. Documentation should be organized according to software or hardware systems.	
3.06.02.01	IMDRF	3	Software/Firmware Description	The software description should include: a) A comprehensive overview of significant software features and functions, which may include images, flow charts, and state diagrams as needed to adequately explain the software functionality, b) The version of the software - The version tested must be clearly identified and should match the release version of the software, otherwise justification must be provided, c) Identification of the IVD medical device features that are controlled by the software, the programming language, hardware platform, operating system (if applicable), use of Off-the-shelf software (if applicable), a description of the realization process. If the product is a machine learning-enabled medical device (such as adaptive models, natural language processing, neural networks,	**ANVISA** For Medical Device or Independent Software, see the appropriate documentation required in ANVISA Resolutions RDC nº 751/2022 and RDC nº 657/2022; And Anvisa Guidance nº 38/2020 - Cybersecurity principles and practices in medical devices. If the Medical device adopts artificial intelligence technology, it should provide algorithm description, including basic algorithm information, data collection, algorithm training, algorithm performance evaluation, validation, etc. **EU** Appropriate documentation is required if the IVD is either stand-alone software or relies upon software. See IVDR Annex I GSPR 16 and Annex II Section 6.4 for requirements. Guidance is also available in EN 62304 Medical

				and related approaches), please provide, as applicable: i. a detailed description of each algorithm/model, including its inputs, outputs, data selection and management for training, testing, and validation (terminology may differ in different regions); ii. model selection and evaluation; iii. risk management activities; iv. materials/approaches used to provide transparency; and v. post-market performance monitoring activities.	device software – Software life-cycle processes and, if applicable, EN 82304-1 Health Software - General requirements for product safety. **USFDA** Identify the Level of Documentation (Basic or Enhanced) and include a description of the rationale for that level. For guidance on what specific software documentation to submit, refer to the Guidance for the Content of Premarket Submissions for Device Software Functions **TGA** Refer to guidance on 'Regulation of Software based medical devices'. **NMPA** a) Software

					For products and independent software that contain software components, software research materials should be provided, including basic information, implementation processes, core functions, conclusions, etc. The degree of detail depends on the software security level (severe, moderate, and minor). Among them, basic information includes software identification, security level, structural function, physical topology, operating environment, and registration history. The realization process includes development overview, risk management, requirement specification, life cycle, verification and confirmation, traceability analysis, defect management, update history, clarify the correspondence between core functions, core algorithms, and expected uses. b) Ready-made software If the product uses off-the-shelf software, corresponding software research data and network security research data should be provided based on the type and usage of the off-the-shelf software. c) Artificial intelligence If the product adopts artificial intelligence technology such as deep learning to achieve the expected function and purpose, it should provide algorithm research materials, including basic algorithm information, data collection, algorithm training, algorithm performance evaluation, etc. d) Other

					If products adopt mobile computing, cloud computing, virtual reality and other information and communication technologies to achieve expected functions and uses, corresponding technical research materials should be provided, including basic information, requirements specifications, risk management, verification and confirmation, maintenance plans, etc.
3.06.02.02	IMDRF	3	Risk Management File (including Hazard Analysis)	The risk management file should be provided and include the risk management plan, risk assessment (e.g. hazard analysis), and risk management report. The risk assessment (e.g. hazard analysis) should take into account all device hazards associated with the IVD medical device's intended use. For Software that is part of a system, a risk assessment should be performed on the system comprising the software and its whole hardware environment and noted in the software documentation with reference to the particular section of the premarket submission.	**EU** See EN 62304 and ISO 14971 for further guidance. **HC** The risk management file in this section should specifically relate to the software/hardware. Overall risk analysis should be placed in section 2.08. **HC, USFDA** For the risk control measures in the risk assessment or hazard analysis, there should be verification of the implementation of the risk control measures and verification of the effectiveness of the implemented risk control measures (i.e. the implemented risk control measure reduces risk). This can be accomplished by tracing the identified hazard to the verified specific risk control measures (e.g. a requirement ID in the SRS and SDS, a test name and identifier in the testing documentation that shows pass/fail results, a user manual name and identifier, a training manual name and identifier).
3.06.02.03	IMDRF	3	Software Requirement	The Software Requirements Specifications (SRS) documentation should describe the	**EU**

			Specifications (SRS)	needs or expectations for a system or software, presented in an organized format, at the software system level or subsystem level, as appropriate, and with sufficient information to understand the traceability of the information with respect to the other software documentation elements (e.g. risk management file, software design specification, system and software architecture design chart, software testing). The SRS documents the requirements for the software which typically specifies inputs and outputs, functions that the software will perform, hardware, performance, interfaces, user interaction, error definition and handling, intended operating environment, safety and security related requirements derived from a risk assessment (hazard analysis) and all ranges, limits, defaults, and specific values that the software will accept.	See IVDR Annex I Section 13.2 (d) for requirements. Further guidance is also available in EN 62304.
3.06.02.04	EU, HC, JP, TGA, USFDA	3	System and Software Architecture Design (SAD) Chart	The System and Software Architecture Design (SAD) Chart should consist of detailed diagrams of the modules, layers, and interfaces that comprise the device, their relationships, the data inputs/outputs and flow of data, and how users or external products (including information technology (IT) infrastructure and peripherals) interact with the system and software. If the System and Software Architecture Design Chart is included in another document, such as the SRS, a reference to the location of the System and Software Architecture Design Chart in the submission should be included.	**EU** See EN 62304 for further guidance.

3.06.02.05	EU, HC, JP, TGA, USFDA	3	Software Design Specification (SDS)	Software Design Specification (SDS) documentation should be provided, including sufficient information to understand the technical design details of how the software functions, how the software design completely and correctly implements all the requirements of the SRS, and how the software design traces to the SRS in terms of intended use, functionality, safety, and effectiveness. In terms of the relationship between the SRS and the SDS, the SRS describes what the software function will do and the SDS describes how the requirements in the SRS are implemented. The information presented in the SDS should be sufficient to ensure that the work performed by the software engineers who created the device software function was clear and unambiguous, with minimal ad hoc design decisions.	**EU** See EN 62304 for further guidance.
3.06.02.06	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.	**USFDA, HC** The Traceability Analysis can be incorporated into the SRS documentation.
3.06.02.07	IMDRF	3	Software Life Cycle Process Description / Software Development, Configuration Management, and Maintenance Practices	The Software Life Cycle Process Description / Software Development, Configuration Management, and Maintenance Practices description should describe the software development life cycle and the processes that are in place to manage the various life cycle activities.	**EU** For specific IVDR requirements see IVDR Annex I GSPR 16.2 and Annex II Section 6.4. See EN 62304 for further guidance.

3.06.02.08	IMDRF	3	Software Testing as Part of Verification and Validation	You should provide an overall description of the verification and validation activities performed for the final software version. You should provide the applicable test protocols and reports including the expected results, observed results and pass/fail determination. **NOTE**: Discussion should address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.	**EU** See EN 62304 and EN 82304-1, if applicable, for further guidance
3.06.02.09	IMDRF	3	Software Version / Revision Level History	The Software Version / Revision Level History documentation should include the history of software versions that were tested and documented as part of verification and validation activities. This typically takes the form of a line-item tabulation including the date, version number that was tested and a brief description of all changes in the version relative to the previously tested version. The last entry in a line-item tabulation should be the final version to be incorporated in the released device. This entry should also include any differences between the tested version of software and the released version.	**EU** See EN 62304 for further guidance.
3.06.02.10	IMDRF	3	Unresolved Software Anomalies	Documentation should include a list of unresolved anomalies present in the software with the following items (e.g. in tabular format) for each unresolved anomaly: i) A description of what the anomaly is and what root cause(s) of the anomaly could be; ii) Identification of how the anomaly was discovered and, where possible,	**EU** See EN 62304 for further guidance.

				identification of the root cause(s) of the anomaly; iii) Evaluation of the impact of the anomaly on the device's safety and effectiveness, including operator usage and human factors considerations; iv) Outcome of the evaluation; and v) Risk-based rationale for not correcting or fixing the anomaly in alignment with the risk management plan or procedure(s).	
3.06.02.11	EU, USFDA, HC, HSA, NMPA, TGA	3	Cybersecurity	For a description of the Cybersecurity Common Content, please refer to IMDRF/CYBER WG/N60 FINAL:2020 "Principles and Practices for Medical Device Cybersecurity"	**HC** Guidance Document: Pre-market Requirements for Medical Device Cybersecurity **USFDA** Guidance for Industry and Staff – "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" **TGA** Guidance for industry and consumers "Medical device cyber security guidance for industry". **NMPA**

					Independent software with electronic data exchange, remote control or user access functions and products containing software components shall provide network security research materials, including basic information, implementation process, vulnerability assessment, conclusions, etc. The degree of detail depends on the software security level . Among them, basic information includes software information, data architecture, network security capabilities, network security patches, and security software. The implementation process includes risk management, requirements specification, verification and confirmation, traceability analysis, update maintenance plans, and vulnerability assessments to identify known vulnerabilities. Related Information. **HSA** Regulatory Guidelines for Software Medical Devices - A Life Cycle Approach – available at www.hsa.gov.sg
3.06.02.12	EU, USFDA, HC, HSA, NMPA	3	Interoperability	If the IVD medical device can communicate with other devices. Evidence to support the interoperability should be provided.	**EU** For specific IVDR requirements see IVDR Annex I GSPR 13.5 and Annex II Section 6.5 (d). **USFDA** Guidance for Industry and Staff – “Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices”

					NMPA If products exchange and use information with other medical devices or non-medical devices through electronic interfaces, interoperability research materials should be provided, including basic information, requirements specifications, risk management, verification and confirmation, maintenance plans, etc.
3.06.03	ANVISA, EU, HC, HSA, TGA, USFDA	2	Cleaning and Disinfection Validation	Contains information on the validation of cleaning and disinfection instructions for reusable devices, including evidence to support maintenance of performance when subject to this procedure over a number of cycles that is representative of the IVD medical device's expected useful life. Information to be included in this section includes: a) If applicable, a discussion of how the number of cycles that is representative of the IVD medical device's expected useful life has been determined. b) A justification of the selection of the studies performed. c) A summary of the evidence that falls within this category d) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR** e) A statement of why this category of laboratory study is not applicable to this case. **NOTES:**	**EU** For specific IVDR requirements see IVDR Annex I GSPR 20.4.1 (n) (vi). **TGA** This may involve validating for carry-over contamination rates (where high positive samples have been used in series alternating with negative samples). However, is dependent on the operational function of the device.

				i. This applies most typically to devices intended for Point of care and/or home use (near patient testing) involving whole blood. ii. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject IVD medical device.	
3.06.03.01	ANVISA, EU, HC, HSA, TGA, USFDA	3	[Study description, study identifier, date of initiation, date of completion]	**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.	
3.06.03.01.01	ANVISA, EU, HC, HSA, TGA, USFDA	4	Summary	A summary of the specific study described in the custom heading above.	

3.06.03.01.02	ANVISA, EU, HC, HSA, TGA, USFDA	4	Full Report	The test report for the test described in the custom heading above.	**TGA** The study may include statistical analysis of the data depending on the device classification. **USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.
3.06.03.01.03	USFDA	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **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**.
3.06.04	IMDRF	2	Usability/Human Factors	Studies specifically assessing the instructions and/or IVD medical device design in terms of impact of human behavior, abilities, limitations, and other characteristics on the ability of the IVD medical device to perform as intended should be included here. This should include: a) State the test environment and relation to the intended use environment b) A justification of the selection of the studies performed. c) A summary of the evidence that falls within this category d) A discussion and conclusion to support why the evidence presented is sufficient to support the application.	**EU** For specific IVDR requirements see IVDR Annex I GSPR 5. Guidance is also available in EN 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices. **USFDA** Please consult the "Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Medical Devices"

				OR e) A statement of why this category of 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 study results provided in this section regarding the subject IVD medical device.	
3.06.04.01	IMDRF	3	[Study description, study identifier, date of initiation, date of completion]	**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.	
3.06.04.01.01	IMDRF	4	Summary	A summary of the specific study described in the custom heading above.	
3.06.04.01.02	IMDRF	4	Full Report	The test report for the test described in the custom heading above.	**TGA** The study may include statistical analysis of the data depending on the device classification.

					USFDA 510(k) If referencing a standard, refer to Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.
3.06.04.01.03	USFDA	4	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **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**.
3.06.05	IMDRF	2	Stability of the IVD	**NO CONTENT AT THIS LEVEL**	
3.06.05.01	IMDRF	3	Claimed Shelf-life	Contains details and evidence supporting the claimed shelf-life of the IVD medical device components (e.g. reagents, calibrators/reference materials, control material, any other components susceptible to degradation). Information provided in this section should include: a) A description of recommended environmental conditions for storage of the IVD medical IVD medical device (e.g. temperature, pressure, humidity, light conditions). b) A statement of the claimed shelf-life indicated as a period of time or any other means of appropriate quantification.	**ANVISA, EU, HC, HSA, JP, and TGA** 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. **EU** For specific IVDR requirements see IVDR Annex I GSPRs 7, 11.5 and Annex II Section 6.3.1. If shelf-life testing is based on accelerated age testing, this should be accompanied by a plan for real time testing.

				c) An indication of the packaging used in any studies conducted in support of the shelf-life. If the packaging used in the studies differs from the final device packaging, a discussion of why the evidence can be consider valid in support of the claimed shelf-life. d) A description of the simulated transport conditions that the IVD was exposed to before the start of shelf-life studies. e) A justification of the selection of the studies performed. f) A summary of the evidence that falls within this category g) A discussion and a conclusion to support why the evidence presented is sufficient to support the claimed shelf-life. **OR** h) A rationale that, for an indefinite period, the storage conditions could not affect IVD medical device safety or performance. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject device.	Real time testing should be underway by the time documentation is submitted for review. **HC** For shelf-life testing of IVDs, both a stability protocol and a stability report must be included. The protocol must contain at a minimum a protocol number, revision number and date, claimed and tested use and storage conditions, observation time points, replicate number, time of baseline observations relative to stress conditions, a description of the data analysis, acceptance criteria to be met, and a description of the testing panel. **NMPA** If applicable, shelf life and packaging research materials should be provided to prove that during the shelf life, under the transportation and storage conditions specified by the manufacturer, the product can maintain performance and function to meet the use requirements, and products with microbial limit requirements should also meet the microbial limit requirements. Products delivered in a sterile state should also be kept sterile.
3.06.05.01.01	IMDRF	4	[Study description, study identifier, date of initiation, date of completion]	**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.	

3.06.05.01.01.01	IMDRF	5	Summary	A summary of the specific study described in the custom heading above.	
3.06.05.01.01.02	IMDRF	5	Full Report	The test report for the test described in the custom heading above.	**TGA** The study may include statistical analysis of the data depending on the device classification. **USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.
3.06.05.01.01.03	USFDA	5	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **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**.
3.06.05.02	IMDRF	3	In Use Stability	Contains details and evidence supporting the stability during actual routine use of the IVD medical device (real or simulated), including all applicable components (e.g. reagents, reaction cartridges). This may include open vial stability and/or, for automated instruments, onboard stability. Information provided in this section should include: a) A description of recommended environmental conditions for use of the IVD medical device (e.g. temperature, pressure, humidity, light conditions). b) A justification of the selection of the studies performed.	**ANVISA, EU, HC, HSA, and TGA** 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. **EU** For specific IVDR requirements see IVDR Annex II Section 6.3.2.

				c) A summary of the evidence, covering shelf-life period when stored at the proposed storage condition, that falls within this category d) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR** e) A rationale that, for an indefinite period, the storage conditions could not affect IVD medical device safety or performance. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject IVD medical device.	**TGA** 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) **NMPA** a) In use stability, If applicable, use stability/reliability research materials should be provided to prove that the product's performance and functions meet the use requirements under normal use, maintenance and calibration (if applicable) within the use period/number of use specified by the manufacturer. b) Shipping stability, Shipping stability and packaging research data should be provided to prove that under the transportation conditions specified by the manufacturer, the environmental conditions during transportation (such as vibration, vibration, temperature and humidity fluctuations) will not affect the characteristics and performance of the medical device, including Integrity and cleanliness are adversely affected.
3.06.05.02.01	IMDRF	4	[Study description, study identifier, date of initiation, date of completion]	**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.	
3.06.05.02.01.01	IMDRF	5	Summary	A summary of the specific study described in the custom heading above.	
3.06.05.02.01.02	IMDRF	5	Full Report	The test report for the test described in the custom heading above.	**TGA** The study may include statistical analysis of the data depending on the device classification. **USFDA 510(k)** If referencing a standard, refer to Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.
3.06.05.02.01.03	USFDA	5	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **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**.
3.06.05.03	IMDRF	3	Shipping Stability	Contains details and evidence supporting the tolerance of IVD medical device, or if provided separately, the components (e.g. reagents, calibrators/reference materials) to the specified or expected shipping conditions. Information provided in this section should include: a) An indication of environmental conditions for correct shipment of the IVD medical	**ANVISA, TGA, EU 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.

				device (temperature, pressure, humidity, light conditions, mechanical protection etc.). b) A justification of the selection of the studies performed. c) A summary of the evidence, covering shelf-life period, that falls within this category d) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR** e) A rationale that, for an indefinite period, the storage conditions could not affect IVD medical device safety or performance. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject IVD medical device.	**EU** For specific IVDR requirements see IVDR Annex II Section 6.3.3. **HC, TGA** Shipping stability should contain details and evidence supporting the tolerance of device components to the anticipated shipping conditions.
3.06.05.03.01	IMDRF	4	[Study description, study identifier, date of initiation, date of completion]	**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.	
3.06.05.03.01.01	IMDRF	5	Summary	A summary of the specific study described in the custom heading above.	
3.06.05.03.01.02	IMDRF	5	Full Report	The test report for the test described in the custom heading above.	**TGA** The study may include statistical analysis of the data depending on the device classification. **USFDA 510(k)**

					If referencing a standard, refer to Guidance for Industry and FDA Staff - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.
3.06.05.03.01.03	USFDA	5	Statistical Data		This is the location for statistical data associated with the test described in the custom heading above. This includes metadata and data line listings in their native formats, such as, but not limited to: SAS; XPORT; XML; SGML; S-Plus; R files; ASCII; Molfiles; and Excel. **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	HC, HSA, USFDA	1	Analytical Performance and Other Evidence Bibliography	a) A listing of published studies relevant to the context of this Chapter that involve this specific IVD medical device (e.g. analytical specificity, analytical sensitivity) b) A legible copy of key articles, including translation where applicable to meet the regulators language requirements. c) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **OR** d) A statement that no literature related to the IVD medical device was found.	

3.08	IMDRF	1	Other 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. For example, for tests performed to ensure the safety and/or performance of the IVD medical device that are not delineated in the rest of the Chapter 3. In addition a) Describe the purpose of the test, the risk/safety issue the test is addressing; the test methods and results of the test b) A justification of the selection of the studies performed. c) A summary of the evidence that is being submitted under this heading d) A discussion and a conclusion to support why the evidence presented is sufficient to support the application. **NOTE:** The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the study results provided in this section regarding the subject IVD medical device.	**EU** For specific IVDR requirements see IVDR Annex I and Annex II Section 6.5 for additional information required in specific cases: (a) Devices placed on the market in a sterile or defined microbiological condition, (b) Devices containing tissues, cells and substances of animal, human or microbial origin (c) Devices with a measuring or diagnostic function, (d) Devices intended to be connected to other devices to operate as intended: If the device is intended to be connected to other devices to operate as intended, (e) Devices classed as companion diagnostics. **NMPA** a) Risk of explosion For medical devices that are exposed to flammable and explosive substances or used in combination with other combustibles or combustibles, the explosion risk research data shall be provided to prove that the explosion risk is acceptable under normal conditions and single fault conditions. b) Joint use If the declared product is expected to be used in combination with other medical devices, drugs, and non-medical device products to achieve the same intended use, research materials that prove the safety and effectiveness of the combined use should be provided, including basic interconnection information (connection type, interface, protocol, minimum performance), joint Use risks and control

					measures, restrictions on joint use, compatibility studies, etc. In the case of combined drug use, the drug compatibility research materials shall be provided to prove that the performance of the combined drug and device meets its indications and intended use. c) Dose-effect relationship and energy safety For medical devices that provide energy or material therapy to patients, research data on the dose-effect relationship and energy safety should be provided, and the safety, effectiveness, and rationality of the treatment parameter settings should be provided. Research data on unacceptable harm caused by normal tissues.
3.08.01	IMDRF	2	[Study description, study identifier, date of initiation, date of completion]	**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 - Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.

3.08.01.03	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**.

4. Chapter 4 – Clinical evidence

Row ID	Regions & 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 (e.g. well-controlled studies, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, literature review, post market data from another jurisdiction or from a marketed device)) and provide a discussion of how this is considered sufficient to support request for marketing for the requested indications. A tabular listing of clinical studies may be included in this section. b) If any of the study IVD medical devices differ from the IVD medical devices to be marketed, including competitors' IVD medical devices, a description of these differences and their impact on the validity of the evidence in terms of support for the application for any device referenced in the application. This may include a detailed comparison of the clinical, technical and	**EU** Clinical performance and clinical evidence is always required, regardless of risk class. For specific requirements see IVDR Article 56, Annex II Section 6.2 and Annex XIII. Guidance on clinical performance studies is also available in ISO 20916 In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice. For Class C and Class D devices, a summary of safety and performance (SSP) per IVDR Article 29 must be provided. **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.

Row ID	Regions & Level		Heading	Common Content	Regional Content
				biological characteristics of the two devices, with a detailed critical analysis demonstrating the devices to be similar to such an extent that there would be no clinically significant difference in safety or performance. c) A discussion of the clinical evidence considered for the IVD medical 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.	**TGA** Every medical device requires clinical evidence, appropriate for its intended use and classification of the device, demonstrating that the device complies with the applicable provisions of the Essential Principles, Schedule 2 *Therapeutic Goods (Medical Devices) Regulations 2002.* Refer to the guidance on 'Clinical Evidence Guidelines: Medical Devices' on expected data requirements for each application." **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** 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	2	Expected Values/Reference Ranges	This section should include information on what values to expect in healthy normal patients versus affected patients.	
4.02.02	EU, HC, HSA, NMPA, TGA	2	Clinical Evidence Evaluation Report	a) A clinical evidence evaluation report reviewed and signed by an expert in the relevant field that contains an objective critical evaluation of all of the clinical data	**EU** For specific IVDR requirements see IVDR Article 56, Annex II Section 6.2 and Annex XIII.

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

Row ID	Regions & Level		Heading	Common Content	Regional Content
					that they have the equivalent safety and effectiveness. **<u>TGA</u>** A full clinical evidence evaluation report is required for each Class 3 and 4 IVD. For lower class IVDs (Class 1 and 2 IVDs), summary reports are required with further details to be made available if specifically requested by the TGA. If an IVD medical device to be marketed differs from an approved predicate IVD medical device (i.e. a substantial change is involved) the comparative data of the proposed product and the predicate medical device in terms of a detailed comparison of the clinical features, application scope, technical features and biological properties, with a detailed critical analysis demonstrating the devices to be similar to such an extent that there would be no clinically significant difference in safety or performance. This may involve a seroconversion study to demonstrate clinical performance characteristics between the proposed product and the predicate medical device.
4.02.03	IMDRF	2	IVD medical Device Specific Clinical Studies	**NO CONTENT AT THIS LEVEL** Clinical study information under this heading should be grouped by study	

Row ID	Regions & Level		Heading	Common Content	Regional Content
4.02.03.01	IMDRF	3	[Study description, protocol #, date of initiation, date of completion]	**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 Study Synopsis Level 4: Clinical Study Report Level 3: NA Controlled Study, CT4584, 2011-01-23 Level 4: Clinical Study Summary Level 4: Clinical Study Report	
4.02.03.01.01	IMDRF	4	Clinical Study Summary	a) A summary of the specific study described in the custom heading above that includes: 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, statistical design, interpretation of design, # patients, inclusion/exclusion criteria) and ii. Summary of the results of the analysis iii. Summary of conclusions related to the endpoints **NOTES:**	**USFDA** Collection of Race and Ethnicity Data in Clinical Trials

Row ID	Regions & Level		Heading	Common Content	Regional Content
				i. The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the components of the clinical study summary. ii. The sponsor/applicant should explicitly state whether the data are sex-, gender-, age-, race-, and ethnicity- disaggregated. If the data are not disaggregated, the sponsor/applicant should provide a rationale why.	
4.02.03.01.02	IMDRF	4	Clinical Study Report	a) A clinical study 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 study report.	**EU** For specific IVDR requirements see IVDR Articles 56-77 and Annex XIII Section 2. Pre-market clinical performance studies will be required unless it is duly justified to rely on other sources of performance data (IVDR Article 56). **TGA** Clinical trials must comply with: NHMRC National Statement of Ethical Conduct in Human Research if the study is conducted in Australia (clause 8.4(4) of Part 8 of Schedule 3 of the MD Regs); or the Declaration of Helsinki if the study is conducted outside of Australia (clause 8.4(5) of Part 8 of Schedule 3 of the MD Regs) **USFDA PMA and 510(k)** http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046717.htm#sugforforidepro

Row ID	Regions & Level		Heading	Common Content	Regional Content
4.02.03.01.03	USFDA	4	Clinical Study 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
4.02.04	EU, HC, HSA, JP, TGA, USFDA	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 performance of the IVD medical 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 IVD medical device was found.	**EU** For specific IVDR requirements see IVDR Article 56 (3) and Annex XIII Section 1.2.3. A copy of all literature articles selected and analysed within the performance evaluation report (IVDR Annex XIII Section 1.3.2) should be included in the technical documentation.

Row ID	Regions & Level		Heading	Common Content	Regional Content
				NOTE: i) The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the clinical study and data provided in this section regarding the subject IVD medical device ii) Please see Chapter 2.07 for Post-Market Study Plans	
4.03	NMPA, USFDA	1	Informed Consent Information		**NMPA** Clinical trial protocol, written opinions on the approval of the clinical trial from the Ethics Committee of the clinical trial institution, clinical trial report, and sample Informed Consent Form shall be provided. **USFDA** Any information related to informed consent in the collection of the clinical information used to support the submission, such as copies of Institutional Review Board-approved informed consent forms, is to be provided here.
4.04	HC, USFDA	1	Investigators Sites and IRB contact information		**HC** List the clinical study sites including the name, description, and address. **USFDA** 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

Row ID	Regions & Level		Heading	Common Content	Regional Content
					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 e) Laboratory facilities (central lab and/or local lab that participated in the study)-name, address, contact information
4.05	HC, HSA, TGA, USFDA	1	Real World Data (RWD)	Where applicable, other clinical experience data/real world data (including device registries, post-market studies conducted in other jurisdictions)	
4.06	EU, HC, HSA, TGA, USFDA	1	Post-Market Surveillance Data		**EU** IVDR Chapter VII and Annex III on post-market surveillance as well as Annex XIII for requirements relating post-market performance follow-up (PMPF); procedures to be in section 6.09.
4.07	IMDRF	1	Other Clinical Evidence	Heading for other information that may be important to the submission but that does not fit in any of the other headings of this chapter.	

5. Chapter 5 – Labelling and promotional material

Row ID	Regions & Level		Heading	Common Content	Regional Content
5.01	ANVISA, EU, HC, HSA, 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.	
5.02	ANVISA, NMPA, EU, HC, HSA, TGA, USFDA	1	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 regulatory framework c) In case the product is marketed with original labels, (PDFs of) stickers with local information will need to be provided. **NMPA** Product instructions for use shall be submitted, with the contents conforming to the Provisions on the Administration of Instructions for Use and Labels of Medical Devices, relevant laws,

					regulations, normative documents and mandatory standards. **EU** For specific IVDR requirements see IVDR Annex I GSPRs 20.1, 20.2, 20.3 and Annex II Section 2. **HC** a) All labelling must comply with sections 21 to 23 of the Medical Devices Regulations. b) Consult the guidance for the labelling of in vitro diagnostic devices. **TGA** 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 d) meet the requirements of the Standard for the Uniform Scheduling of Medicines and Poisons, if the device contains a substance listed in Schedule 4 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

					For a medical device that is software, or that incorporates software, the current version number and current build number of the software must a) meet the requirements of Essential principle 13B b) be accessible by, and identifiable to, users of the device c) be in English **USFDA** Follow device labelling regulations found in 21 CFR Part 801 and 21 CFR 809.10 **HSA** 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	ANVISA, EU, HC, HSA, TGA, USFDA	1	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. **NOTE:** 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) The current version of the instruction for use must be informed. **NMPA**

					a）Product instructions for use shall be submitted, with the contents conforming to the Provisions on the Administration of Instructions for Use and Labels of Medical Devices, relevant laws, regulations, normative documents and mandatory standards. b）Overseas applicants shall submit the product instructions for use in original language. **EU** See IVDR Annex I GSPRs 20.1, 20.4 and Annex II Section 2 for detailed requirements For self-test and near patient testing devices, manufacturers must provide a clear demonstration of conformity to the specific requirements (IVDR Annex I GSPRs 19 and 20.4.2). **HC** a) All labelling must comply with sections 21 to 23 of the Medical Devices Regulations. b) Consult the guidance for the labelling of in vitro diagnostic devices. c) Package inserts must include all relevant information, including a summary of the performance characteristics. d) The current version and date of the instructions for use must be stated. **TGA** The labels and instructions for use (including any package inserts) must a) meet the requirements of Essential Principle 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 **USFDA PMA** Package inserts include a summary of clinical data **HSA** Refer to GN-23 – available at www.hsa.gov.sg for labelling requirements.
5.04	ANVISA, EU, HC, HSA, USFDA	1	e-labelling	In addition to the e-labelling itself, the following should be provided: a) For eligible IVD medical devices and Software as a Medical Device, the applicant needs to identify which form of e-labelling is being used (e.g. electronic storage system or built-in system, website). b) Provide details of risk management in relation to e-labelling. If this is part of the overall risk management, refer to it here c) When IFUs are requested, a description of the procedure and operations on providing these IFUs. d) Provide written information for users on the webpage identifying where the IFU	**EU** • Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent, and only under the conditions, set out in Commission Implementing Regulation (EU) 2021/2226, as per GSPR 20.1(f) • If the manufacturer has a website, the instructions for use shall be made available and kept up to date on the website and comply with Article 9 of Commission Implementing Regulation (EU) 2021/2226. The URL of the website where such information will be made available should be included.

				and further information can be found in relevant languages. e) A description on how the e-labelling requirements for the website have been met. f) If a video/App is available to demonstrate how the test is intended to perform and be interpreted, provide a link as well as details about how it is maintained and updated throughout the life cycle of the device.	**HC** For devices that are not sold to the general public, IFUs may be provided as downloadable from the internet and/or on electronic data storage devices, e.g. compact disc, digital video disc, USB flash drive, etc. The electronic label or URL must accompany the device at the time of sale and/or delivery and be displayed in a manner that alerts the user to its purpose. A Letter of Attestation must also be included with the application. Refer to the guidance for the labelling of in vitro diagnostic devices for additional information. If a video/App is available as described in f) above, the video should be available in both French and English. **HSA** Refer to GN-23 – available at www.hsa.gov.sg for e-labelling requirements.
5.05	ANVISA, EU, HC, HSA, USFDA	1	Patient Labelling	Labelling directed at the patient other than the package insert, such as informational material written to be comprehended by the patient or lay caregiver	
5.06	ANVISA, EU, HC, HSA, TGA, USFDA	1	Technical and/or Operators Manuals	Labelling directed to the technical users and operators of IVD medical devices focusing on the proper use and maintenance of the IVD medical device	
5.07	EU, HC	1	Product Brochures		**EU** • Product brochures and promotional material containing devices (including claims) available for the user within the EU

					• The identification number of the NB shall also be indicated in any promotional material which mentions that a device fulfils the requirements for CE marking as per IVDR Article 18 (5) **HC** Draft product brochures available at the time of application
5.08	ANVISA, EU, HC, TGA, USFDA	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. Individual jurisdictions may have their own regulations or requirements regarding other labelling elements or advertising and promotional materials. If necessary, this section can be used to address jurisdiction-specific regulations or requirements involving other labelling elements other than those described elsewhere in this section, including advertising and promotional materials.	**NMPA** Where applicable, other documents supplementing the product information shall be provided. **TGA** Labelling elements or advertising and promotional materials must also comply with the requirements of the Therapeutic Goods Advertising Code

6. Chapter 6 – Quality management system

Row ID	Regions & Level		Heading	Common Content	Regional Content
6.01	TGA, USFDA, NMPA	1	Cover Letter	A Cover Letter is only required under this chapter when the submission only includes quality system information.	**USFDA PMA** Any modular PMA submission of quality system information requires a cover letter containing the information describe in Chapter 1 under the Cover Letter heading. **NMPA** The applicant shall undertake to have established a corresponding quality management system in accordance with the requirements of relevant laws and regulations and accept the inspection by the quality management system at any time.
6.02	NMPA, 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.	
6.03	EU, NMPA, TGA, USFDA	1	Product Descriptive Information	Abbreviated description of the device, operating principles and overall manufacturing methods. This section includes general information such as: • A description of the device, including pictures, and where possible, the proprietary name, common name, model number(s), product code, and intended use; and • A description of how the device works Product Descriptive Information is only provided under this chapter when the	**USFDA** Any modular PMA submission of quality system information requires the contents of this subchapter. **EU** IVDR Article 49 (4) The notified body may require any information or data from the manufacturer, which is necessary in order to properly conduct the chosen conformity assessment procedure. However, such information (i.e., Risk

Row ID	Regions & Level		Heading	Common Content	Regional Content
				submission includes quality system information and Chapter 2.04 “Device Description” is not provided as part of the submission.	Management, Clinical Evaluation related procedures, etc.) should be incorporated in the relevant chapters / subchapters.
6.04	ANVISA, EU, HSA, NMPA, USFDA, TGA	1	General Manufacturing Information	a) Name, address, scope/role, and contact information for all sites where the device or its components are manufactured. b) Description of any relationship between the facilities to the applicant when there is more than one involved in the manufacturing process for the applicable device. c) Where applicable, addresses for all critical subcontractors, such as outsourced production, critical component, or raw material production (e.g. animal tissue, drugs), and sterilisation, will need to be provided.	**EU** For specific IVDR requirements see IVDR Annex II Section 3.2 (b). See also IVDR Annex IX Section 2.1 for additional requirements related to the legal manufacturer, additional manufacturing sites and authorised representative. **USFDA PMA** Any modular PMA submission of quality system information requires the contents of this subchapter. Please consult the guidance document ***Quality System Information for Certain Premarket Application Reviews, Guidance for Industry and FDA Staff.*** In this QS PMA guidance, please refer to section A.2 (Cover Letter) and provide the following information: • Full name and street address (no P.O. Box number), • Telephone number (with area code), • FDA Facility Establishment Identifier (FEI) or registration number, • Relationship of (each) manufacturing facility to applicant. • Contact person (and alternates) and their telephone number(s). • The date the facility site(s) will be ready for inspection.

Row ID	Regions & Level		Heading	Common Content	Regional Content
					NMPA For change registration, if manufacturing site of the Imported Medical Device applicant changes, provide Comparative table and description. **TGA** • For the manufacturer (as specified on device labelling), specify manufacturer name or trading name (if applicable), Australian Business number (ABN) / Australian Company number (ACN) (if applicable), TGA Client ID, manufacturer's physical address, manufacturer's postal address, scope of manufacturing facility (design, key production steps, labelling, final release, warehousing and dispatch). • For each manufacturing facility, specify facility name, physical address, scope of facility (design, key production steps (specify), labelling, final release, warehousing and dispatch) • For all manufacturing facilities include contact information (including full name of contact person, position of contact person, telephone number and email address) • Where applicable, for each critical supplier such as outsourced production, critical component, or raw material production (e.g. supplier of antibodies) and sterilisation, specify supplier's name, physical address, scope (for each relevant device, manufacturing stages performed at this site or services provided)

Row ID	Regions & Level		Heading	Common Content	Regional Content
6.05	USFDA	1	Required Forms	Any regional specific forms to be completed associated with Quality management Systems in the premarket review process	**USFDA** Any forms needed related to Quality Management.
6.06	NMPA, TGA, USFDA, WHO PQ	1	Quality Management System	High level quality management system documents, including procedures for establishing and maintaining the quality management system such as the quality manual, quality policy, quality objectives, and control of documents and records, as well as records providing evidence of conformance to requirements, and of the effective operation of the quality management system (when applicable). • ISO 13485 Elements– SOPs and device specific documentation to satisfy clause 4	**USFDA PMA** Please provide documentation according to QS PMA Guidance, Section II. Manufacturing Information, Item (1) Quality System Procedures 820.20(e) **NMPA** According to the above procedures of the quality management system, applicants shall form documents and records related to the quality management system. The following materials shall be submitted for inspection during the inspection on the quality management system. 1. Basic information form of applicant. 2. Organizational chart of the applicant. 3. General layout of the enterprise and the distribution map of production areas. 4. Where there are requirements for purification in the production process, a copy of the environmental testing report (with the layout plan attached) issued by a qualified testing institution shall be provided. 5. The flow chart of the product production process, which shall indicate the main control points and items, main raw materials and sources of purchased parts and the quality control methods.

Row ID	Regions & Level		Heading	Common Content	Regional Content
					6. Catalogue of main production equipment and inspection equipment (including the equipment required for incoming inspection, process inspection and final factory inspection; environmental monitoring equipment shall also be provided for the production conducted under the purification conditions). 7. Self-inspection report of the quality management system. 8. Where applicable, the explanation on the comparison of the product to be inspected and products previously passing the inspection in terms of production conditions and production process shall be provided. **<u>TGA</u>** **New certificate application (initial)** • Overview of manufacturing stages for each device Details of the manufacturing steps, or services provided by the responsible party • Latest version of the Quality Manual This must at a minimum include a reference to documented procedures. • List of validated processes. For each process validation considered critical to the safety and performance of the device, e.g. drug coating process, sterilisation. Protocols/procedures for the validated process. Process validation report. The procedures for monitoring and controlling the process parameters of a validated process should be fully described. The frequency of re-validation

Row ID	Regions & Level		Heading	Common Content	Regional Content
					Substantial change application • Details of the changes relating to the scope of a Schedule 3, Part 1, 4 or 5 TGA conformity assessment certificate. e.g. If the change relates to the device category, critical suppliers or manufacturer facilities listed on the certificate. • Details of changes to Quality Manual. Note: At minimum, this must include a reference to documented procedures. • Details of changes to manufacturing process. This must include details of the changed manufacturing process, or services provided and the party responsible. • Details of changes to protocols and reports for the validated processes. **WHO PQ** a) A list of all current quality management SOPs b) Risk management
6.07	NMPA, TGA, USFDA	1	Management Responsibilities	Documents, including procedures that provide evidence of the management commitment to the establishment and maintenance of the QMS by addressing quality policy, planning, responsibilities/authority/communication and management review, as well as records providing evidence of conformance to requirements, and of the effective operation of the quality management system (when applicable).	**USFDA PMA** Please provide documentation according to QS PMA Guidance, Section II. Manufacturing Information, Item (1): • Management review SOPs **TGA** • An undertaking (in writing) by the manufacturer to continue to comply with the requirements of the quality management system after assessment.

Row ID	Regions & Level		Heading	Common Content	Regional Content
				• ISO 13485 Elements – SOPs and device specific documentation to satisfy clause 5	• An undertaking (in writing) by the manufacturer to ensure that the quality management system is at all times is adequate and efficacious. • An undertaking (in writing) by the manufacturer to notify the TGA, or the Australian sponsor, of any information of the kind mentioned in subparagraphs 1.4(3)(c), 4.4(3)(c), or 5.4(3)(c) (for Parts 1, 4 or 5 CA procedures respectively), that the manufacturer becomes aware of in relation to the kind of medical device.
6.08	NMPA, USFDA, WHO PQ	1	Resource Management	Documents, including procedures that provide evidence of the adequate provision of resources to implement and maintain the QMS, as referenced in regulator's guidance or regulation, including human resources, infrastructure, and work environment, as well as records providing evidence of conformance to requirements, and of the effective operation of the quality management system (when applicable). • ISO 13485 Elements – SOPs and device specific documentation to satisfy clause 6	**USFDA PMA** Please provide documentation according to QS PMA Guidance, Section II. Manufacturing Information, Item: • (5) Production and Process Controls, 820.70 – SOPs for environmental and contamination controls **WHO PQ** Staff organogram
6.09	EU, NMPA, TGA	1	Planning of Product Realization and Customer Related Processes	High level product realization documents, including procedures such as those addressing planning and customer related processes, as well as records providing evidence of conformance to requirements, and of the effective operation of the quality management system (when applicable).	**EU** Annex II 3. DESIGN AND MANUFACTURING INFORMATION (b) complete information and specifications, including the manufacturing processes and their validation, their adjuvants, the continuous

Row ID	Regions & Level		Heading	Common Content	Regional Content
				Records demonstrating conformance to requirements are only provided under this chapter when the submission includes quality system information, and these records were not provided within the submission as part of a previous subchapter. • ISO 13485 Elements – SOPs and device specific documentation implementing sub clause 7.1 and 7.2	monitoring and the final product testing. Data shall be fully included in the technical documentation **Note**: Information provided in this subchapter should be concerning the relevant ISO 13485 clauses in the left column and should not cover manufacturing processes. • Design and Development information should be provided as per information in 6.10. • Manufacturing process related information should be provided as per information in 6.12. Annex III Technical Documentation on Post-Market Surveillance Please provide relevant Procedures describing the preparation and implementation of Post Market Activities and how these activities are linked to other activities such as Risk Management, Performance Evaluation, Periodic Safety Update Report, Summary on Safety and Performance. Do not provide the records or outputs of the processes here.
6.10	EU, NMPA, TGA, USFDA, WHO PQ	1	Design and Development	Documents, including procedures that provide evidence of the systematic and controlled development of the device design from initiation of the project to transfer to production, as well as records providing evidence of conformance to requirements,	**EU** For specific IVDR requirements see IVDR Annex II Section 3.1. See also IVDR Annex IX Section 2.2 (c) for additional requirements related to design and development procedures, if applicable.

Row ID	Regions & Level		Heading	Common Content	Regional Content
				and of the effective operation of the quality management system (when applicable). Records demonstrating conformance to requirements are only provided under this chapter when the submission includes quality system information, and these records were not provided within the submission as part of a previous subchapter. • ISO 13485 Elements – SOPs and device specific documentation implementing sub clause 7.3	**<u>USFDA PMA</u>** Any modular PMA submission of quality system information requires records providing evidence of conformance to requirements with respect to this subchapter. Please provide documentation according to the QS PMA Guidance, Section I. Design Control Information, Items: (1) Design Controls, General, 820.30(a) – Explanation of where in your design and development process the device became subject to your design control program. (2) Design and Development Planning, 820.30(b) SOPs (3) Design Input, 820.30(c) SOPs (4) Design Output, 820.30(d) SOPs (5) Design Review, 820.30(e) SOPs (6) Design Verification, 820.30(f) SOPs (7) Design Validation, 820.30(g) SOPs (8) Design Transfer, 820.30(h) SOPs (9) Design Changes, 820.30(i) SOPs (10) Design History File, 820.30(j) SOPs Please also include: (2) Design and Development Planning, 820.30(b) – Provide the design development plan for the subject device – Risk Analysis Procedure(s) (4) Design Output, 820.30(d) – Provide a list of the design outputs you consider essential for the proper functioning of the device for the device under review.

Row ID	Regions & Level		Heading	Common Content	Regional Content
					(7) Design Validation, 820.30(g) – Summarize the scientific method or process used to prove the equivalence of the units used in validation testing to production units. – Summarize how the clinical evaluations of the device ensure the device meets user needs and the intended uses. – Explain how you have (or will) complete your software validation, and include any system integration testing **WHO PQ** a) Change control and Change notification SOPs
6.11	EU, NMPA, TGA, USFDA, WHO PQ	1	Purchasing	Documents, including procedures that provide evidence that purchased products/services conform to established relevant quality and/or product specifications, as well as records providing evidence of conformance to requirements, and of the effective operation of the quality management system (when applicable). • ISO 13485 Elements – SOPs and device specific documentation implementing sub clause 7.4	**USFDA PMA** Please provide documentation according to QS PMA Guidance, Section II. Manufacturing Information, Items: (4) Purchasing Controls, 820.50 – SOPs – List of suppliers and controls for suppliers of outsourced design and manufacturing function (9) Receiving Acceptance Activities, 820.80(b) – SOPs – Discussion of how Receiving Acceptance is balanced with Purchasing Control activities **EU** Detailed information on elements of Annex II 3. DESIGN AND MANUFACTURING INFORMATION (a) information and to allow the manufacturing processes such as production,

Row ID	Regions & Level		Heading	Common Content	Regional Content
					assembly, final product testing, and packaging of the finished device to be understood. More detailed information shall be provided for the audit of the quality management system or other applicable conformity assessment procedures; (b) identification of all sites, including suppliers and sub-contractors, where design and manufacturing activities are performed. Please provide here only information on components and products provided by suppliers & subcontractors focusing on controls relevant for those components and products (Purchasing, Incoming Inspection, Final Product Testing) **TGA** A description of how purchasing requirements are fulfilled for the suppliers. This must include the supporting procedures and records of supplier evaluations by the manufacturer or suitable third party; and any agreement between the manufacturer and supplier defining responsibilities and authorities. **WHO PQ** a) Supplier evaluation and control b) Verification of purchased product
6.12	ANVISA, EU, HC, HSA,	1	Production and Service Controls	• ISO 13485 Elements – SOPs and device specific documentation implementing sub clause 7.5	**USFDA PMA** Please submit documentation according to QS PMA Guidance II. Manufacturing Information, Items:

Row ID	Regions & Level		Heading	Common Content	Regional Content
	NMPA, TGA, USFDA, WHO PQ				(2) Production Flow and summary of in-process acceptance activities (3) Use of Standards (7) Process Validation 820.75 (Master Plan), and list of process that will not be validated but verified by inspection and test instead, (8) Process Validation 820.75(a) – process validation protocols and validation reports (10) Final Acceptance Activities, 820.80(d) SOPs (14) Servicing, 820.200 SOPs **HC** 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

Row ID	Regions & Level		Heading	Common Content	Regional Content
					HC Note: a) Manufacturing flow diagram is required to describe the methods used in, and quality controls used for, the manufacture, processing, packaging, storage and, where appropriate, the installation of the device. Sufficient detail must be provided to enable the judgement of the appropriateness of the quality controls in place. b) If multiple facilities are involved in the manufacture of a device, the applicable information for each facility must be submitted. If the information is identical for a number of sites, this should be stated. **EU** Detailed information on elements of Annex II 3. DESIGN AND MANUFACTURING INFORMATION (a) information to allow the manufacturing processes such as production, assembly, final product testing, and packaging of the finished device to be understood. More detailed information shall be provided for the audit of the quality management system or other applicable conformity assessment procedures; (b) identification of all sites, including suppliers and sub-contractors, where manufacturing activities are performed. Note: Please provide only information on processes and their validation that are not

Row ID	Regions & Level		Heading	Common Content	Regional Content
					covered in other chapters and subchapters. Information about the following topics should be provided in the relevant subchapters of Chapter 3: - Software/Firmware - Biocompatibility and Toxicology Evaluation - Non-Material-Mediated Pyrogenicity - Safety of Materials of Biological Origin (human/animal) - Sterilization Validation - Animal Testing - Usability/Human Factors - Expiration Period and Package Validation Note: Information on suppliers and subcontractors see 6.11 **<u>HSA and ANVISA</u>** Manufacturing process for the medical device should be provided in the form of a list of resources and activities that transform inputs to the desired output. - Information should include the appropriate manufacturing methods and procedures, manufacturing environment or condition, and the facilities and controls used for the manufacturing, processing, packaging, labeling, and storage. - Information on the manufacturing process should be provided in sufficient detail to allow

Row ID	Regions & Level		Heading	Common Content	Regional Content
					a general understanding of the manufacturing processes and enable judgement of the appropriateness of the controls in place. Detailed proprietary information on the manufacturing process is not required. The information may be presented in the form of a process flow chart showing an overview of production, controls, assembly, final product testing and packaging of the finished medical device. - If multiple facilities are involved in the manufacture of medical device, o Applicable information for each facility must be submitted o Manufacturing activities carried out at each site should be clearly identified **<u>WHO PQ</u>** a) Full address, including latitude and longitude of the manufacturing facility(s) b) Site floor plan c) Manufacturing flowchart including in-process control points d) List of critical raw materials (including details of the supplier of each material) List of outsourced processes with direct product impact (e.g. outsourced manufacturing of components (conjugated antibodies, strips, reagents…), outsourced laboratory testing, packaging, printing, etc) including details of the supplier for each process

Row ID	Regions & Level		Heading	Common Content	Regional Content
6.13	NMPA, TGA, USFDA	1	Control of Monitoring and Measuring Equipment	Documents, including procedures that provide evidence of monitoring and measuring equipment used in the QMS is controlled and continuously performing per the established requirements, as well as records providing evidence of conformance to requirements, and of the effective operation of the quality management system (when applicable). • ISO 13485 Element- SOPs and device specific documentation for implementing sub clause 7.6	**USFDA PMA** Please submit documentation according to QS PMA Guidance II. Manufacturing Information, Item: (6) Inspection, Measuring, and Test Equipment, 820.72
6.14	NMPA, TGA, USFDA, WHO PQ	1	QMS Measurement, Analysis and Improvement	Documents, including procedures that provide evidence of how monitoring, measurement, analysis and improvement to ensure the conformity of the product and QMS, and to maintain the effectiveness of the QMS, as well as records providing evidence of conformance to requirements, and of the effective operation of the quality management system (when applicable). • ISO 13485 Element – SOPs and device specific documentation for implementing clause 8	**USFDA PMA** Please submit the following documentation according to QS PMA Guidance II. Manufacturing Information, Items: (1) Quality System SOPs – Quality audit (820.22) or internal audit procedure(s) (11) Nonconforming Products, 820.90 (12) Corrective and Preventive Action (CAPA), 820.100 (13) Complaint Files, 820.198 Please also explain: – How complaint handling ties to Adverse Event Report procedures – How risk management is tied to the CAPA activities **WHO PQ** a) Complaint handling and vigilance b) Control of non-conforming goods/processes c) Batch/lot release SOPs

Row ID	Regions & Level		Heading	Common Content	Regional Content
6.15	HC	1	Device Specific Quality Plan		The review requirement for a quality plan is not met by the ISO 13485 certificate alone, instead refer to ISO 10005. A quality plan should specify "which processes, procedures and associated resources will be applied by whom and when to meet the requirements of a specific project, product, process or contract…". This information may be provided in an application in the form of a flow chart, process may, document matrix, table or text description. A quality plan specific for the subject device should link device requirements to the processes, resources and projects used by the manufacturer in producing that device.
6.16	NMPA	1	Quality management system verification document		According to the above procedures of the quality management system, applicants shall form documents and records related to the quality management system. The following materials shall be submitted for inspection during the inspection on the quality management system. 1. Basic information form of applicant. 2. Organizational chart of the applicant. 3. General layout of the enterprise and the distribution map of production areas. 4. Where there are requirements for purification in the production process, a copy of the environmental testing report (with the layout plan attached) issued by a qualified testing institution shall be provided. 5. The flow chart of the product production process, which shall indicate the main control points and items, main raw materials and

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

7. Document revision history

Version	Description of Changes	Author	Date
PD1	Version for Public Consultation	B. Dowling & IMDRF's RPS ToC WG Members	9 September 2013
R1	Final Version following public consultation and piloting	B. Dowling & IMDRF's RPS ToC WG Members	27 May 2014
R2	Revisions for NMPA requirements, WHO PQ inclusion, addition of "Cybersecurity" and "Interoperability" headings to software section, other minor revisions based on review and experience	B. Dowling & IMDRF's RPS ToC WG Members	27 March 2018
R3	Addition of Singapore (HSA) requirements, revised summary definition, other minor editorial changes.	B. Dowling & IMDRF's RPS ToC WG Members	21 March 2019
R4	Significant revisions based on policy changes in regions since last update	P. Axtell, D. Yoon, & IMDRF's RPS ToC WG Members	25 June 2024

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