GUIDELINE FOR CONSOLIDATED DOSSIER NEW APPLICATION SUBMISSION AND EVALUATION OF GENERAL MEDICAL DEVICES AND IN VITRO DIAGNOSTIC MEDICAL DEVICES

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Guideline for Consolidated Dossier New Application Submission and Evaluation

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1 INTRODUCTION

This document "Guidelines for Consolidated Dossier New Application Submission and Evaluation of General Medical Devices and In Vitro Diagnostics Medical Devices" will serve as the reference guide for the registration process of medical device, as defined in the NMRA Act 2015, in Sri Lanka.

The contents of this Guideline should also be read in conjunction with relevant information provided in existing reference documents and guidelines issued by the South-East Asia Regulatory Network (SEARN), the Global Harmonization Task Force (GHTF), and the Tanzania Medicines and Medical Devices Authority (TMDA).

Applicants shall familiarize with the contents of this document and the governing legislations before they submit applications for registration of medical devices.

The Authority reserves the right to amend any part of this document whenever it deems necessary. The National Medicines Regulatory Act (NMRA Act) 2015 is the main legislation that control medical devices in Sri Lanka. The Authority established under NMRA Act is tasked with ensuring the quality, safety and efficacy of medical devices.

2 PURPOSE

To establish a standardized process for the preparation and submission of a consolidated dossier application, ensuring compliance with the regulatory requirements of the National Medicines Regulatory Authority (NMRA).

3 SCOPE

This guideline applies to all stakeholders involved in the compilation and submission of new medical device applications for regulatory approval.

4 ABBREVEATIONS

NMRA	- National Medicines Regulatory Authority
FMSA	- Foreign Manufacturing Site Application
PRD	- Product Registration Dossier
IVDD	- In vitro Diagnostics Devices
CEO	- Chief Executive Officer
SIL	- Sample Import License
MDRD	- Medical Device Regulatory Division
MDEC	- Medical Device Evaluation Committee
LOA	- Letter of Authorization
FSC	- Free Sale Certificate
GMP	- Good Manufacturing Practices
SMF	- Site Master File
STED	- Summary Technical Evaluation Documents
COA	- Certificate of Analysis
EO	- Ethylene Oxide
BSE	- Bovine Spongiform Encephalopathy
IFU	- Instruction for Use

PIL - Patient Information Leaflet
SEARN - South-East Asia Regulatory Network
GHTF - Global Harmonization Task Force
TMDA - Tanzania Medicines and Medical Device Authority
GMDN - Global Medical Device Nomenclature

5 DEFINITION OF TERMS

Authority
Means the National Medicines Regulatory Authority

Act
Means the National Medicines Regulatory Authority Act, No. 05 of 2015.

Applicant
The person or legal entity who submits an application to the Authority for the registration of a medical device. The applicant is legally responsible for the accuracy, completeness, and integrity of all product-related information provided in the submission and shall ensure ongoing compliance with applicable regulatory requirements throughout the product's lifecycle.

Dossier
Means a file that contains detailed information on the device description, manufacturing, quality control and biomedical studies that demonstrates quality, safety and performance of the finished medical device.

Consolidated Dossier
A consolidated dossier for medical devices is a comprehensive submission that includes documentation required for the all three components of medical device registration; manufacturing site registration, sample import license application and product registration in a single, organized file.

Medical Device
Means products falling within the definition of medical devices as mentioned in the NMRA Act 2015.

General Medical Device
Means products falling within the definition of medical devices except in vitro diagnostic medical device.

Listed devices
Means products that do not fall within the definition of medical devices but are used for personal hygiene or general medical purposes.

In Vitro Diagnostic Medical Device
Means a device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus.

Manufacturer

Means any natural or legal person responsible for the design and/or manufacturer of a medical device with the intention of making the medical device available for use, regardless of whether they do so themselves or on behalf of another.

Quality System

Means a system which consists of the organizational structure, responsibilities, procedures, processes and resources for implementing quality management and achieving the objectives.

Quality Management System

Means a management system to direct and control an organization with regard to quality, from establishing quality policy, quality objectives and implementing and maintaining quality system.

Declaration of Conformity

Means a document in which the manufacturer declares, under sole responsibility, that the product meets the applicable legal and regulatory requirements, such as safety, performance, and labeling standards.

Performance Evaluation

Means review of the performance of a medical device based upon data already available, scientific literature and, where appropriate, laboratory, animal or clinical investigations.

Label

Any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled marked, embossed or impressed on, or attached to a container of medical device.

Labeling

The label and any written printed or graphic matter relating to and accompanying the medical device.

6 RESPONSIBILITIES OF AN APPLICANT

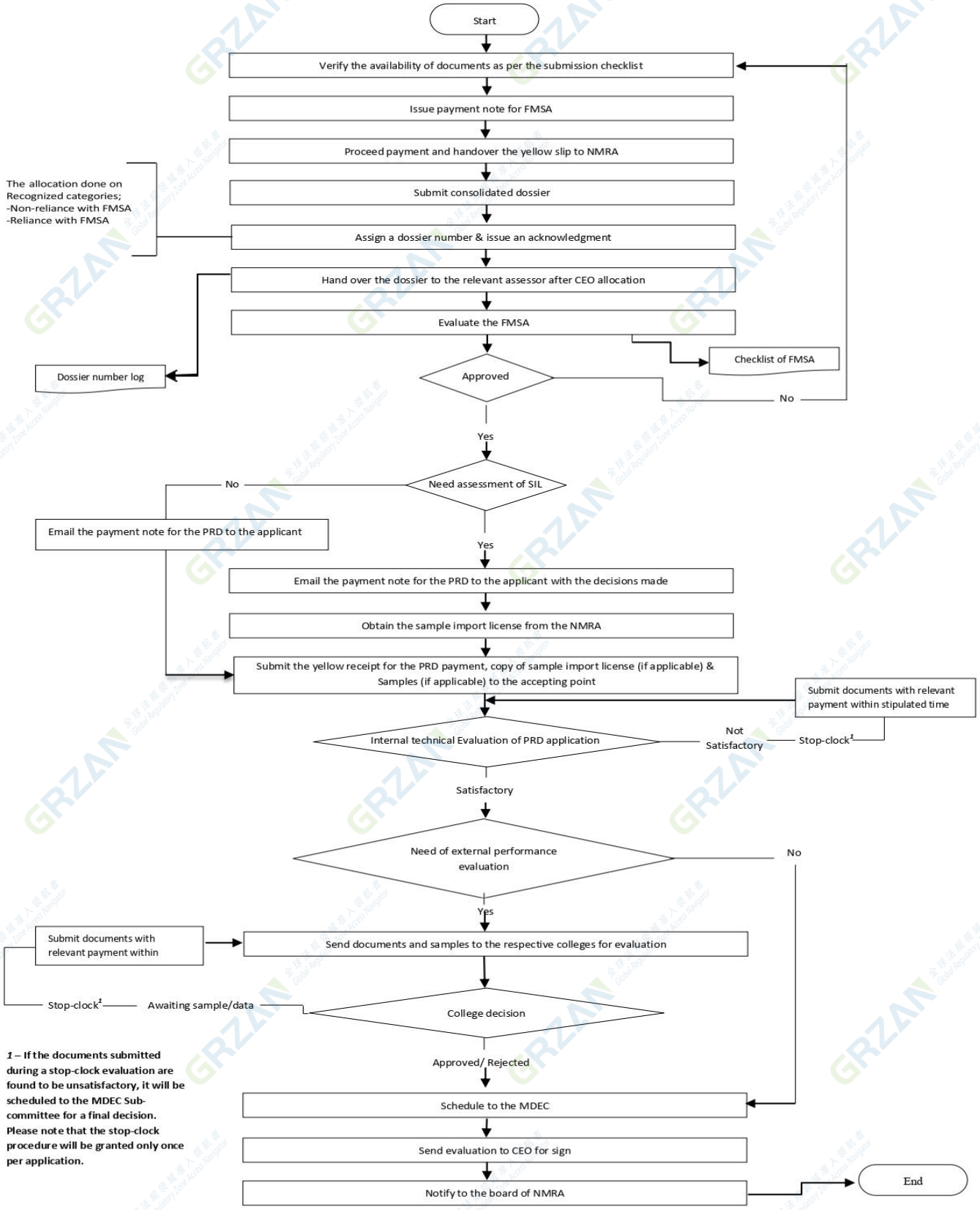
The applicant-whether a manufacturer or importer—must provide a written statement confirming that they are responsible for the safety, quality, and effectiveness of the registered device. They must also confirm that the product meets all current regulations and standards.

Responsibilities include:

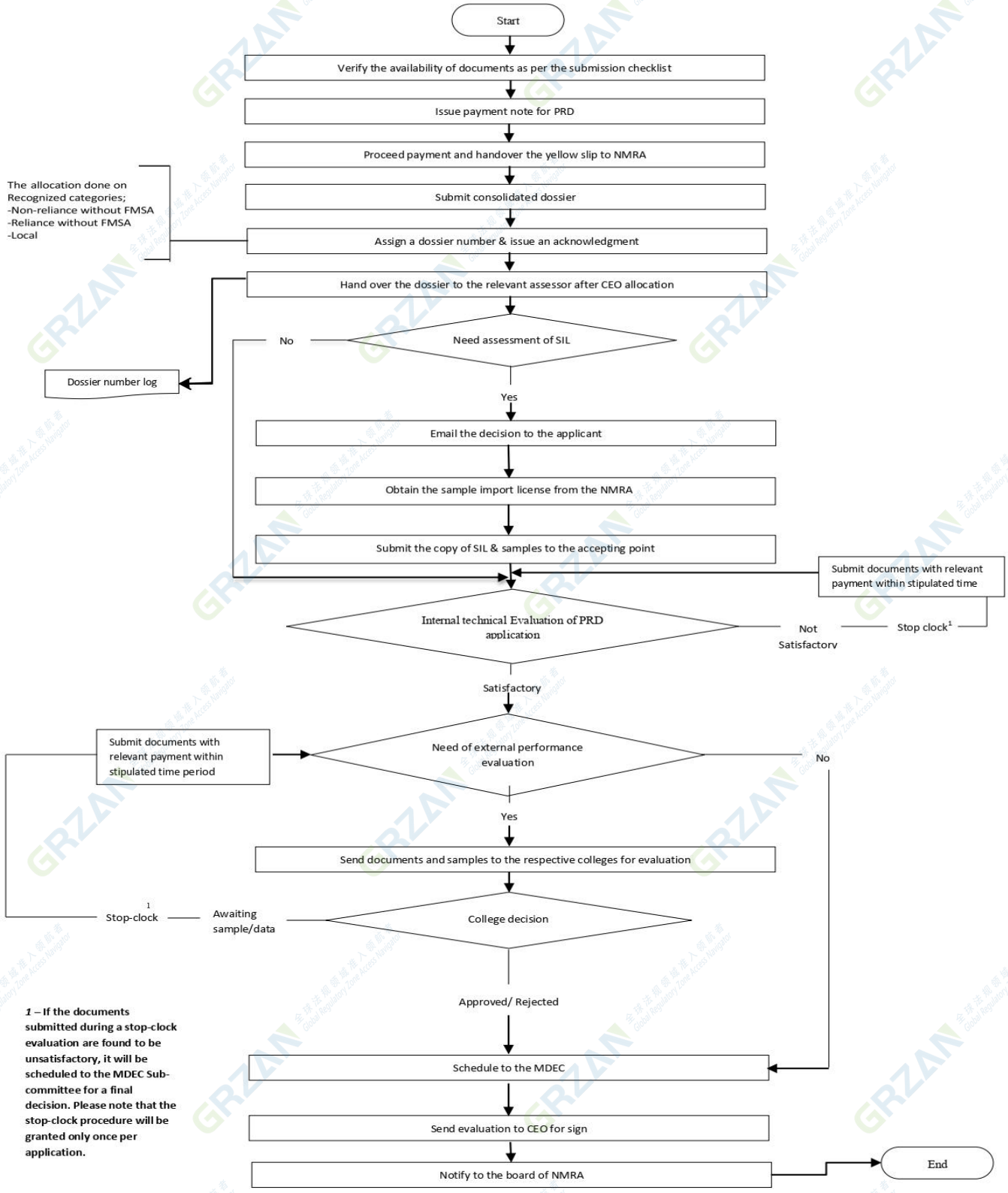
- Being responsible for the product and all information provided in the application, and keeping this information up to date.
- Having a proper system in place to handle any side effects or problems with the product.
- Carrying out appropriate quality control checks.
- Using suitable packaging materials to protect the quality of the product

7 PROCEDURE FOR CONSOLIDATED DOSSIER SUBMISSION AND EVALUATION

7.1 FLOW CHART FOR CONSOLIDATED DOSSIER (FMSA + PRD)



7.2 FLOW CHART FOR CONSOLIDATED DOSSIER (PRD)



1 **– If the documents submitted during a stop-clock evaluation are found to be unsatisfactory, it will be scheduled to the MDEC Sub-committee for a final decision. Please note that the stop-clock procedure will be granted only once per application.**

There are two main types of consolidated dossiers for product registration:

- **FMSA + Product Registration Dossier for General Medical Devices and IVDDs.**
- **Product Registration Dossier without FMSA for General Medical Devices, IVDDs & Listed devices (For both foreign & local manufacturers)**

*****Listed Medical Devices are exempted from manufacturing site registration for foreign manufacturers*****

Process

❖ **Verification of Submitted Documents**

- The applicant shall submit the complete consolidated dossier to the NMRA accepting point and the accepting officer shall verify the availability and completeness of documents in accordance with the submission checklist prior to issuing the payment note.

❖ **Processing of Payment**

- The accepting officer shall process the relevant payment based on; the type of application (Site Registration or Product Registration) and the information provided by the local agent in the Google form for medical device accepting.

❖ **Payment Submission**

- The applicant shall submit the bank slip to the Accounts Division of NMRA and shall obtain the original payment receipt and a yellow receipt from the Accounts Division.

❖ **Consolidated dossier submission with Payment Confirmation**

- The applicant shall submit the consolidated dossier accompanied by the yellow payment receipt, to the accepting point.

❖ **Assigning a dossier number**

- The accepting officer shall verify the yellow receipt issued by the accounts division and assign a dossier reference number to the submitted dossier.

❖ **Dossier Number Formats**

- Depending on the type of application, one of the following dossier number formats shall be used:

Application Type	Dossier Number Format
Non-reliance Listed Devices, General Medical Devices, and IVDDs	***D/Serial Number***
Non-reliance General Medical Devices and IVDDs with FMSA	***D/Serial Number/F***
Reliance General Medical Devices (except Class I) and IVDDs	***D/Serial Number/RLC***
Reliance General Medical Devices and IVDDs with FMSA	***D/Serial Number/RLC/F***
Locally Manufactured Listed Devices, General Medical Devices, and IVDDs (with NMRA GMP audit)	***D/Serial Number/L***

❖ **Issuance of Acknowledgment**

- Upon submission, the accepting officer shall issue an acknowledgment to the applicant, including the assigned dossier reference number.

❖ **FMSA + PRD Application**

- Upon approval of the FMSA, the MDRD shall email the applicant a scanned copy of the FMSA approval & if applicable attaching the approved form (schedule IV form C and evaluation sheet) for processing Sample Import License (SIL)**. The email will also include the payment note for the Product Registration Dossier (PRD).
- In the case of rejection or awaiting data for FMSA, an evaluation sheet will be shared with the applicant without a payment note.
- The applicant shall make the payment for PRD and submit the bank slip to the Accounts Division of NMRA. After receiving the original payment receipt and a yellow receipt from the Accounts Division, the yellow receipt shall be submitted to the accepting point.
- The accepting officer shall issue an acknowledgment confirming receipt of the PRD payment note.

***Applicable payments for issuance of the SILs will be handled by the NMRA Licensing division.*

❖ **PRD Application without FMSA**

- The MDRD shall email the scanned copy of the approved form (schedule IV form C and evaluation sheet) for processing Sample Import License (SIL) to the applicant, if applicable.

❖ **SIL Application Process (For Both FMSA + PRD and PRD Only Applications)**

- The applicant shall submit a scanned copy of the approved form (schedule IV form C and evaluation sheet) to the Licensing Division of the NMRA, proceed with the SIL payment, and submit the relevant payment slip to the Licensing Division for issuing the SIL.
- The applicant must submit a **copy of the SIL & a request letter to initiate the evaluation process** to the accepting point & the accepting officer shall issue an acknowledgment confirming receipt of the SIL copy.

❖ **Reliance Pathway – Recognized Countries**

- **For General Medical Devices**, registration from the following countries will be considered under the reliance pathway:

  USA, UK, Australia, Canada, Japan, Norway, Switzerland & All European Union (EU) member countries

- **For In Vitro Diagnostic (IVD) Medical Devices**:

  USA, UK, Australia, Canada, Japan, Norway, Switzerland, Singapore & All European Union (EU) member countries

❖ **Stop-Clock Procedure**

- If deficient data or samples are requested:
  - The applicant must submit the required information and relevant payment within two (2) months from the date of notification email.
  - Submissions shall be made to the accepting point.

❖ **Final Approval and Licensing**

- Approved PRD applications shall be forwarded to the Licensing Division for issuing and the Registration Certificate and Import License to the applicant.

8 REQUIREMENTS WHICH NEED TO BE FULFILLED AT THE SUBMISSION OF CONSOLIDATED DOSSIER APPLICATION

8.1 Basic Requirements for Consolidated dossiers

- Documents should be in a box file and a green tape should be pasted on the side of the box file.
- In the front page of the box file must include the Generic Name, Brand Name, Manufacturer name & address, local agent, type of dossier (refer to the 'dossier number formats' in the guideline) & separate space should be allocated for the dossier number.
- All the pages of the documents should be numbered from bottom to top.
- Index should be pasted on the inner side of the file indicating headings and correct page numbers.
- Details of the responsible person for the regulatory affairs including the name, company details, designation, email ID, contact number should be available in the dossier.
- Consolidated dossiers should be clearly separated as follows;
    - **Type dossiers -'FMSA + PRD' for General Medical Devices & IVDDs**
        - General Documents - common administrative documents & common technical documents
        - Section 1 - documents required for FMSA application
        - Section 2 - documents required for PRD
    - **Type dossiers -'PRD without FMSA ' for General Medical Devices & IVDDs for foreign & local manufacturers**
        - General Documents – common administrative documents & common technical documents
        - Section 1 – documents required for PRD

8.2 Common administrative documents required for consolidated dossiers

Following documents are mandatory;

- **Letter of Authorization (LOA)** from the legal manufacturer

  If the legal manufacturer appointed more than one local agent, tabulated LOA including the details of all local agents, product range and manufacturing site should be submitted.
- Declaration letter confirming the type of dossier from the local agent
- Declaration letter confirming the submission of samples upon request of the authority
- Agency transfer letter issued by NMRA (If applicable)

8.3 Common Technical documents required for consolidated dossiers

- **Valid Free Sale Certificate(FSC)**

  For verification and confirmation purposes, original FSC or any other verification method (QR code, web link etc.) should be provided at the time of writing the processing fee.

- **Copy of GMP report issued by the NMRA for local manufacturers** (If applicable)
- **Copy of FMSA approval issued by NMRA or NMRA product registration certificate** as evidence.
- **ISO quality management system certificate**

  For Listed device - (ISO 13485:2016/2021 or ISO 9001:2015)

  Medical devices (except Listed Device) - ISO 13485:2016/2021)
- **Foreign country registration evidence documents** (Product registration certificate or FSC issued by the relevant health authority)

8.4 Documents required for the FMSA application + PRD

Following documents should be submitted for FMSA application.

- Application form for FMSA
- Copy of Business Registration of the authorized local agent
- Copy of Board of Directors' Registration of the authorized local agent (if applicable)
- Company Registration (Form 01/15/40)
- Declaration letters
  - Declaration from manufacturer for local representation, manufacturing site status, readiness for inspection and accuracy of submitted documents
  - Declaration letter from local regulatory Pharmacist/qualified person stating that information given in this application is correct
  - Declaration letter from legal manufacturer mentioning the details of other manufacturing sites belong to the legal manufacturer which are not included in the application
  - Consent Letter from local agent to withdraw the application when the NMRA noticed duplications
- Site Master File (SMF) - Site Master File should be submitted along with all the applications for FMSA of Medical Devices.

  Note: It is required to submit information as per the NMRA requirements for Site Master File (Refer NMRA website)
- List of exporting countries

Following documents should be submitted for PRD application.

- Application form for Sample Import License (Form C)
- Application Form (Form A)
- Application Form (Form B)

- Device Details from the manufacturer
- Manufacturer declaration of conformity/ EC full quality assurance system certificate/ EU quality management system certificate or manufacturer EC declaration of conformity
- If CE marked medical devices: EC design examination certificate (If applicable)
- Summary Technical Documentation (STED) – ***refer GHTF guidelines***
- Essential Requirement Check list – ***refer GHTF guidelines***
- Risk Analysis Report (Eg: ISO 14971 standard)
- Certificate of Analysis (COA)/ finished product test report/ final product inspection test report
- Stability protocol with data report (if applicable)
- For Sterile medical devices;
    - Sterility report
    - Sterilization validation protocol with report
    - EO residual test data for EO sterilized products
    - Package Integrity data report
- Biological evaluation report (if applicable)
- Clinical evaluation test report (if applicable)
- For active medical devices; Electrical safety data and Electromagnetic Compatibility data report (Eg: IEC standard)
- For medical devices with measuring function; certification on medical devices, metrology or equivalent
- For radiation emitting medical devices; Atomic Energy Authority Approval certificate
- Third party test report (If applicable)
- Software Verification and Validation Report (If applicable)
- For devices containing biological material; a list of all materials used in the medical device and its manufacturing process that come from animal, human, microbial, or genetically modified (recombinant) sources.
- Bovine Spongiform Encephalopathy (BSE) report (If applicable)
- Product labels (Original/ artwork/ draft)
- Product catalogue or brochure
- For IVDD; Performance evaluation test report (Eg: Analytical , clinical)

- Instructions For Use (IFU) (If applicable)
- Patient Information Leaflet in Sinhala, Tamil & English languages for the point of care medical devices
- List of standard accessories, reagents and consumables (If applicable)

8.5 Documents related to the PRD application - without FMSA

Please refer to Section 8.4: 'Documents Required for PRD Application' for the list of documents applicable to the above-mentioned type of dossier.

Special Note:

One copy of **checklist for document accepting of consolidated new medical device applications** and **two copies** of the acknowledgment should be submitted along with the application.

9 RELATED LEGISLATIONS

- National Medicines Regulatory Authority Act No. 05 of 2015

10 REFERENCES

- Global Harmonization Task Force (GHTF) guidelines
- Tanzania Medicines & Medical Devices Authority (TMDA) guidelines
- SEARN Strategy to facilitate reliance
- Global Medical Device Nomenclature (GMDN)

11 FEEDBACK

Staff and customers may provide feedback about this document by emailing **info@nmra.gov.lk & mdrd@nmra.gov.lk**

12 APPROVAL AND REVIEW

	NAME	DESIGNATION	SIGNATURE
Prepared by			
Reviewed By			
Recommended By			
Approved by			

Next Review Date	22.07.2028