Guideline for Application Submission and Processing of Listed devices, Class I General Medical devices and Class A In-vitro Diagnostic Devices (Applicable for Attached Appendix 1)

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NATIONAL MEDICINES REGULATORY AUTHORITY
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1 INTRODUCTION

This document "Guidelines for **Application Submission and Processing of Listed devices, Class I General Medical devices and Class A In-vitro Diagnostic devices (Applicable for attached appendix 1)**" will serve as the reference guide for the registration process of medical devices, which are low risk general medical devices and class A IVDDs. The content of this Guideline shall also be read in conjunction with relevant information described in other existing South-East Asia Regulatory Network (SEARN), EU classification guideline MDCG 2021-24, Global Harmonization Task Force (GHTF) & Tanzania Medicines and Medical Device Authority (TMDA) reference documents and guidelines.

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 and the list of products whenever it deems necessary. List may be update time to time and the updated list will be available at NMRA official website (www.nmra.gov.lk).

The National Medicines Regulatory Authority 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 provide a standardized process for the preparation, submission and processing of applications of **listed devices, Class I General Medical devices and Class A In-vitro Diagnostic Devices(Applicable for attached Appendix 1)** to ensure compliance with National Medicines Regulatory Authority (NMRA) regulatory requirements.

3 SCOPE

This guideline applies to all stakeholders involved in compiling, and submitting the dossiers for **low risk Devices** for regulatory approval.

This guideline applies to the following categories of Low risk devices intended for human use in Sri Lanka:

a) Class I general medical devices and Class A IVDDs which are non-active, non-sterile or without measuring function.
b) Listed devices

Herein after in this Guideline **Low risk Devices will be refer as above.**

4 POLICY FRAMEWORK

This guideline serves as a policy framework outlining the requirements and procedures for the submission and processing of technical documentation for low risk devices. It is intended to guide both applicants and NMRA officials in applying consistent standards and efficient evaluation practices.

5 CLASSIFICATION BASIS

The classification of General medical devices and IVDDs shall follow the principles and rules outlined in the guidelines for classification of medical devices and IVDDs under the European Union (EU) Medical Device Regulations.

6 EXEMPTIONS

This guideline is not applicable to

i. Class 1 General medical device and class A IVDDs which are sterile, active or with a measuring function.
ii. General medical devices falls under Class II a, II b, III as per EU Classification
iii. IVDDs fall under Class B, Class C and Class D as per EU Classification.

7 ABBREVEATIONS

COA - Certificate of Analysis
CEO - Chief Executive Officer
EU -European Union
FMSA - Foreign Manufacturing Site Application
FSC - Free Sale Certificate
GHTF - Global Harmonization Task Force
GMP - Good Manufacturing Practices
IMDRF - International Medical Device Regulators Forum
IVDD - In vitro Diagnostics Devices
IFU - Instruction for Use
LOA - Letter of Authorization
MDEC - Medical Device Evaluation Committee
MDRD - Medical Device Regulatory Division
NMRA - National Medicines Regulatory Authority
PRD - Product Registration Dossier
SEARN - South-East Asia Regulatory Network
SIL - Sample Import License
SMF - Site Master File
TMDA - Tanzania Medicines and Medical Device Authority

8 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 General medical device or In Vitro Diagnostic 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.

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

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 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.

Listed Device
Means a devices does not fall under the statutory definition of a 'Medical Device'; these devices are characterized by a **lack of direct physiological or clinical impact**. That is generally posing the **lowest risk** to the user and do not fall into the higher clinical classes (I, IIa, IIb, or III).

Manufacturer
Means a person who is engaged in the manufacture of such medical device

Legal Manufacturer
Means the person with responsibility for design of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed by that person himself.

Actual Manufacturer
Means the person with responsibility for manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is manufactured by that person himself or on his behalf by another person(s).

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
Means written or printed information that appears on a medical device packaging that comes with it. It provides important details such as the generic name of the device, brand name, manufacturer details, country of origin, manufacturing date, expiry date (if applicable), how to use it safely, warnings & storage instructions.

Accessories to a medical device
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.

Accessory to an IVD medical device
Means an article intended specifically by its manufacturer to be used together with a particular IVD medical device to enable or assist that device to be used in accordance with its intended use.

9 REGISTRATION PROCEDURE OF LOW RISK DEVICES (APPLICABLE FOR ATTACHED APPENDIX 1) (Updated version can be found from NMRA website)

Persons who intend to import or locally manufacture low risk devices are responsible for applying to the

NMRA to get the registration. The applicant shall be responsible for the product and all the information supplied in support of the application for registration of medical device product which coming under this criterion.

Low risk devices are exempted from manufacturing site registration (for foreign manufacturing sites and GMP inspections for local manufacturers) and end-user performance evaluation, due to the low risk associated with their use.

10 SUBMISSION PROCESS OF DOSSIERS

10.1 Verification of submitted documents

The applicant shall submit the dossiers for **low risk devices** to the NMRA accepting point. The accepting officer shall verify the availability and completeness of documents as per the submission checklist (Appendix 2, F-MDR-046|)(Updated version can be found from NMRA website) prior to issuing the payment note.

10.2 Processing of payments

The accepting officer shall process the relevant payment for completed dossiers, according to the details filled by the local agent in the Google form for medical device accepting.

10.3 Payment submission

The applicant shall submit the bank slip to the Accounts Division of NMRA and original payment receipt and a yellow receipt shall be issued to the applicant by the Accounts Division of NMRA.

10.4 Dossier submission with payment confirmation

The applicant shall submit the dossier along with the yellow payment receipt to the accepting point.

10.5 Assigning a dossier number

The accepting officer shall verify the payment slip issued by the NMRA Accounts Division and assign a dossier number to the consolidated dossier.

A dossier numbers shall be issued for the dossiers as follows:

- **D/Serial Number/LR**

The Accepting Officer shall issue the acknowledgment with the dossier reference number and shall maintain an updated relevant registry.

10.6 Process of granting a decision for the application

If the documents are deemed satisfactory according to the evaluation checklist the application will be approved and the evaluation sheet shall be forwarded to the Medical Device Evaluation Committee (MDEC), NMRA. If the submitted documents or data are deemed unsatisfactory or deficient according to the evaluation checklist the application may hold on stop-clock .In which the Assessor shall inform the applicant deficient data or documents via email through the evaluation report. The applicant shall submit the required deficient data or documents, along with the relevant payment, within two months from the date of the email to the accepting point. In case of failure to submit the requested data within stipulated time period the application will be given awaiting data and the evaluation report shall be forwarded to the Medical Device Evaluation Committee (MDEC), NMRA.

In the case of rejection of the application the evaluation report shall be forwarded to the Medical Device Evaluation Committee (MDEC), NMRA.

10.7 Final approval and licensing

The application with the final decisions from the MDEC shall be forwarded to the CEO for approval.

The CEO-approved application shall be forwarded to the Licensing Division to communicate the decisions with applicant. The Licensing Division shall issue the registration certificate and import license for the approved low risk device to the applicant.

11 DOCUMENTS REQUIRED FOR REGISTRATION

Documents must be submitted according to the list provided in checklist (F-MDR-046|), which will be published in NMRA Website.

12 RELATED LEGISLATIONS

- National Medicines Regulatory Authority Act No. 05 of 2015

13 REFERENCES

- EU classification Guideline
- Global Harmonization Task Force (GHTF) guidelines
- Tanzania Medicines & Medical Devices Authority (TMDA) guidelines
- SEARN Strategy to facilitate reliance

14 FEEDBACK

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

15 CHANGE HISTORY

Revision No	Effective Date	Description of Change(s)	Section(s) modified
Initial publication	13.05.2026	**N/A**	**N/A**

16 APPROVAL AND REVIEW

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Next Review Date	13.05.2029

Appendix 1

Low risk devices list of products-Listed devices, Class I General Medical devices and Class A In-vitro Diagnostic Devices

The listing is tabulated with the following items:

Item	*Explanation*
Keyword	An aid to facilitate the search of product in the exempted list.
Device identifier	The name (presented in bold) that is selected to represent a generic device group. Synonym term: (names presented in italic) are other names that are commonly used, in place of, or to identify, the device, the device identifier.

Keyword	Device Identifier
Adhesive	Adhesive Bandage- Bandage/dressing, adhesive, Bandage/tape, adhesive
	Adhesive strip- general purpose; Closure, wound, adhesive; Strip, adhesive,
	Adhesive tape-First-aid adhesive tape; Tape, cotton/gauze/hypoallergenic/waterproof
Applicator	Applicator- absorbent tipped
Bag	Ice bag
Bandage	Bandage- self-adherent
	Bandage- clavicle
	Bandage- elastic
	Bandage- gauze; Cotton gauze swabs
	Bandage- gauze, roller; Cotton gauze dressing
	Bandage- pressure; Compression dressing; Elastic/Crepe Bandage
	Bandage- traction
Bed	Bed-hospital; Bed- nursing
	Bed-general-purpose, manually-operated; Bed, hospital, manual/mechanical
	Bed- general-purpose, hydraulically-powered; Bed, hydraulic hospital
	Bed-general-purpose, electrically-powered; Bed, AC-powered hospital
Bedpan	Bedpan- fracture
	Bedpan- general purpose
Binder	Abdominal binder
	Ankle binder
	Breast binder
	Chest binder
	Sternum binder

	Wrist binder
Board	Board- arm
	Board- cardiac Compression; CPR board; Cardiopulmonary resuscitation board
	Board-spinal; Spine board
Bottle	Bottle- heating/cooling; Hot/cold water bottle
Chair	Chair- blood donor
	Chair- examination/treatment
	Chair- toilet, Commode (fixed or mobile)
	Chair- wheelchair
Compress	Compress- hot/cold; Pack chemical; Heating/Cooling pad,
	Compress- cold pack
	Compress- hot/cold pack
	Ice collar compress
Cotton	Cotton ball- Rayon balls
	Cotton roll- dental
	Cotton roll- general purpose
Depressor	Depressor- tongue; Wooden tongue depressors
Immobiliser	Immobiliser- ankle
	Immobiliser- arm
	Immobiliser- elbow
	Immobiliser- infant (reusable or single use)
	Immobiliser- knee
	Immobiliser- shoulder (reusable)

	Immobiliser- whole body
	Immobiliser- wrist; Wrist restrainer
Light	Light- head-worn; Headlamp, operating; Surgical headlight
	Light- surgical; Operating room light; Surgical lamp
	Light- examination, hand held, battery-powered
	Light-Examination (ceiling or wall mounted)
	Light- ear; Ear light
	Light- dental, intraoral; Lamp, intraoral
	Light- dental, general-purpose; Dental operating light
Loupe	Loupe- binocular; Surgical binoculars; Operating magnifier
Mask	Mask- CPR Mask; Pocket Mask
	Mask-surgical, N95
Mirror	Mirror-ENT (Hand-held or Headband)
	Mirror-dental, handheld
	Mirror- general & plastic surgery
	Mirror-headband, ophthalmic
Orthosis	Orthosis-foot/ankle; Ankle support/brace
	Orthosis- sacroiliac Spine; Sacroiliac orthosis, soft
	Orthosis- thoracic spine; Thoracic orthosis (TO)
	Orthosis- Cervicothoracic spine (CTO); Orthosis, cervical-thoracic, rigid
	Orthosis-cervical spine; Cervical collar; Neck support
	Orthosis- lumbosacral Spine; Belt, lumbosacral (LSO)
Pressure pad	Pressure alleviation pad-Air/Foam/Gel/Water pressure pad
Protector	Finger protector-Finger splint

Retainer	Retainer- bandage; Bandage clasp/retainer; Elastic net
Shield	Shield-eye; Eye patch
	Shield- face; Goggles
	Shield-hip
	Shiel- wound; Protector, wound
Shoe	Orthotic shoe- Orthopaedic shoe; Corrective shoe
	Cast boot Shoe, Cast
Sling	Sling-Arm/Knee/Leg sling; Clavicle strap
Splint	Splint-Traction/Wire/Hand/Finger/Air splint
	Splint-nasal, external
Stocking	Stocking- anti-oedema, arm/leg; Compression stocking/socks
	Stocking- medical Support; Sock, fracture; Stocking, elastic
Stretcher	Stretcher- Mobile/Powered/Transfer/Wheeled stretcher
	Stretcher- ambulance (Air/Marine/Land)
	Stretcher- portable; Hand-carried/Basket/Scoop stretcher
Table	Table- examination/treatment; Examination bed
	Table- Operation; Gynecological/Ophthalmic/Orthopaedic table
	Table- birthing; Obstetrical table
Traction unit	Traction unit-non-active; Static traction unit
	Traction Unit- non-invasive component; Pelvic belt; Head halter
Transfer Aid	Transfer aid- person; Patient transfer board/sheet; Sliding mat
Walking Aid	Walking crutch (Axillary/Elbow/Forearm)
	Walking Frame (Standard/Folding/Wheeled)

	Walking table
	Walking Stick (Cane); Quad cane; Tripod base cane
Absorbent	Adult / Baby Diapers, Under pads
Infant Care	Soother, Nipple, Teat, Pacifier
Breast Care	Breast Pump (Manual)
Maternal	Girdle, Maternity Belt, Breast Shield
Eye Care	Eye Shield (Non-sterile)
Hospital Ware	Galley Pot, Urinal, Instrument Tray
Therapy	Hot and Cold Packs
Active/Skin	Micro-needling Pen / Machine
Dental	Die Stones / Mounting Stones
Laboratory	Bio-safety Cabinet / Workstation
Culture Media	General microbiological culture media; Selective media; Agar/Broth
Chromogenic Agent	Antimicrobial chromogenic agent; Culture media additive
Laboratory Solution	Cleaner; Buffer solution; Lysing solution; Diluent
Specific Pipette	Fixed-volume pipette; Assay-specific pipette
General Stain	Hematoxylin; Eosin; Pap stain; Gram's iodine
Extraction Kit	Nucleic acid isolation kit; DNA/RNA purification kit

Appendix 2

CHECKLIST FOR DOCUMENT ACCEPTING OF MEDICAL DEVICE APPLICATIONS OF LOW RISK DEVICES

National Medicines Regulatory Authority, Sri Lanka

Local Category A ☐ Local Category B ☐ Foreign ☐

Generic Name of the device *(according to the GMDN)*	
Brand Name	
Legal Manufacturer	
Actual Manufacturer	
Local Agent	

All following documents are mandatory for accepting application. At the accepting point, only check the availability of such documents.

1.General Section

1.1 Common Administrative documents required

Type of document	Page number	Availability (Yes/No)
1. Original Letter of Authorization (LOA) from the legal manufacturer		
2. Declaration letter intention to submit the samples upon request of the authority		
3. Agency transfer letter issued by NMRA (If applicable)		
1.2 Common Technical documents required		
4. Original, Valid Free Sale Certificate (FSC)/Hygienic certificate		
5. ISO quality management system certificate a. For Listed devices - i. Foreign manufacturing sites-ISO 13485:2016/2021 or ISO		

9001:2015) ii. Local manufacturing sites- ISO 9001:2015 accredited by SLAB or equivalent competent body b. Low risk Class 1 general medical devices and IVD A medical devices i. Foreign manufacturing sites-ISO 13485:2016/2021 ii. Local manufacturing sites- ISO 13485:2016/2021 accredited by SLAB or equivalent competent body.		
6. Foreign country registration evidence documents (Product registration certificate or FSC issued by the relevant health authority)		
2. **Section 01 - Documents required for site confirmation**		
7. Copy of Business Registration of the authorized local agent		
8. Copy of Board of Directors' Registration of the authorized local agent (if applicable)		
9. Company Registration (Form 01/15/40)		
10. Declaration letter from manufacturer stating the local representation, manufacturing site status, readiness for inspection and, accuracy of submitted documents		
11. Declaration letter from regulatory Pharmacist/qualified person stating that information given in this application is correct.		
12. Declaration letter from legal manufacturer mentioning the details of other manufacturing sites belong to the legal manufacturer and which are not included in the application		
13. Consent Letter from local agent to withdraw the application when the NMRA noticed duplications		
14. List of exporting countries		
3. Section 02 - Documents required for PRD		
15. Application Form (Schedule I Form A)		
16. Application Form (Schedule I Form B)		
17. Acknowledgement		
18. Device description from the manufacturer		
19. Manufacturer declaration of conformity/ EC full quality assurance		

system certificate/ EU quality management system certificate or manufacturer EC declaration of conformity		
20. Essential Requirement Check list		
21. Certificate of Analysis (COA)/ Finished product test report/ final product inspection test report		
22. Declaration for shelf life (if applicable)		
23. Electrical Safety report (if applicable)		
24. Product labels (Original/ artwork/ draft) (As per prescribed guideline)		
25. Product catalogue or brochure		
26. Instructions For Use (IFU) (If applicable) (As per prescribed guideline)		
27. Patient Information Leaflet (In 03 languages for the point of care medical devices		
28. List of standard accessories, reagents and consumables (If applicable)		

……..
Signature of the applicant
Name:
Designation:
Contact No:
E-mail Address:
Date:

……..…….
Signature of the Accepting officer (NMRA)
Name:
Designation:
Date:

Remarks:

1. Letter of Authorization should be addressed to CEO/NMRA and product range should be mentioned clearly.
2. If the local manufacturer is a new they can submit the dossier with ISO 9001 and ISO 13485:2016 certificate should be submitted within two years.
3. If the local manufacturer already audited by NMRA also should submit ISO 13485:2016 certificate within two years.