National Agency for Food and Drug Administration & Control (NAFDAC)

Vaccines, Biologics and Medical Devices - Registration and Agencyy Affairs (VBM-R&RA) Directorate

Guidelines for Compilation of a Product Dossier for Registration of Non-In Vitro Diagnostic (nIVD ToC)

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A. ACKNOWLEDGMENT

The Agency acknowledges the adoption of IMDRF/RPS WG/N9 Final:2024 (Edition 4) and also the technical support of the International Medical Device Agencys Forum (IMDRF) in developing this guidance document.

B. SCOPE

These guidelines have been developed in pursuance to the NAFDAC Act N1, LFN,2004 and made to provide guidance to applicant in the organization of information to be provided to the Agency in seeking marketing authorization for non in vitro diagnostics for human use. It also provides guidance to the industry on the expectation of NAFDAC as it concerns submission of technical documents.

C. Introduction

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

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

NAFDAC may request, during the course of the registration process, additional information that is notspecifically described in this document. This will be done in order to facilitate a clearer understanding of the quality, safety and performance of a product to be registered. The rationale for any additional requests will be clearly documented in correspondence to the manufacturers.

For the purpose of this document, the verbal forms used follow the usage described below:

- “shall” indicates that the manufacturer is required to comply with the instructions in thedocument below.
- “should” indicates that the manufacturer is recommended to comply with the instructions, butit is not a requirement.
- “may” indicates that the instructions are a suggested method to compile the documentationrequest, but it is not a requirement.

D. Purpose

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 Agencyy requirements.

E. Definitions

Accessory – Means an article intended specifically by its manufacturer to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended use (see GHTF SG1 N71:2012).

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 monized/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.

SUBMISSION – A Agency submission can be any type of information related to a medical device Agency 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 Agency policy.

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:

- Why the characteristic being evaluated is of interest;

- Why the particular methods are being used to evaluate the characteristic, if applicable including why an Agency or harmonized/recognized standard/guidance has or has not been complied with;
- How the stated acceptance criteria and sample size are scientifically supported.
- What device was tested and how it relates to the devices that will be marketed;
- Why the tested components are representative of the range of devices that will be marketed.
- Whether the summary has been previously submitted and reviewed by the Agency, including identification of the device and the reference number for the submission; and
- The extent to which the duties and functions of a study (e.g. testing, monitoring, etc.) have been conducted by an external organization (e.g. contract research organisation or individual contractor).

Language requirements

Each jurisdiction has its own language requirements. 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 Agencyy requirements are met, and that clear and transparent evidence of conformity to these requirements are provided.

Acronyms

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 Agencys Forum

JP	Japan
MDSAP	Medical Device Single Audit Program
MFDS	Ministry of Food and Drug Safety - Korea
MHRA	Medicines and Healthcare products Agencyy Agency - UK
NB	Notified Body
NMPA	National Medical Products Administration – China
PMDA	Pharmaceuticals and Medical Devices Agency – Japan
RCT	Randomized Controlled Trial
SUD	Single Use Device
TGA	Therapeutic Goods Administration – Australia
ToC	Table of Contents
UK	United Kingdom
USFDA	United States Food and Drug Administration

Hierarchy presentation

The following is a hierarchical presentation of the submission structure. The numbering should remain consistent regardless of whether the heading is required or not. For example, if heading 1.02 is not required for the submission type or jurisdiction, but headings 1.01 and 1.03 are, then the numbering would remain 1.01 followed by 1.03. More detailed guidance regarding where elements belong is provided following this table.

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1.11	Acceptance for Review Checklist
1.12	Statements/Certifications/Declarations of Conformity
1.12.01	Performance and Voluntary Standard
1.12.02	Environmental Assessment
1.12.03	Clinical Trial Certifications
1.12.04	Indications for Use Statement with Rx and/or OTC designation Enclosure
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2.04.05	Substantial Equivalence Discussion
2.05	Indications for Use and/or Intended Use and Contraindications
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2.05.03	Pediatric Use
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2.06	Global Market History
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2.06.03	Sales, Incident and Recall Rates
2.06.04	Evaluation/Inspection Reports

2.07	Post-Market Study Plans
2.08	Risk Management
2.09	Essential Principles (EP) Checklist
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3.03	Not Applicable
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3.05.01.01	[Study description, study identifier, date of initiation]
3.05.01.01.01	Summary
3.05.01.01.02	Full Report
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3.05.02.01	[Study description, study identifier, date of initiation]
3.05.02.01.01	Summary
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3.05.03.01	[Study description, study identifier, date of initiation]
3.05.03.01.01	Summary
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3.05.05.04	System and Software Architecture Design (SAD) Chart

3.05.05.05	Software Design Specification (SDS)
3.05.05.06	Traceability Analysis
3.05.05.07	Software Life Cycle Process Description / Software Development, Configuration Management, and Maintenance Practices
3.05.05.08	Software Testing as Part of Verification and Validation
3.05.05.09	Software Version / Revision Level History
3.05.05.10	Unresolved Software Anomalies
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3.05.06.01.01	Summary
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3.05.07.01	[Study description, study identifier, date of initiation]
3.05.07.01.01	Summary
3.05.07.01.02	Full Report
3.05.07.01.03	Statistical Data
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3.05.08.01	Certificates
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3.05.08.02.02	Full Report
3.05.08.02.03	Statistical Data
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3.05.09.01	End-User Sterilization
3.05.09.01.01	[Study description, study identifier, date of initiation]
3.05.09.01.01.01	Summary
3.05.09.01.01.02	Full Report
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3.05.09.02	Manufacturer Sterilization Validation
3.05.09.02.01	[Study description, study identifier, date of initiation]
3.05.09.02.01.01	Summary
3.05.09.02.01.02	Full Report
3.05.09.02.01.03	Statistical Data
3.05.09.03	Residual Toxicity
3.05.09.03.01	[Study description, study identifier, date of initiation]
3.05.09.03.01.01	Summary
3.05.09.03.01.02	Full Report
3.05.09.03.01.03	Statistical Data
3.05.09.04	Cleaning and Disinfection Validation
3.05.09.04.01	[Study description, study identifier, date of initiation]
3.05.09.04.01.01	Summary

3.05.09.04.01.02	Full Report
3.05.09.04.01.03	Statistical Data
3.05.09.05	Reprocessing of Single Use Devices Validation Data
3.05.09.05.01	[Study description, study identifier, date of initiation]
3.05.09.05.01.01	Summary
3.05.09.05.01.02	Full Report
3.05.09.05.01.03	Statistical Data
3.05.10	Animal Testing
3.05.10.01	[Study description, study identifier, date of initiation]
3.05.10.01.01	Summary
3.05.10.01.02	Full Report
3.05.10.01.03	Statistical Data
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3.05.11.01.01	Summary
3.05.11.01.02	Full Report
3.05.11.01.03	Statistical Data
3.05.12	Evidence for devices with preservatives or antimicrobial claims
3.06	Non-clinical Bibliography
3.07	Expiration Period and Packaging Validation
3.07.01	Product Stability
3.07.01.01	[Study description, study identifier, date of initiation]
3.07.01.01.01	Summary
3.07.01.01.02	Full Report
3.07.01.01.03	Statistical Data
3.07.02	Package Validation
3.07.02.01	[Study description, study identifier, date of initiation]
3.07.02.01.01	Summary
3.07.02.01.02	Full Report
3.07.02.01.03	Statistical Data
3.08	Other non-clinical Evidence
3.08.01	[Study description, study identifier, date of initiation]
3.08.01.01	Summary
3.08.01.02	Full Report
3.08.01.03	Statistical Data
CHAPTER 4 – CLINICAL EVIDENCE	
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4.02	Overall Clinical Evidence Summary
4.02.01	Clinical Evaluation Report
4.02.02	Device Specific Clinical Trials
4.02.02.01	[Trial description, protocol #, date of initiation]
4.02.02.01.01	Clinical Trial Summary
4.02.02.01.02	Clinical Trial Report

4.02.02.01.03	Clinical Trial Data
4.02.03	Clinical Literature Review and Other Reasonable Known Information
4.03	Informed Consent Information
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5.08	Patient File Stickers/Cards and Implant Registration Cards
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6.01	Cover Letter
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6.03	Product Descriptive Information
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6.05	Required Forms
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6.09	Planning of Product Realization and Customer Related Processes
6.10	Design and development
6.11	Purchasing
6.12	Production and service controls
6.13	Control of monitoring and measuring equipment
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

Chapter 1 – Administrative

Row ID	Regions & Level		Heading	Common Content
1.01	NAFDAC	1	Cover Letter	a) The cover letter should state applicant or sponsor name and/or their authorized representative, the type of submission, the common name of the device (if applicable), device trade name or proprietary name (both of the base device and a new name if one is given to the new version/model of the device) and include the purpose of the application, including any changes being made to existing approvals. b) If applicable and accepted by the Agency, 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 Agency to view or access the device (when the Agency 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.

Row ID	Regions & Level		Heading	Common Content
				e) If the submission is in response to a request for information from the Agency this should be stated and the date of that letter should be included as well as any reference number(s). f) If the submission is unsolicited information (where accepted), this should be stated and any related reference number(s) provided. g) Identification of the Agencyy jurisdiction(s) in which marketing is sought. **NOTE:** The cover letter should not contain any detailed scientific information.

1.01	NAFDAC	1	Cover Letter	h) The cover letter should state applicant or sponsor name and/or their authorized representative, the type of submission, the common name of the device (if applicable), device trade name or proprietary name (both of the base device and a new name if one is given to the new version/model of the device) and include the purpose of the application, including any changes being made to existing approvals. i) If applicable and accepted by the Agency, it should include information pertaining to any Master Files referenced by the submission. j) If applicable, acknowledgement that a device sample has been submitted or offered alternatives to allow the Agency to view or access the device (when the Agency requests a sample). k) If the submission is requesting approval of a change that is the result of CAPA due to a recall, this should be stated. l) If the submission is in response to a request for information from the Agency this should be stated and the date of that letter should be included as well as any reference number(s). m) If the submission is unsolicited information (where accepted), this should be stated and any related reference number(s) provided. n) Identification of the Agencyy jurisdiction(s) in which marketing is sought. **NOTE:** The cover letter should not contain any detailed scientific information.
1.02	NAFDAC	1	Submission Table of	a) Includes at least level 1 & 2 headings for the

			Contents	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	NAFDAC	1	List of Terms/Acronyms	Terms or acronyms used in the submission that require definition, should be defined here.
1.04	NAFDAC	1	Application Form/Administrative Information	
1.05	NAFDAC	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 variant/model: a) the identifier (e.g. bar code, catalogue, model or part number, UDI) b) a statement of its name/description that provides (e.g. Trade name, size, material) **NOTE:** i. A model/variant/configuration/component/accessory of a device has common specifications, performance and composition, within limits set by the applicant. ii. Typically each item listed should be available for sale. For example, if everything is sold as part of a kit, then this list would only include the kit. You do not need to list all components that may be sold within a kit/set, unless the component is available for sale independently of the kit.
1.06	NAFDAC	1	Quality Management System, Full Quality System or Other Agencyy Certificates	
1.07	NAFDAC	1	Free Sale Certificate/ Certificate of Marketing authorization	a) List of the Agencyy Authorities that have provided current Agencyy approval for the supply of this product in their country/region of authority b) Details of the type of Agencyy approval obtained from each Agencyy Authority

				c) Current evidence of the Agencyy approval, such as certificates provided by the Agencyy 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 Agencyy approvals should be clearly identifiable as export-only approvals.
1.08	NAFDAC	1	Expedited Review Documentation	
1.09	NAFDAC	1	User Fees	
1.10	NAFDAC	1	Pre-Submission Correspondence and Previous Agency Interactions	a) During the product lifecycle, pre-submission correspondence, including teleconferences or meetings, may be held between the Agency and the applicant. Further, the specific subject device may have been subject to previous Agencyy submissions to the Agency. The contents should be limited to the subject device as similar devices are addressed in other areas of the submission. If applicable, the following elements should be provided: i. List prior submission or pre-submissions where Agency feedback was provided ii. Prior submissions should include identification of submission # iii. For any pre-submission activities that have not previously been assigned any tracking/reference number, include the information package that is submitted prior to pre-submission meetings, the meeting agenda, any presentation slides, final meeting minutes, responses to any action items arising from the meetings, and any email correspondence related to specific aspects of the application. iv. Issues identified by the Agency in prior submissions (i.e., clinical study applications, withdrawn/deleted/denied Agencyy submission) for the subject device. v. Issues identified and advice provided by the Agency in pre-submission interactions between the Agency 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 Agency to which the submission is being submitted (e.g. Health Canada does not need pre-submission information relating to interactions with ANVISA).
1.11	NAFDAC	1	Acceptance for Review Checklist	
1.12	NAFDAC	1	Statements/Certifications/ Declarations of Conformity	**NO CONTENT AT THIS LEVEL**
1.12.01	NAFDAC	2	Chapter Retired	Content redundant with 2.10
1.12.02	NAFDAC	2	Environmental Assessment	
1.12.03	NAFDAC	2	Clinical Trial Certifications	
1.12.04	NAFDAC	2	Indications for Use Statement with Rx and/or OTC designation Enclosure	
1.12.05	NAFDAC	2	Truthful and Accurate Statement	
1.12.06	NAFDAC	2	USFDA Class III Summary and Certification	
1.12.07	NAFDAC	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
1.13	NAFDAC	1	Letters of Reference	Where applicable, letter from the owner of any separate document referenced in the submission (e.g. Master File or previous Agencyy 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 Agencyy 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	NAFDAC	1	Letter of Authorization	
1.15	NAFDAC	1	Other Administrative Information	Heading for other administrative information that may be important to the submission but that does not fit in any of the other headings of this chapter. **NOTE:** To ensure all elements of your submission are adequately reviewed, please be sure that any content placed here does not belong under any heading described above.

Chapter 2 – Submission Context

Row ID	Regions & Level		Heading	Common Content
2.01	NAFDAC	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	NAFDAC	1	General Summary of Submission	a) Statement of the device type (e.g. hip implant, infusion pump, standalone software) and name (e.g. trade name, proprietary name), its general purpose, and a high-level summary of key supporting evidence (i.e., studies that are unique to the risks of this device type, for example burst testing of a ceramic femoral head; electrical safety evaluation (IEC 60601) testing for an infusion pump). b) Summary of submission, including i. The type of submission (e.g. new, amendment, change of existing application, renewal); ii. if amendment/supplement, the reason of the amendment/supplement; iii. if a change to existing approval, description of the change requested (e.g. changes in design, performance, indications, changes to manufacturing processes, manufacturing facilities, suppliers); iv. any high-level background information or unusual details that the manufacturer wishes to highlight in relation to the device, its history or relation to other approved devices or previous submissions (provides context to submission).
2.03	NAFDAC	1	Summary and Certifications for Agencyy Submissions	
2.04	NAFDAC	1	Device Description	**NO CONTENT AT THIS LEVEL**
2.04.01	NAFDAC	2	Comprehensive Device Description and Principle of Operation	a) A general description of the device, including: i. A statement of the device name ii. What the device does? iii. Who uses it and for what? (high level statement) iv. Where to use it? (places/environment where the device is intended to be used)

Row ID	Regions & Level		Heading	Common Content
				v. How it works? Including a description of the features/variants/operating modes that enable the device to be used for indications/intended use (principle of operation/mechanism of action) and if not readily apparent or typical for the device type, a brief description of the underlying science/technology, design concepts, and/or theoretical principles supporting the device's function. vi. If applicable, labelled pictorial representation (diagrams, photos, drawings). vii. If system, how the components relate? viii. If applicable, identify if the device incorporates software/firmware and its role b) Product specification, including: i. Physical characteristics or relevance to the end user (dimensions, weight) ii. Features and operating modes iii. Input specifications (e.g. electrical power requirements, settings and associated allowable ranges/limits) iv. Output and performance characteristics (e.g. range and type of energy delivered, resolution of images) v. If applicable, an indication of the variants/models of the devices and a summary of the differences in specifications of the variants (comparison table and/or pictures/diagrams with supporting text). c) List of accessories intended to be used in combination with the devices. d) Indication of any other medical devices or general product intended to be used in combination with the medical device (e.g. infusion sets and infusion pumps, bipolar electrode and RF equipment). e) Components or accessories that can be sold separately should be identified. f) If approved by the Agency, provide the approval number and identification for each component or accessory. g) If the device is to be sterilized, an indication of who is to perform the sterilization and by what method (e.g. EtO, gamma irradiation, dry heat) **OR** an affirmative statement that the device is non-sterile when used.

Row ID	Regions & Level		Heading	Common Content
				NOTE: The validation report is not expected be presented at this point, only the device sterility condition shall be indicated here. If appropriate, for the validation report, see Chapter 3 – Non-Clinical Studies. h) Summary of the composition of the device including, at minimum, the material specification and/or chemical composition of the materials that have direct or indirect contact with the user and/or patient. When required, full details to support how these specifications are met are to be provided in 3.5.02 – Chemical/Material Characterization. **NOTE:** If applicable, chemicals may be identified using either the IUPAC (International Union of Pure and Applied Chemistry) or the CAS (Chemical Abstract Service) Registry number. Reference to applicable material standards may also be useful in this description. i) If applicable, indication of biological material or derivate used in the medical device, including: origin (human, animal, recombinant or fermentation products or any other biological material), source (e.g. blood, bone, heart, any other tissue or cells), and the intended reason for its presence and, if applicable, its primary mode of action. j) If the device contains an active pharmaceutical ingredient (API) or drug, an indication of the substance, should be provided. This should include its identity and source, and the intended reason for its presence and its primary mode of action. k) Engineering diagrams/prints/schematics of the device (should be provided as a separate file within the submission). **NOTE**: The sponsor/applicant should explicitly address any existing Agency guidance related to the comprehensive device description and principles of operations provided in this section regarding the subject device
2.04.02	NAFDAC	2	Description of Device Packaging	a) Information regarding the packaging of the devices, including, when applicable, primary packaging, secondary and any other packaging associated; b) Specific packaging of accessories marketed together with the medical devices shall also be described; c) If the user needs to package the medical device or its accessories before they

Row ID	Regions & Level		Heading	Common Content
				perform sterilization, information about the correct packaging (e.g. material, composition, dimension) should be provided.
2.04.03	NAFDAC	2	History of Development	For any device versions/prototypes referenced in the evidence presented in the submission, a table describing the version/name, with 4 columns (Device Name and/or Version; Description of changes from previous row; motivation for the change; list of verification/validation activities, including clinical studies, conducted using this version). For any design verification or validation activities presented in this submission (including clinical studies) performed on any earlier versions of the subject device, include a justification for why the changes do not impact the validity of the data collected under those activities in supporting the safety and effectiveness of the final device design.
2.04.04	NAFDAC	2	Reference and Comparison to Similar and/or Previous Generations of the Device	a) A list of similar devices (available on local and international market) and/or previous generation of the devices (if existent) relevant to the submission. This should include any similar/previous generation devices that were previously reviewed and refused by the subject Agency. 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.
2.04.05		2	Substantial Equivalence Discussion	
2.05	NAFDAC	1	Indications for Use and/or Intended Use and Contraindications	**NO CONTENT AT THIS LEVEL**
2.05.01	NAFDAC	2	Intended Use; Intended Purpose; Intended User; Indications for Use	This section should include, as appropriate: a) **Intended Use:** The statement of intended use should specify the therapeutic or diagnostic function provided by the device and may describe the medical procedure in which the device is to be used (e.g. Diagnosis *in vivo* or *in vitro*, treatment monitoring rehabilitation, contraception, disinfection).

Row ID	Regions & Level		Heading	Common Content
				b) **Intended Purpose:** What is expected with the use of this medical device? Which results are expected? c) **Intended user** and skills/knowledge/training that the user should have to operate or use the device. d) Identify if the device is intended for **single or multiple use** e) **Indications for Use:** i. Disease or medical condition that the device will diagnose, treat, prevent, mitigate, or cure, parameters to be monitored and other considerations related to indication for use. ii. If applicable, information about patient selection criteria. iii. If applicable, information about intended patient population (e.g. adults, pediatrics or newborn) or a statement that no subpopulations exist for the disease or condition for which the device is intended. f) For amendments/supplements or changes to existing approvals, identify any changes to the previously approved intended use/intended purpose/intended user/indications. If there are no changes, this should be stated, and a reference should be made to the precise Agencyy tracking number associated with the previous submission/approval. **NOTES:** i. The statements of intended use and purpose and the intended user and indications for use must be **as presented in the labelling**. ii. If more than one device is included, the information should be provided for each device
2.05.02	NAFDAC	2	Intended Environment/Setting for use	a) The setting where the device is intended to be used (e.g. domestic use, hospitals, medical/clinical laboratories, ambulances, medical/dental offices). Multiple options can be indicated. b) If applicable, environmental conditions that can affect the device's safety and/or performance (e.g. temperature, humidity, power, pressure, movement).
2.05.03	NAFDAC	2	Pediatric Use	
2.05.04	NAFDAC	2	Contraindications	If applicable, specify the disease or medical conditions that would make use of the

Row ID	Regions & Level		Heading	Common Content
			For Use	device inadvisable due to unfavorable risk/benefit profile. **NOTE:** The statement of contraindications for the device must be as presented in the labelling.
2.06	NAFDAC	1	Global Market History	**NO CONTENT AT THIS LEVEL**
2.06.01	NAFDAC	2	Global Market History	a) Up to date identification of the markets (all countries or jurisdictions) where the device is approved for marketing. b) Should include history of the marketing of the device by any other entity, acknowledging that detailed information may not be available in all cases. c) Include a list of all countries in which the device has been removed from marketing for any reason related to the safety or effectiveness of the device.
2.06.02	NAFDAC	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 adverse events is voluminous, provide a summary by event type that state the number of reported events for each event type. c) List of the medical device recalls and/or advisory notice, and a discussion of the handling and solution given by the manufacturer in each case. d) A description of any analysis and/or corrective actions undertaken in response to items listed above. e) If there have been no adverse events/incidents, recalls and/or advisory notice to date, provide an attestation from device owner on company letterhead, that there have been no adverse events/incidents, recalls and/or advisory notice since commercial introduction of the device. NOTES

Row ID	Regions & Level		Heading	Common Content
				i. It is acknowledged that the definition of recall may vary from one sdiction to another.
2.06.03	NAFDAC	2	Sales, Incident and Recall Rates	a) A summary of the number of units sold in each country/region and a statement of the period associated with this data. b) Provide the rates calculated for each country/region, for example: i. Incident rate = # adverse events/incidents divided by # units sold, expressed as a percentage ii. Recall rate = # recalls divided by # units sold, expressed as a percentage Rates may be presented in other appropriate units such as per patient year of use or per use. In this case, methods for determining these rates should be presented and any assumptions supported. 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 sdiction to another. ii. Sales in this context should be reported as the number of units sold. iii. The summary of sales should be broken down by components when ɔropriate.
2.06.04	NAFDAC	2	Evaluation/Inspection Reports	
2.07	NAFDAC	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

Row ID	Regions & Level		Heading	Common Content
				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.
2.08	NAFDAC	1	Risk Management	a)A summary of the risks identified during the risk analysis process and how these risks have been controlled to an acceptable level. 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.
2.09	NAFDAC	1	Essential Principles (EP) of Safety and Performance Checklist	a) An EP checklist established for the medical devices, information about method(s) used to demonstrate conformity with each EP that applies, references for the method adopted and identification of the controlled document with evidence of conformity with each method used. b) For the controlled documents indicated which are required for inclusion in the submission: a cross-reference of the location of such evidence within the submission. c) If any EP indicated in the checklist does not apply to the device: a documented rationale of the non-application of each EP that does not apply. NOTE: Methods used to demonstrate conformity may include one or more of the following: a) conformity with recognised or other standards; b) conformity with a commonly accepted industry test method(s); c) conformity with an in-house test method(s); d) the evaluation of pre-clinical and clinical evidence;

Row ID	Regions & Level		Heading	Common Content
				comparison to a similar device already available on the market.
2.10	NAFDAC	1	Standards	**NO CONTENT AT THIS LEVEL**
2.10.01	NAFDAC	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 Agencys 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.
2.10.02	NAFDAC	2	Declaration and/or Certification of Conformity	
2.11	NAFDAC	1	Other Submission Context Information	Heading for other submission context information that may be important to the submission but that does not fit in any of the other headings of this chapter. **NOTE:** To ensure all elements of your submission are adequately reviewed, please be sure that any content placed here does not belong under any heading described above.

Chapter 3 – Non-clinical evidence

Row ID	Regions & Level		Heading	Common Content
3.01	NAFDAC	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.

Row ID	Regions & Level		Heading	Common Content
3.02			Not Applicable	Original content moved to Chapter 2
3.03			Not Applicable	Original content moved to Chapter 2
3.04			Not Applicable	Original content moved to Chapter 2
3.05	NAFDAC	1	Non-clinical Studies	**NO CONTENT AT THIS LEVEL**
3.05.01	NAFDAC	2	Physical and Mechanical Characterization	Evidence that supports the physical or mechanical properties of the subject device is to be included in this section. This should include: a) A summary of the non-clinical evidence that falls within this category b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e., what tests were considered and why they were or were not performed) c) If applicable, particulate testing from wear or device coatings. d) Discussion to support why the evidence presented is sufficient to support the application. **OR** e) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing Agencyy guidance related to the non-clinical study results provided in this section regarding the subject device.
3.05.01.01	NAFDAC	3	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL**. This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone. For example, the structure will look something like this Component A Fatigue Test, MT4203, 2010-10-10 Summary of MT4203 Full Report for MT4203 Assembly B Compatibility Test, MT4584, 2011-01-23 Summary of MT4584 Full Report for MT4584

Row ID	Regions & Level		Heading	Common Content
3.05.01.01.01	NAFDAC	4	Summary	A summary of the specific study described in the custom heading above.
3.05.01.01.02	NAFDAC	4	Full Report	The test report for the test described in the custom heading above.
3.05.01.01.03	NAFDAC	4	Statistical Data	
3.05.02	NAFDAC	2	Chemical/Material Characterization	Tests that describe the chemical or structural composition of the device and its components are to be included in this section. This should include: a) A summary of the non-clinical evidence that falls within this category. b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e., what tests were considered and why they were or were not performed). c) Discussion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing Agency guidance related to the non-clinical study results provided in this section regarding the subject device.
3.05.02.01	NAFDAC	3	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.
3.05.02.01.01	NAFDAC	4	Summary	A summary of the specific study described in the custom heading above.
3.05.02.01.02	NAFDAC	4	Full Report	The test report for the test described in the custom heading above.
3.05.02.01.03	NAFDAC	4	Statistical Data	
3.05.03	NAFDAC	2	Electrical Systems: Safety, Mechanical and Environmental Protection, and Electromagnetic Compatibility	Evidence supporting electrical safety, mechanical and environmental protection, and electromagnetic compatibility are to be included in this section. This should include: a) A summary of the non-clinical evidence that falls within this category b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e., what tests were considered and why they were or were not performed)

Row ID	Regions & Level		Heading	Common Content
				c) Discussion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing Agency guidance related to the non-clinical study results provided in this section regarding the subject device
3.05.03.01	NAFDAC	3	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.
3.05.03.01.01	NAFDAC	4	Summary	A summary of the specific study described in the custom heading above.
3.05.03.01.02	NAFDAC	4	Full Report	The test report for the test described in the custom heading above.
3.05.03.01.03	NAFDAC	4	Statistical Data	
3.05.04	NAFDAC	2	Radiation Safety	Studies supporting radiation safety, where the device emits ionizing and/or non-ionizing radiation or where the device is exposed to radiation are to be included in this section. This includes bench tests ensuring safety and performance to support the MRI safety labelling of the device. This should include: a) A summary of the non-clinical evidence that falls within this category b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e., what tests were considered and why they were or were not performed) c) Discussion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing Agency guidance related to the non-clinical study results provided in this section regarding the subject

Row ID	Regions & Level		Heading	Common Content
				device
3.05.04.01	NAFDAC	3	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.
3.05.04.01.01	NAFDAC	4	Summary	A summary of the specific study described in the custom heading above.
3.05.04.01.02	NAFDAC	4	Full Report	The test report for the test described in the custom heading above.
3.05.04.01.03	NAFDAC	4	Statistical Data	
3.05.05	NAFDAC	2	Software/Firmware /Programmed or programmable medical device	**NO CONTENT AT THIS LEVEL** Studies and supporting information on the software design, development process and evidence of the validation of the software, as used in the finished device, are to be included in this section and the associated sub-sections. It should also address all the different hardware configurations and, where applicable, operating systems identified in the labelling. Documentation should be organized according to software or hardware systems.
3.05.05.01	NAFDAC	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 device features that are controlled by the software, the programming language, hardware platform, operating system (if applicable), use of Off-the-shelf software (if applicable), a description of the realization process. If the product is a machine learning-enabled medical device (such as adaptive models, natural language processing, neural networks, and related approaches), please provide, as applicable: i. a detailed description of each algorithm/model, including its inputs, outputs, data selection and management for training, testing, and validation (terminology may differ in different regions); ii. model selection and evaluation;

Row ID	Regions & Level		Heading	Common Content
				iii. risk management activities; iv. materials/approaches used to provide transparency; and v. post-market performance monitoring activities.
3.05.05.02	NAFDAC	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 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.
3.05.05.03	NAFDAC	3	Software Requirement Specifications (SRS)	The Software Requirements Specifications (SRS) documentation should describe the needs or expectations for a system or software, presented in an organized format, at the software system level or subsystem level, as appropriate, and with sufficient information to understand the traceability of the information with respect to the other software documentation elements (e.g. risk management file, software design specification, system and software architecture design chart, software testing). 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.
3.05.05.04	NAFDAC	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.
3.05.05.05	NAFDAC	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

Row ID	Regions & Level		Heading	Common Content
				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.
3.05.05.06	NAFDAC	3	Traceability Analysis	A Traceability Analysis links together your product design requirements, design specifications, and testing requirements. It also provides a means of tying together identified hazards with the implementation and testing of the mitigations.
3.05.05.07	NAFDAC	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.
3.05.05.08	NAFDAC	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.
3.05.05.09	NAFDAC	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.
3.05.05.10	NAFDAC	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:

Row ID	Regions & Level		Heading	Common Content
				i) A description of what the anomaly is and what root cause(s) of the anomaly could be; ii) Identification of how the anomaly was discovered and, where possible, identification of the root cause(s) of the anomaly; iii) Evaluation of the impact of the anomaly on the device's safety and effectiveness, including operator usage and human factors considerations; iv) Outcome of the evaluation; and v) Risk-based rationale for not correcting or fixing the anomaly in alignment with the risk management plan or procedure(s).
3.05.05.11	NAFDAC	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"
3.05.05.12	NAFDAC	3	Interoperability	If the device can communicate with other devices. Evidence to support the interoperability should be provided.
3.05.06	NAFDAC	2	Biocompatibility and Toxicology Evaluation	Studies supporting biocompatibility and assessing toxicology are to be included in this section. Studies to assess the immunological response to animal or human tissues, tissue components or derivatives are to be included in this section. This should include: a) A list of all materials in direct or indirect contact with the patient or user. b) State conducted tests, applied standards, test protocols, the analysis of data and the summary of results c) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e., what tests were considered and why they were or were not performed) d) Discussion to support why the evidence presented is sufficient to support the application. **OR** e) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTES:** i. The sponsor/applicant should explicitly address any existing Agency guidance related

Row ID	Regions & Level		Heading	Common Content
				to the non-clinical study results provided in this section regarding the subject device ii. Tests should be conducted on samples from the finished, sterilized (when supplied sterile) device.
3.05.06.01	NAFDAC	3	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.
3.05.06.01.01	NAFDAC	4	Summary	A summary of the specific study described in the custom heading above.
3.05.06.01.02	NAFDAC	4	Full Report	The test report for the test described in the custom heading above.
3.05.06.01.03	NAFDAC	4	Statistical Data	
3.05.07	NAFDAC	2	Non-Material-Mediated Pyrogenicity	Studies to support pyrogenicity evaluation of final release, such as endotoxin levels, are to be included in this section. This should include: a) A summary of the non-clinical evidence that falls within this category b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e., what tests were considered and why they were or were not performed) c) Discussion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing Agencyy guidance related to the non-clinical study results provided in this section regarding the subject device
3.05.07.01	NAFDAC	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	NAFDAC	4	Summary	A summary of the specific study described in the custom heading above.
3.05.07.01.02	NAFDAC	4	Full Report	The test report for the test described in the custom heading above.
3.05.07.01.03	NAFDAC	4	Statistical Data	

Row ID	Regions & Level		Heading	Common Content
3.05.08	NAFDAC	2	Safety of Materials of Biological Origin (human/animal)	Evaluations performed to demonstrate the safety of materials of biological origin (e.g. animal sourced, human sourced material) are to be included in this section. This should include: a) A description of biological material or derivate b) State the harvesting, processing, preservation, testing and handling of tissues, cells and substances c) If applicable, discussion of infectious agents/transmissible agents known to infect the source animal d) Clarify the origin (including details of donor screening and source country) and describe the tests on validation of removal or inactivation methods of viruses and other pathogens in the manufacturing process. e) A brief summary of process validation should be included to substantiate that manufacturing and screening procedures are in place to minimize biological risks, in particular, with regard to viruses and other transmissible agents. f) The system for recordkeeping to allow traceability from sources to the finished device should be fully described g) Discussion to support why the evidence presented is sufficient to support the application. **OR** h) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing Agency guidance related to the non-clinical study results provided in this section regarding the subject device
3.05.08.01	NAFDAC	3	Certificates	Certificates that support the safety of materials of biological origin (e.g. certificate of abattoir inspection).
3.05.08.02	NAFDAC	3	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.
3.05.08.02.01	NAFDAC	4	Summary	A summary of the specific study described in the custom heading above.
3.05.08.02.02	NAFDAC	4	Full Report	The test report for the test described in the custom heading above.

Row ID	Regions & Level		Heading	Common Content
3.05.08.02.03	NAFDAC	4	Statistical Data	
3.05.09	NAFDAC	2	Sterilization and Reprocessing Validation	**NO CONTENT AT THIS LEVEL**
3.05.09.01	NAFDAC	3	End-User Sterilization	Information and validation of end-user sterilization where it is necessary for the end-user to sterilize the device. This should include: a) A description of the sterilization process (method, parameters) and Sterility Assurance Level (SAL) b) A summary of the non-clinical evidence that falls within this category c) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e., what tests were considered and why they were or were not performed) d) If applicable, state the rationale on the durability of the product against two or more sterilization. e) Discussion to support why the evidence presented is sufficient to support the application. **OR** f) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existingAgency guidance related to the non-clinical study results provided in this section regarding the subject device
3.05.09.01.01	NAFDAC	4	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.
3.05.09.01.01.01	NAFDAC	5	Summary	A summary of the specific study described in the custom heading above.
3.05.09.01.01.02	NAFDAC	5	Full Report	The test report for the test described in the custom heading above.
3.05.09.01.01.03	NAFDAC	5	Statistical Data	

Row ID	Regions & Level		Heading	Common Content
3.05.09.02	NAFDAC	3	Manufacturer Sterilization Validation	Information and validation of manufacturer sterilization where the device is provided sterile. This should include: a) A description of the sterilization process (method, parameters) and Sterility Assurance Level (SAL) b) State if parametric release is used c) A summary of the non-clinical evidence that falls within this category d) Information on the ongoing revalidation of the process. Typically, this would consist of arrangements for, or evidence of, revalidation of the packaging and sterilization processes. e) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e., what tests were considered and why they were or were not performed) f) Discussion to support why the evidence presented is sufficient to support the application. **OR** g) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing agency Agencyy guidance related to the non-clinical study results provided in this section regarding the subject device
3.05.09.02.01	NAFDAC	4	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.
3.05.09.02.01.01	NAFDAC	5	Summary	A summary of the specific study described in the custom heading above.
3.05.09.02.01.02	NAFDAC	5	Full Report	The test report for the test described in the custom heading above.
3.05.09.02.01.03	NAFDAC	5	Statistical Data	
3.05.09.03	NAFDAC	3	Residual Toxicity	Contain the information on the testing for sterilant residues, where the device is supplied sterile and sterilized using a method susceptible to residues. This should include: a) A summary of the non-clinical evidence that falls within this category

Row ID	Regions & Level		Heading	Common Content
				b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e., what tests were considered and why they were or were not performed) c) Discussion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing agency Agencyy guidance related to the non-clinical study results provided in this section regarding the subject device.
3.05.09.03.01	NAFDAC	4	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.
3.05.09.03.01.01	NAFDAC	5	Summary	A summary of the specific study described in the custom heading above.
3.05.09.03.01.02	NAFDAC	5	Full Report	The test report for the test described in the custom heading above.
3.05.09.03.01.03	NAFDAC	5	Statistical Data	
3.05.09.04	NAFDAC	3	Cleaning and Disinfection Validation	Contains information on the validation of cleaning and disinfection instructions for reusable devices. This should include: a) A summary of the non-clinical evidence that falls within this category b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e., what tests were considered and why they were or were not performed) c) Discussion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of non-clinical laboratory study is not applicable to this case.

Row ID	Regions & Level		Heading	Common Content
				NOTE: The sponsor/applicant should explicitly address any existing agency Agencyy guidance related to the non-clinical study results provided in this section regarding the subject device.
3.05.09.04.01	NAFDAC	4	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.
3.05.09.04.01.01	NAFDAC	5	Summary	A summary of the specific study described in the custom heading above.
3.05.09.04.01.02	NAFDAC	5	Full Report	The test report for the test described in the custom heading above.
3.05.09.04.01.03	NAFDAC	5	Statistical Data	
3.05.09.05	NAFDAC	3	Reprocessing of Single Use Devices, Validation Data	The required validation data including cleaning and sterilization data, and functional performance data demonstrating that each single use device (SUD) will continue to meet specifications after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification. **NOTE:** The sponsor/applicant should explicitly address any existing agency Agencyy guidance related to the non-clinical study results provided in this section regarding the subject device.
3.05.09.05.01	NAFDAC	4	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.
3.05.09.05.01.01	NAFDAC	5	Summary	A summary of the specific study described in the custom heading above.
3.05.09.05.01.02	NAFDAC	5	Full Report	The test report for the test described in the custom heading above.
3.05.09.05.01.03	NAFDAC	5	Statistical Data	
3.05.10	NAFDAC	2	Animal Testing	Contains information about any animal studies conducted to support the submission. This should include: a) A summary of the non-clinical evidence that falls within this category b) A discussion of the non-clinical testing considered for the device and support for their

Row ID	Regions & Level		Heading	Common Content
				selection or omission from the verification and validation studies conducted in this category (i.e., what tests were considered and why they were or were not performed) c) Discussion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing agency Agencyy guidance related to the non-clinical study results provided in this section regarding the subject device.
3.05.10.01	NAFDAC	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	NAFDAC	4	Summary	A summary of the specific study described in the custom heading above.
3.05.10.01.02	NAFDAC	4	Full Report	The test report for the test described in the custom heading above.
3.05.10.01.03	NAFDAC	4	Statistical Data	
3.05.11	NAFDAC	2	Usability/Human Factors	Studies specifically assessing the instructions and/or device design in terms of impact of human behaviour, abilities, limitations, and other characteristics on the ability of the device to perform as intended should be included here. This should include: a) A summary of the non-clinical evidence that falls within this category b) A statement of the test environment and relation to the intended use environment c) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e., what tests were considered and why they were or were not performed) d) If a clinical study has been conducted that includes human factors/usability endpoints, reference to the studies and endpoints should be made, but full results do not need to be repeated. e) Discussion to support why the evidence presented is sufficient to support the

Row ID	Regions & Level		Heading	Common Content
				application. **OR** f) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTES:** i. If a clinical study has been conducted that includes usability/human factors endpoints, **reference to the studies and endpoints should be made, but full results do not need to be repeated and should be included in Chapter 4 – Clinical Evidence.** ii. The sponsor/applicant should explicitly address any existing agency Agencyy guidance related to the non-clinical study results provided in this section regarding the subject device.
3.05.11.01	NAFDAC	3	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.
3.05.11.01.01	NAFDAC	4	Summary	A summary of the specific study described in the custom heading above.
3.05.11.01.02	NAFDAC	4	Full Report	The test report for the test described in the custom heading above.
3.05.11.01.03	NAFDAC	4	Statistical Data	
3.05.12	NAFDAC	2	Evidence for devices with preservatives or antimicrobial claims	Applications for: • multi-use products such as eye lubricants and contact lens care products that contain a preservative, evidence to support its preservation efficacy must be provided. • products such as sterile dressings with antimicrobial claims, evidence to support its antimicrobial efficacy must be provided.
3.06	NAFDAC	1	Non-clinical Bibliography	This heading should include: a) A listing of published non-clinical studies involving this specific device (e.g. cadaveric evaluations, biomechanical assessments) b) Legible copies of key articles, including translation where applicable to meet the

Row ID	Regions & Level		Heading	Common Content
				Agencys language requirements c) Discussion to support why the evidence presented is sufficient to support the application. **OR** d) A statement that no literature related to the device was found.
3.07	NAFDAC	1	Expiration Period and Packaging Validation	This heading should include: a) An indication of environmental conditions for correct storage of the device (e.g. temperature, pressure, humidity, luminosity). b) A statement of the expiration period considering the materials and sterilization (when applicable), indicated as a period of time or any other means of appropriate quantification. **OR** c) A rationale that storage conditions could not affect device safety or effectiveness
3.07.01	NAFDAC	2	Product Stability	Contains details relating to product stability under specified storage conditions and in final packaging or simulated conditions. This should include: a) A statement of the shelf-life (for each component if there are differences between components) and the proposed storage condition for the device b) A summary of the non-clinical evidence, covering shelf-life period when stored at the proposed storage condition, that falls within this category c) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e., what tests were considered and why they were or were not performed) d) Discussion to support why the evidence presented is sufficient to support the application. e) Evidence to support stability of the medicinal substance contained in the device at the proposed storage condition f) Evidence of in-use stability supporting the stability during actual routine use of the device (real or simulated); **OR**

Row ID	Regions & Level		Heading	Common Content
				g) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing agency Agencyy guidance related to the non-clinical study results provided in this section regarding the subject device.
3.07.01.01	NAFDAC	3	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.
3.07.01.01.01	NAFDAC	4	Summary	A summary of the specific study described in the custom heading above.
3.07.01.01.02	NAFDAC	4	Full Report	The test report for the test described in the custom heading above.
3.07.01.01.03	NAFDAC	4	Statistical Data	
3.07.02	NAFDAC	2	Package Validation	Contains details relating to package integrity over the claimed shelf-life and in the packaging and distribution environment (transport and packaging validation) and when applicable, following exposure to the sterilization process. This should include: a) A summary of the non-clinical evidence, covering shelf-life period, that falls within this category b) A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e., what tests were considered and why they were or were not performed) c) Discussion to support why the evidence presented is sufficient to support the application. **OR** d) A statement of why this category of non-clinical laboratory study is not applicable to this case. **NOTE:** The sponsor/applicant should explicitly address any existing agency Agencyy guidance related to the non-clinical study results provided in this section regarding the subject device.

Row ID	Regions & Level		Heading	Common Content
3.07.02.01	NAFDAC	3	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.
3.07.02.01.01	NAFDAC	4	Summary	A summary of the specific study described in the custom heading above.
3.07.02.01.02	NAFDAC	4	Full Report	The test report for the test described in the custom heading above.
3.07.02.01.03	NAFDAC	4	Statistical Data	
3.08	NAFDAC	1	Other non-clinical Evidence	Heading for other information that may be important to the submission but that does not fit in any of the other headings of this chapter. This section is specifically intended for tests performed to ensure the safety and/or effectiveness of the device **that are not delineated in the rest of the Chapter 3.** This should include a) A description of the purpose of the test, the risk/safety issue the test is addressing; the test methods and results of the test **NOTE:** The sponsor/applicant should explicitly address any existing agency Agencyy guidance related to the non-clinical study results provided in this section regarding the subject device.
3.08.01	NAFDAC	2	[Study description, study identifier, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone.
3.08.01.01	NAFDAC	3	Summary	A summary of the specific study described in the custom heading above.
3.08.01.02	NAFDAC	3	Full Report	The test report for the test described in the custom heading above.
3.08.01.03	NAFDAC	3	Statistical Data	

Chapter 4 – Clinical evidence

Row ID	Regions & Level	Heading	Common Content

Row ID	Regions & Level		Heading	Common Content
4.01	NAFDAC	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	NAFDAC	1	Overall Clinical Evidence Summary	a) This should be a brief (1-2 page) summary of the available clinical evidence being presented in support of the submission. The document should list the evidence presented, its characteristics (RCT, case study, literature review, post market data from another jurisdiction or from a marketed device) and provide a discussion of how this is considered sufficient to support request for marketing for the requested indications. A tabular listing of clinical studies may be included in this section. b) If any of the study devices differ from the devices to be marketed, including competitor's devices, a description of these differences and their impact on the validity of the evidence in terms of support for the application for any device referenced in the application. This may include a detailed comparison of the clinical, technical and biological characteristics of the two devices, with a detailed critical analysis demonstrating the devices to be similar to such an extent that there would be no clinically significant difference in safety or performance. c) A discussion of the clinical evidence considered for the device and support for their selection (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.
4.02.01	NAFDAC	2	Clinical Evaluation Report	a) A clinical evaluation report reviewed and signed by an expert in the relevant field that contains an objective critical evaluation of all of the clinical data submitted in relation to the device. b) A complete curriculum vitae, or similar documentation, to justify the manufacturer's choice of the clinical expert.
4.02.02	NAFDAC	2	Device Specific	**NO CONTENT AT THIS LEVEL**

Row ID	Regions & Level		Heading	Common Content
			Clinical Trials	Clinical trial information under this heading should be grouped by trial
4.02.02.01	NAFDAC	3	[Trial description, protocol #, date of initiation]	**NO CONTENT AT THIS LEVEL** This heading should be CUSTOM AND BASED ON STUDY DETAILS and created **for each study** under the parent heading. The sub headings below would be for this study alone. For example, the structure will look something like this Level 3: EU Pilot Study, CT4203, 2010-10-10 Level 4: Clinical Trial Summary Level 4: Clinical Trial Report Level 3: NA RCT Study, CT4584, 2011-01-23 Level 4: Clinical Trial Summary Level 4: Clinical Trial Report
4.02.02.01.01	NAFDAC	4	Clinical Trial 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, # patients, inclusion/exclusion criteria) and ii. Summary of the results of the analysis iii. Summary of conclusions related to the endpoints **NOTES:** i. The sponsor/applicant should explicitly address any existing Agency guidance related to the components of the clinical trial summary. ii. The sponsor/applicant should explicitly state whether the data are sex-, gender-, age-, race-, and ethnicity- disaggregated. If the data are not disaggregated, the sponsor/applicant should provide a rationale why.
4.02.02.01.02	NAFDAC	4	Clinical Trial Report	a) A clinical trial report of the specific study described in the custom heading above. NOTES: i. The clinical study report should include elements such as the

Row ID	Regions & Level		Heading	Common Content
				estigational plan/study protocol, protocol changes and deviations, description of ients, data quality assurance, analysis/results. ii. The sponsor/applicant should explicitly address any relevant existing Agencyy guidance related to the components of the clinical trial report.
4.02.02.01.03	NAFDAC	4	Clinical Trial Data	
4.02.03	NAFDAC	2	Clinical Literature Review and Other Reasonable Known Information	a) A critical evaluation of the relevant scientific literature currently available relating to the safety and/or effectiveness of the device. This should incorporate: i. A documented search protocol to a level of detail that allows the search to be reproduced; ii. A selection strategy (inclusion/exclusion criteria); iii. Criteria for appraising the data (both favourable and unfavourable) to determine the contribution of each data set to support the conclusions; iv. Results of the literature search; and v. A documentation of the appraisal to the extent that it can be critically reviewed by others. b) A legible copy of key articles, including translation where applicable to meet the Agencys language requirements. OR c) A statement that no literature related to the device was found. **NOTES:** i) The sponsor/applicant should explicitly address any existing Agency guidance related to the clinical study and data provided in this section regarding the subject device ii) Please see Chapter 2.07 for Post-Market Study plans.
4.03	NAFDAC	1	Informed Consent Information	

Row ID	Regions & Level		Heading	Common Content
4.04	NAFDAC	1	Investigators Sites and IRB Contact Information	
4.05	NAFDAC	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	NAFDAC	1	Post-Market Surveillance Data	
4.07	NAFDAC	1	Other Clinical Evidence	Heading for other information that may be important to the submission but that does not fit in any of the other headings of this chapter.

Chapter 5 – Labelling and promotional material

Row ID	Regions & Level		Heading	Common Content
5.01	NAFDAC	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	NAFDAC	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 Agency guidance related to labelling the subject nIVD medical device.
5.03	NAFDAC	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 Agency guidance related to labelling the subject device
5.04	NAFDAC	1	e-labelling	In addition to the e-labelling itself, the following should be provided: a) For eligible medical devices and Software as a Medical Device, the applicant needs to identify which form of e-labelling is being used (e.g. electronic storage system or built-in system, website). b) Details of risk management in relation to e-labelling. If this is part of the overall risk management, refer to it here c) When IFUs are requested, a description of the procedure and operations on providing IFU's when requested

Row ID	Regions & Level		Heading	Common Content
				d) Written information for users on the webpage identifying where the IFU and further information can be found in relevant languages. e) A description on how the e-labeling requirements for the website have been met. f) If a video/App is available to demonstrate how the device is intended to function, provide a link as well as details about how it is maintained and updated throughout the life cycle of the device.
5.05	NAFDAC	1	Healthcare Professional Labelling	Labelling directed at the healthcare professional other than the package insert, such as the surgical manual
5.06	NAFDAC	1	Patient Labelling	Labelling directed at the patient other than the package insert, such as informational material written to be comprehended by the patient or lay caregiver
5.07	NAFDAC	1	Technical and/or Operator Manual	Labelling directed the technical users and operators of medical devices focusing on the proper use and maintenance of the device and surgical technique instructions
5.08	NAFDAC	1	Patient File Stickers/Cards and Implant Registration Cards	
5.09	NAFDAC	1	Product Brochures	
5.10	NAFDAC	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.

Chapter 6 – Quality management system

Row ID	Regions & Level		Heading	Common Content
6.01	NAFDAC	1	Cover Letter	A Cover Letter is only required under this chapter when the submission only includes quality system information.

6.02	NAFDAC	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	NAFDAC	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 submission includes quality system information and Chapter 2.04 “Device Description” is not provided as part of the submission.
6.04	NAFDAC	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.
6.05	NAFDAC	1	Required Forms	Any specific forms to be completed associated with Quality management Systems in the premarket review process
6.06	NAFDAC	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
6.07	NAFDAC	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).

				• ISO 13485 Elements – SOPs and device specific documentation to satisfy clause 5
6.08	NAFDAC	1	Resource Management	Documents, including procedures that provide evidence of the adequate provision of resources to implement and maintain the QMS , as referenced in Agency'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
6.09	NAFDAC	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). Records demonstrating conformance to requirements are only provided under this chapter when the submission includes quality system information, and these records were not provided within the submission as part of a previous subchapter (e.g. as part of "Biocompatibility and Toxicology Evaluation" Chapter 3.05.06). • ISO 13485 Elements – SOPs and device specific documentation implementing sub clause 7.1 and 7.2
6.10	NAFDAC	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, 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 (e.g. as part of "Biocompatibility and Toxicology Evaluation" Chapter 3.05.06). • ISO 13485 Elements – SOPs and device specific documentation implementing sub clause 7.3

6.11	NAFDAC	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
6.12	NAFDAC	1	Production and Service Controls	• ISO 13485 Elements – SOPs and device specific documentation implementing sub clause 7.5
6.13	NAFDAC	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
6.14	NAFDAC	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
6.15	NAFDAC	1	Device Specific Quality Plan	
6.16	NAFDAC	1	Quality management system verification document	
6.17	NAFDAC	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.

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