

ZAMBIA MEDICINES REGULATORY AUTHORITY



GUIDELINES ON APPLICATION FOR GRANT OF MARKETING AUTHORISATION OF NON *IN - VITRO* DIAGNOSTIC MEDICAL DEVICES FOR HUMAN USE

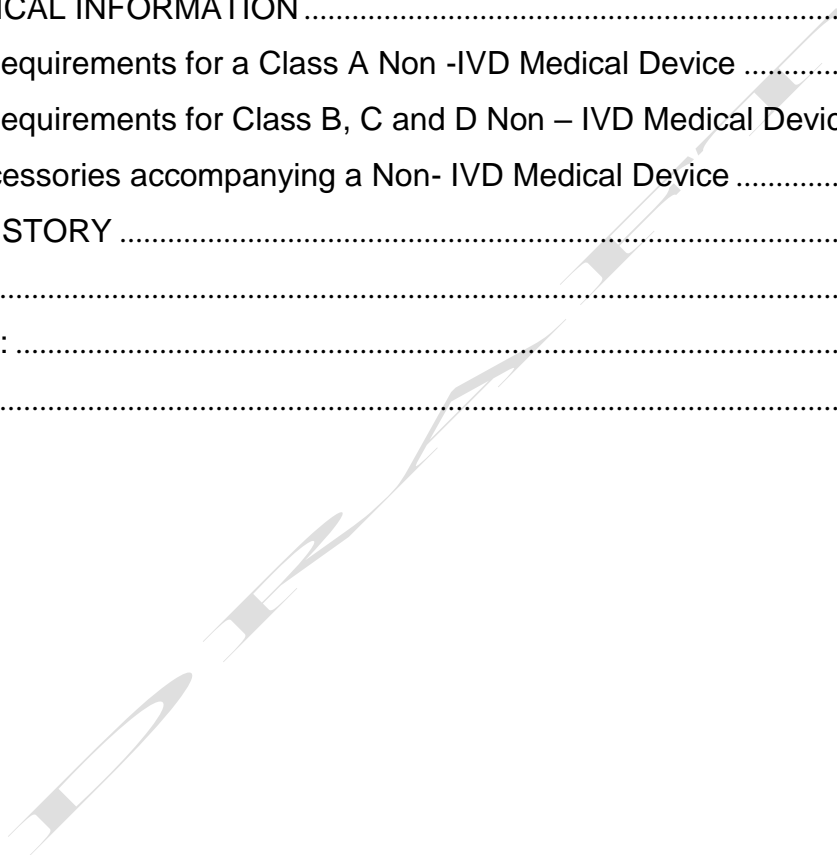
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ABBREVIATIONS AND ACRONYMS

GMDN	Global Medical Device Nomenclature
GHTF	Global Harmonisation Task Force
IMDRF	International Medical Devices Regulators Forum
ISO	International Organisation for Standardisation
MAH	Marketing Authorisation Holder
NDQCL	National Drug Quality Control Laboratory
REC	Regional Economic Community
SADC	Southern Africa Development Community
UDI	Unique Device Identifier
WHO	World Health Organisation
ZAMRA	Zambia Medicines Regulatory Authority

INTERPRETATION

In these guidelines, unless the context otherwise requires -

“accessory” means an article which, is intended specifically by its manufacturer to:

- (i) be used together with a medical device to enable that device to be used in accordance with its intended use as a medical device.
- (ii) augment or extend the capabilities of that device in fulfilment of its intended use as a medical device;

“Act” means the Medicines and Allied Substances Act (No. 3) of 2013;

“applicant” means a person or entity that submits an application for marketing authorisation of a non *In-Vitro* Diagnostic Medical Device (Non IVD);

“Authority” means the Zambia Medicines Regulatory Authority;

“authorised representative” means a person or entity legally appointed and authorised to act on behalf of an applicant with matters relating to applications for grant of marketing authorisation;

“expedited evaluation” means the express evaluation of a product application within a 90 – day period;

“instructions for use” means information provided by the manufacturer to inform the device user of the medical device’s intended purpose and proper use and handling of a device;

“intended use” means the objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer;

“label” means written, printed, or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices;

“labelling” means the label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents;

“local responsible person” means a natural or legal person, resident in Zambia, appointed by a foreign-based Marketing Authorisation Holder to be responsible for all regulatory matters in respect of products granted marketing authorisation with a valid Power of Attorney;

“manufacture” means operations involved in the production, preparation, processing, compounding, formulating, filling, refining, transformation, packing, packaging, repackaging or labelling of medical devices;

“manufacturer” means any person and/or institution with the responsibility to design and/or manufacture medical devices with the intention of making the medical device available for use, under their name;

“marketing authorisation” means the authorisation granted under section *thirty-nine* of the Medicines and Allied Substances Act (No. 3) of 2013 for the placement of a medicine or allied substance on the Zambian market;

“medical device” means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- I. diagnosis, prevention, monitoring, treatment or alleviation of disease,
- II. diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- III. investigation, replacement, modification, or support of the anatomy or of a physiological process,
- IV. supporting or sustaining life,
- V. control of conception,

- VI. disinfection of medical devices,
- VII. providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means;

“non *in-vitro* medical devices” means medical devices other than *in-vitro* diagnostics with the exception of condoms and medical gloves

“notified body” means a third-party independent certification organisation which a competent authority designates to carry out certain tasks in respect of the conformity assessment procedures;

“product 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;

“recognised standards” means national or international standards accepted to offer conformity to specific essential principles of safety and performance;

“risk” means a combination of the probability of occurrence of harm and the severity of that harm;

“shelf life” Means the period of time during which a medical device, if handled and stored correctly, is expected to comply with the specification as determined by the Essential Principles of Quality, Safety and Performance;

“site audit” Means an inspection audit conducted at a device manufacturing facility or site in order to determine compliance of that facility to ISO 13485 requirements; and

“user” Means the person(s) who uses a medical device.

INTRODUCTION

The Zambia Medicines Regulatory Authority (ZAMRA) is a statutory body established pursuant to the Medicines and Allied Substances Act, No.3 of 2013 of the Laws of Zambia (“the Act”). The Authority is responsible for the regulation and control of medicines and allied substances including regulating and controlling the manufacture, importation, exportation, distribution and sale of medicines and allied substances; establish, maintain and enforce standards relating to the manufacture, importation, exportation, distribution and sale of medicines and allied substances; serve and protect the public interest in all matters relating to the sale of medicines and allied substances among other things.

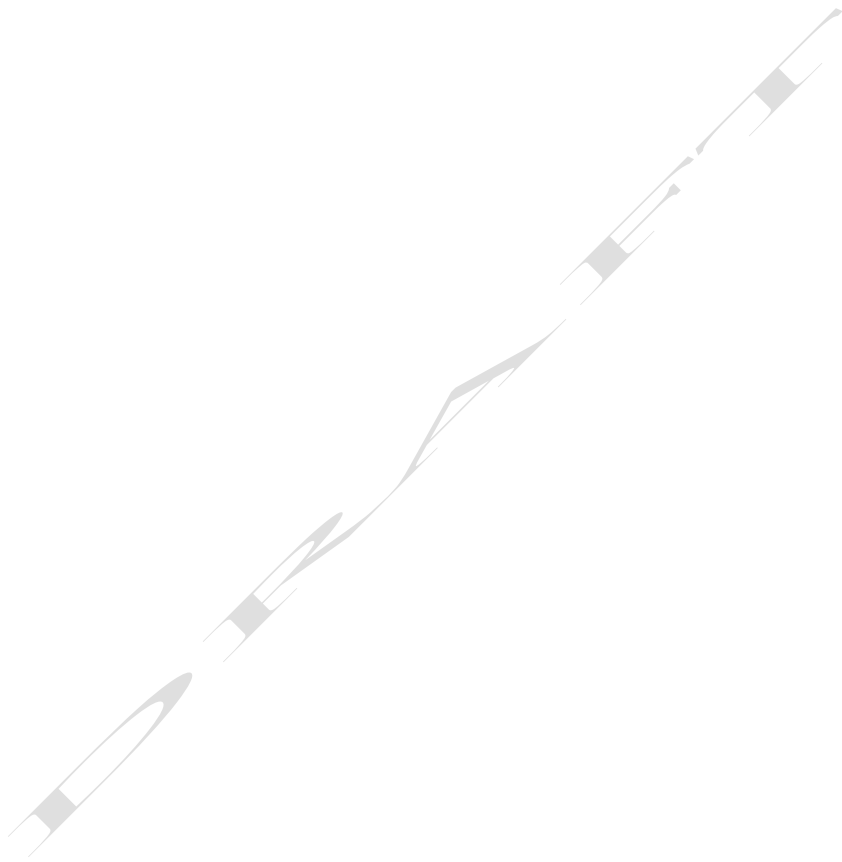
This Guideline for Grant of Marketing Authorisation for non *In-Vitro* Diagnostic Medical Devices (Non IVDs) is issued by the Authority pursuant to Section 68 of the Act and will provide information to be incorporated in the applications for grant of marketing authorisation by an applicant who intends to place on the Zambian market non *in-vitro* medical devices in accordance with Section 39 of the Act. The Authority may amend any part of these Guidelines from time to time.

OBJECTIVE

These guidelines are intended to be the reference document for use by an applicant in the preparation of product dossiers for marketing authorisation of non *in-vitro* medical devices by providing general guidance on the application requirements.

SCOPE

These guidelines apply to non *in-vitro* medical devices for human use and shall be used by local responsible persons, marketing authorization holders, distributors, manufacturers, wholesalers, retailers and the public. The guidelines provide for a stepwise procedure to be followed when compiling a product dossier for submission when applying for grant of marketing authorisation of non *in-vitro* medical devices for human use.



1. GENERAL REQUIREMENTS

a) Applicant

A person who intends to place on the Zambian market a non *in-vitro* medical devices for human use shall apply to the authority as provided in these guidelines.

An applicant who is not resident in Zambia shall appoint a local responsible person with power of attorney who shall be responsible for compliance to regulatory requirements with respect to non *in-vitro* medical devices.

An applicant shall be responsible for the product information in support of the application for Marketing Authorisation and variations thereof.

b) Product application

An applicant shall submit an application as provided in these guidelines that shall be accompanied by a product dossier that is presented in an electronic text selectable/editable PDF, submitted via the Authority's online portal.

Where an application has product variants such as size, design, dimensions or capacity, the variants shall be considered as different products and shall require separate applications as determined by the Authority.

c) Requirements for an application

An Application shall comprise the following:

- (i) Cover letter from the applicant;
- (ii) A duly completed and signed application form set out in Annex 1;
- (iii) Proof of payment of the prescribed application fee;
- (iv) At least two samples of the non *in-vitro* medical device packaged in the smallest commercial pack size, and labelled primarily in English;
- (v) A duly completed checklist as set out in Annex 2 indicating the sections of the application that have been completed and the pages thereof; and
- (vi) Product dossier.

An incomplete application for grant of marketing authorisation for a non *in-vitro* medical device shall not be accepted where one of the documents listed from (i) to (vi) is not attached to the application.

d) Documentation

To facilitate the review of information submitted, an applicant shall take into consideration the following when submitting the application:

e) Language

Applications and supporting documents shall be in English.

f) Text formatting and layout

Information shall be presented in legible letters of 12 font size in Times New Roman or Arial font type of 1.5 line spacing and standard margin.

Each page shall be numbered sequentially. Extension sheets, tables, diagrams and other supporting documents shall as far as possible be of the same size, well annotated, numbered and appropriately cross-referenced.

g) Payment of Application fees

An application for grant of Marketing Authorisation for a non *in-vitro* medical device shall be accompanied by proof of payment of the fee set out in the Medicines and Allied Substance (Fees) Regulations, 2016.

Bank charges in relation to the application shall be borne by the applicant who shall ensure that proof of payment is submitted to the Authority. Marketing Authorisation fees for non *in-vitro* medical devices shall cover the costs of evaluating the initial submission only and exclude laboratory testing and site audit fees which shall be charged separately.

h) Processing of received applications

- (i) Where deficiencies are identified during screening of an application, a request for additional information shall be made to the applicant.
- (ii) Subject to (i), an applicant shall be required to submit all the requested additional information within the period specified by the Authority but not exceeding 60 days from the date of receipt of the request.
- (iii) Where an applicant does not respond to the Authority's request for additional information within the period stated in (ii), the application shall be rejected.
- (iv) Where an applicant fails to provide all the requested information, or the submitted information is incomplete, deficient or immaterial, the application shall be rejected.
- (v) Where the application has been rejected in line with clauses (iii) and (iv), an applicant shall be informed in writing.

i) Evaluation of applications for grant of Marketing Authorisation

An application shall be evaluated on a first come first serve basis unless expedited evaluation has been authorised by the Authority.

j) Quality analysis

Where necessary, samples of the non *in-vitro* medical device may be analyzed by the National Drug Quality Control Laboratory (NDQCL) against the claimed manufacturer's specifications in accordance with the current available local Standards or other quality specifications such as those prescribed by International Organisation for Standardisation (ISO) and any other internationally recognised standards.

k) Site Audit for Compliance to ISO 13485 of The Manufacturing Facility

- (i) An applicant shall be required to facilitate for site audits of their manufacturing site in order to demonstrate compliance to ISO 13485. The GMP inspection fees set out in the Medicines and Allied Substances (Fees) Regulations, 2016 shall apply in relation to a site audit.
- (ii) The Authority may in determining whether to conduct a site audit of a manufacturing site referred to in (i) consider:
 - (a) previous satisfactory site audit outcomes conducted by well-resourced or regional regulatory agencies; and
 - (b) that the audit in (ii) was conducted within 24 months preceding receipt of the application.
- (iii) In instances as determined by the Authority, the option to undertake a desk review by the Authority in lieu of a site audit may occur in the following:
 - (a) Where the applicant shows proof of compliance to successful previous site audits conducted by well-resourced or regional regulatory agencies; and
 - (b) The past satisfactory record of the safety, quality and performance of the product on the global and regional market.

l) Grant of Marketing Authorisation

The Authority shall grant Marketing Authorisation where the product meets the requirements of quality, safety and performance and any other requirements as set out in the Regulations and these Guidelines. The Marketing Authorisation once granted shall be valid for a period of five (5) years.

m) Appeals

An applicant who may be aggrieved by a decision made by the Authority in relation to their application for the grant of marketing authorisation may seek redress in accordance with the provisions of the Act.

n) Application for Amendment to Marketing Authorisation for a Non IVD Medical Device

A Marketing Authorisation Holder (MAH) who intends to effect any change(s) to the device shall inform the Authority of such intended change(s) by means of an application for amendment, which shall be accompanied by relevant supporting documentation and proof of payment of the fee set out in the Medicines and Allied Substance (Fees) Regulations, 2016.

Any such change(s) shall require approval by the Authority before implementation.

o) Retention fees

A Marketing Authorisation Holder (MAH) shall pay the prescribed annual product retention fee for the following year by 31st December of each year.

Where the MAH fails to pay the annual retention fee by 31st December:

- (a) the Authority shall not authorise the importation of the non *in-vitro* medical device;
- (b) in case of a locally manufactured non *in-vitro* medical device, the Authority shall not authorise the continued manufacture of the product;
- (c) the Marketing Authorisation issued shall be suspended; and
- (d) the Marketing Authorisation may be revoked by the Authority.

p) Vigilance

A MAH shall put in place a vigilance system to monitor the quality, safety and performance of a non *in-vitro* medical devices placed on the Zambian market. The MAH shall ensure that modalities to provide routine reports to the Authority on any findings regarding the product are in place.

q) Renewal of a Marketing Authorisation

A MAH who intends to renew a Marketing Authorisation shall apply to the Authority on payment of the fee set out in the Medicines and Allied Substance (Fees) Regulations, 2016 at least one hundred and eighty (180) days before the expiry date of the Marketing Authorisation.

2.0 PRODUCT INFORMATION

An applicant shall provide product information which shall include but not limited to the following:

a) Name(s)

- (i) The brand name of the non *in-vitro* medical device.
- (ii) The generic name of the non *in-vitro* medical device.

b) Intended Use/User

Provide details specifying the intended use and user of the device.

c) Instructions for Use (IFU) and User Manual

An applicant shall provide the device Instructions for Use which shall contain clear information, including intended use/user, contraindications, storage conditions, warnings and precautions.

Where applicable, an applicant shall provide a copy of the user manual for a respective medical device.

d) Description

An applicant shall provide a general description on design, size, dimensions of the Non IVD Medical Device. The description shall also include the following:

- (i) material of construction of the device;
- (ii) accessories where available;
- (iii) packaging material;
- (iv) model Numbers;

- (v) Global Medical Device Nomenclature (GMDN) Code; and
- (vi) Pack size.

e) Labelling

Labelling information shall be as per ZAMRA Guidelines for Label and Instructions for Use for Medical Devices.

f) Claimed shelf-life

The claimed shelf-life of a non *in-vitro* medical device shall be stated. The manufacturer shall determine the shelf-life of a product based on stability studies conducted.

g) Storage conditions

An applicant shall state the storage conditions in accordance with the manufacturer's recommendations.

3.0 CLASSIFICATION OF A NON IVD MEDICAL DEVICE

A non IVD Medical device shall be classified as per ZAMRA Guidelines on the Principles of Medical Devices Classification (include hyperlink)

4.0 TECHNICAL INFORMATION

a) Requirements for a Class A Non -IVD Medical Device

An Applicant shall be required to compile a product dossier containing information for a Class A Non IVD Medical Device as prescribed in Annex 3

b) Requirements for Class B, C and D Non – IVD Medical Devices

An Applicant shall be required to compile a product dossier containing technical information for Class B, C and D non *in-vitro* medical devices in the format as set out in annex 4

c) Accessories accompanying a Non- IVD Medical Device

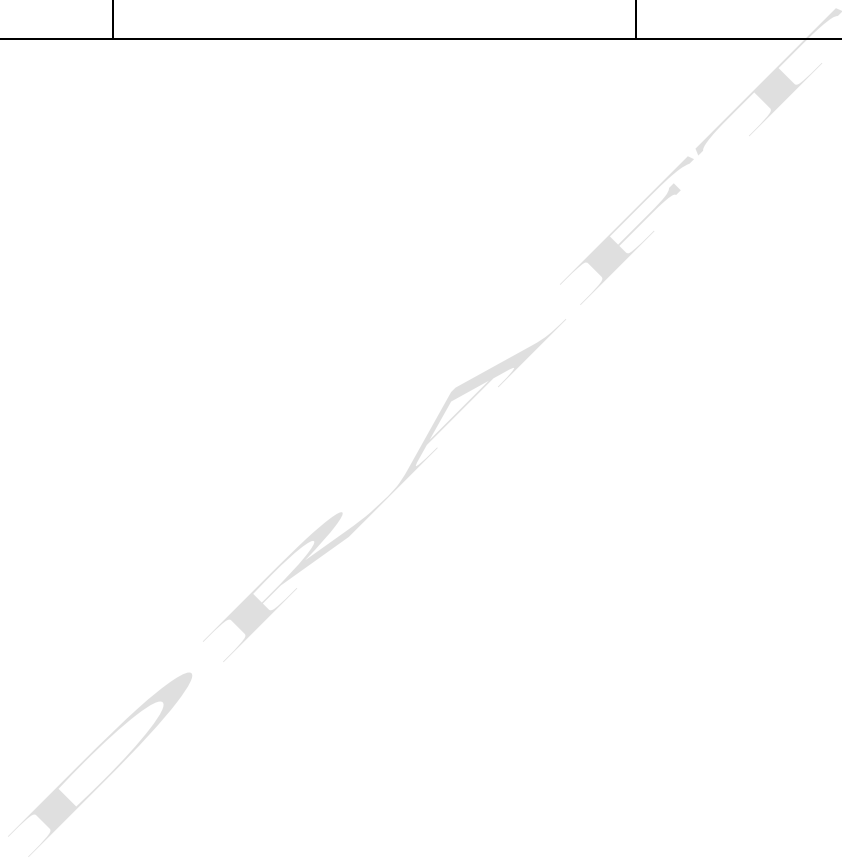
Accessories shall be classified in their own right as a medical device and do not necessarily take the classification of the device with which they are intended to be used.

A product qualifies to be an accessory to a medical device if there is an established intended use in conjunction with a medical device. If a medical device can fulfil its original intended purpose without the supplementary use of a product, that product would not qualify as an accessory to a medical device.

An Accessory that augments or extends the capabilities of that device in fulfilment of its intended use as a medical device shall also be considered as an independent medical device and will be classified under the class of the parent device and shall fulfil the requirements under these Guidelines.

UPDATE HISTORY

Date	Reason for update	Version & publication



ANNEXES

ANNEX I. Application Form



The Medicines and Allied Substances Act, 2013(Act No.3 of 2013)

The Medicines and Allied Substances (Marketing Authorisation of Non *In-vitro* Diagnostic Medical Devices for Human Use) Guidelines, 20...

APPLICATION FOR GRANT OF MARKETING AUTHORISATION OF NON *IN-VITRO* DIAGNOSTIC MEDICAL DEVICES FOR HUMAN USE IN ZAMBIA

For Official Use

Date

Application number

PART I: PARTICULARS OF THE APPLICANT¹

Applicant name and address	Name: Physical and Postal Address: Phone: Fax: Email:
Details of Contact Person²	Name: Designation: Phone: Fax: Email:

¹ The Guidelines on grant of Marketing Authorisation of a Non-In-vitro diagnostic medical device to be consulted in completing this form and preparing of dossiers for submission to ZAMRA

¹ ² Contact person will be responsible for communicating with the Authority and a letter of Authorisation to communicate on behalf of the applicant should be submitted.

Details of Local Responsible Person³(Attach Power of Attorney)	Name: Designation: Phone: Fax: Email:
Details of Authorised Local Distributor (Attach letter of appointment)	Name: Physical and Postal Address: Phone: Fax: Email:

PART II: PARTICULARS OF THE MEDICAL DEVICE

Manufacturers name (s) and site address (s)	Name: Physical and Postal Address: Phone: Fax: Email: GPS Coordinates:
Number of samples of the medical devices submitted	
Generic name of the medical device (<i>Where applicable</i>)	
Brand name of the medical device	
Model/Series/System of the medical device (<i>Where applicable</i>)	
GMDN description of the medical device	
Short description if none of the GMDN descriptions seem appropriate	
GMDN code of the medical device (if known)	

² ³ Should be a person, resident in Zambia, appointed by a foreign-based applicant to be responsible for all regulatory matters in respect of products granted marketing authorisation with Power of Attorney or a letter of acting as an agent.

Intended use of the medical device	
Sample of Instructions for use	
Sample of User's Manual (where applicable)	
Sample (s) of accessory (s) accompanying the medical device if any	
Medical device Classification	<input type="checkbox"/> Class A <input type="checkbox"/> Class B <input type="checkbox"/> Class C <input type="checkbox"/> Class D
Have there been any of the following:	<input type="checkbox"/> Previous recalls <input type="checkbox"/> Reportable adverse incidents <input type="checkbox"/> Banning in other countries <input type="checkbox"/> Post-market surveillance studies
Please provide details on each item you have ticked (attach any relevant documentation)	<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>
International or national standards with which the device complies (enclose a copy of valid certificates)	

List the SADC states where the medical device has obtained marketing approval (Attach documentation)	
Is the device WHO prequalified, US FDA approved, CE Marked or approved in any IMDRF member state? If so attach valid documentation	

PART III: DECLARATION AND SIGNATURE

I declare that all the information I have stated is correct and truthful to the best of my knowledge and belief.

Particulars of the authorised person signing on behalf of the applicant

a) Name:

b) Designation:

c) Signature: d) Date: .../.../..... (dd/mm/yyyy)

d) Company seal or official stamp

ANNEX II:

Product Dossier Checklist



The Medicines and Allied Substances Act, 2013(Act No.3 of 2013)

The Medicines and Allied Substances (Marketing Authorisation of Non *In-vitro* Diagnostic Devices for Human Use) Guidelines, 20xx

APPLICATION FOR GRANT OF MARKETING AUTHORISATION OF NON *IN-VITRO* DIAGNOSTIC DEVICES FOR HUMAN USE IN ZAMBIA

(An Applicant is required to complete the checklist with the necessary information)

A completed copy of the checklist should be included in the dossier.

1. Supporting documents

Supporting documents	Yes (Y)/ No (N)/ Not applicable (N/A)	Comment	For ZAMRA Use Only
Duly signed cover Letter from applicant			
Proof of payment			
Samples (2) of device			
Free Sale Certificate			
Sample Instructions for Use (IFU)			
Mock-up Label			

2. Product Dossier

Description	Dossier sections	Yes (Y) No (N)	Comment	For ZAMRA Use Only
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Administrative information	Completed and signed application form				
Certificates	Original or notarized Free Sale Certificate				
	Notarized Manufacturing Licence				
	Notarized Registration Certificates				
	ISO 13485 certificate				
Technical Information	Information provided as per Non IVD MA ToC (Chapters 1-6) for Class B to D and as per Annex II for Class A Devices.				
Any other relevant documents (please specify)					

Annex III

Product Dossier requirements for a Class A Non IVD Medical Device



The Medicines and Allied Substances Act, 2013(Act No.3 of 2013)

The Medicines and Allied Substances (Marketing Authorisation of Non-In-vitro Diagnostic Medical Devices for Human Use) Guidelines, 20...

GRANT OF MARKETING AUTHORISATION OF A CLASS A NON-IN-VITRO DIAGNOSTIC MEDICAL DEVICE FOR HUMAN USE IN ZAMBIA

Requirements for a Class A Non IVD Medical Device

(An Applicant is required to complete this document with the necessary information and attach the required supporting documentation were necessary)

No.	DEVICE INFORMATION
1.	Brand name of Device
2.	Generic name of Device
3.	Device Description <i>Provide a general description on design/size of the Device. The description should also include the following:</i> <ul style="list-style-type: none">a) <i>material of construction for:</i><ul style="list-style-type: none">(i) the device(ii) packaging material where applicableb) <i>device dimensions</i>c) <i>GMDN Code, Lot No. and UDI</i>
4.	Device model/series

5.	Certificates <i>Provide:</i> <ol style="list-style-type: none"> <i>original Free Sale Certificate specifically address to Zambia (notarized copies are acceptable)</i> <i>Manufacturing Licence of the device manufacturer</i> <i>Documentary proof of compliance to ISO 13485</i> <i>Documentary proof of registration for the product in other countries specifically those in the SADC region</i>
6.	State the intended use of the device
7.	Intended User
8.	Device Shelf-life (in months)
9.	Sample Instructions for Use
10.	Sample label (mock -up)
11.	Storage conditions
12.	Name and address of Applicant
13.	Name and address of authorised local distributor <i>(Provide original letter of authorisation)</i>
14.	Name, contact details and address of appointed local responsible person <i>(include valid power of attorney)</i>
15.	Complete name(s) and address(es) of the manufacturing site(s) of the Device
16.	Contract of manufacture (where applicable)

17.	Summary of manufacturing process <i>(provide narrative and flow diagram)</i>
18.	Provide information of notified body (if device is “CE” marked for example)
19.	Signed and dated device quality release specifications
20.	Provide at least two (2) certificates of analysis
21.	Two (2) samples of the product in the smallest commercial pack size

Annex IV

CHAPTER 1 – ADMINISTRATIVE	
1.01	Cover Letter
1.02	Submission Table of Contents Cover Letter
1.03	List of Terms/Acronyms
1.04	Application Form/Administrative Information
1.05	Listing of Device(s)
1.06	Quality Management System, Full Quality System or Other Regulatory Certificates
1.07	Free Sale Certificate/ Certificate of Marketing authorisation
1.08	Expedited Review Documentation
1.09	Pre-Submission Correspondence and Previous Regulator Interactions
1.10	Acceptance for Review Checklist
1.11	Statements/Certifications/Declarations of Conformity
1.11.01	Performance and Voluntary Standard
1.11.02	Environmental Assessment
1.11.03	Clinical Trial Certifications
1.11.04	Indications for Use Statement with Rx and/or OTC designation Enclosure
1.11.05	Truthful and Accurate Statement
1.11.06	Declaration of Conformity
1.12	Letters of Reference for Master Files
1.13	Letter of Authorisation
1.14	Other Regional Administrative Information
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2.01	Chapter Table of Contents
2.02	General Summary of Submission
2.03	Summary and Certifications for Premarket Submissions
2.04	Device Description
2.04.01	Comprehensive Device Description and Principle of Operation
2.04.02	Description of Device Packaging
2.04.03	History of Development
2.04.04	Reference and Comparison to Similar and/or Previous Generations of the Device
2.04.05	Substantial Equivalence Discussion
2.05	Indications for Use and/or Intended Use and Contraindications
2.05.01	Intended Use; Intended Purpose; Intended User; Indications for Use

2.05.02	Intended Environment/Setting for use
2.05.03	Pediatric Use
2.05.04	Contraindications for Use
2.06	Global Market History
2.06.01	Global Market History
2.06.02	Global Incident Reports and Recalls
2.06.03	Sales, Incident and Recall Rates
2.06.04	Evaluation/Inspection Reports
2.07	Other Submission Context Information
CHAPTER 3 – NON-CLINICAL EVIDENCE	
3.01	Chapter Table of Contents
3.02	Risk Management
3.03	Essential Principles (EP) Checklist
3.04	Standards
3.04.01	List of Standards
3.04.02	Declaration and/or Certification of Conformity
3.05	Non-clinical Studies
3.05.01	Physical and Mechanical Characterization
3.05.01.01	[Study description, study identifier, date of initiation]
3.05.01.01.01	Summary
3.05.01.01.02	Full Report
3.05.01.01.03	Statistical Data
3.05.02	Chemical/Material Characterization
3.05.02.01	[Study description, study identifier, date of initiation]
3.05.02.01.01	Summary
3.05.02.01.02	Full Report
3.05.02.01.03	Statistical Data
3.05.03	Electrical Systems: Safety, Mechanical and Environmental Protection, and Electromagnetic Compatibility
3.05.03.01	[Study description, study identifier, date of initiation]
3.05.03.01.01	Summary
3.05.03.01.02	Full Report
3.05.03.01.03	Statistical Data
3.05.04	Radiation Safety
3.05.04.01	[Study description, study identifier, date of initiation]
3.05.04.01.01	Summary
3.05.04.01.02	Full Report
3.05.04.01.03	Statistical Data
3.05.05	Software/Firmware
3.05.05.01	Software/Firmware Description
3.05.05.02	Hazard Analysis
3.05.05.03	Software Requirement Specification
3.05.05.04	Architecture Design Chart
3.05.05.05	Software Design Specification

3.05.05.06	Traceability Analysis
3.05.05.07	Software Development Environment Description
3.05.05.08	Software Verification and Validation
3.05.05.08.01	[Study description, study identifier, date of initiation]
3.05.05.08.01.01	Summary
3.05.05.08.01.02	Full Report
3.05.05.08.01.03	Statistical Data
3.05.05.09	Revision Level History
3.05.05.10	Unresolved Anomalies (Bugs or Defects)
3.05.05.11	Cybersecurity
3.05.05.12	Interoperability
3.05.06	Biocompatibility and Toxicology Evaluation
3.05.06.01	[Study description, study identifier, date of initiation]
3.05.06.01.01	Summary
3.05.06.01.02	Full Report
3.05.06.01.03	Statistical Data
3.05.07	Non-Material-Mediated Pyrogenicity
3.05.07.01	[Study description, study identifier, date of initiation]
3.05.07.01.01	Summary
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3.05.08.02	[Study description, study identifier, date of initiation]
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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
3.05.09.01.01.03	Statistical Data
3.05.09.02	Manufacturer Sterilization
3.05.09.02.01	[Study description, study identifier, date of initiation]
3.05.09.02.01.01	Summary
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3.05.09.3.01.01	Summary
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3.05.09.3.01.03	Statistical Data

3.05.09.4	Cleaning and Disinfection Validation
3.05.09.4.01	[Study description, study identifier, date of initiation]
3.05.09.4.01.01	Summary
3.05.09.4.01.02	Full Report
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Annex IV

