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

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

Guidelines for Registration of Medical Devices Including In Vitro Diagnostics (IVDs) and Related Products

1.0 General

1.1 These Guidelines are for the general public, manufacturers of medical devices, including IVDs and related products in Nigeria, and importers of medical devices, including IVDs and related products into Nigeria.

1.2 It is necessary to emphasize that no medical devices, including IVDs, shall be manufactured, imported, exported, advertised, sold, distributed, or used in Nigeria unless it has been registered in accordance with the provisions of NAFDAC Act CAP N1 (LFN) 2004, other related Legislation, and the accompanying Guidelines.

1.3 NAFDAC will not entertain new applications for the registration of imported regulated products on the Federal Government Import Prohibition List and NAFDAC Ceiling List,.

1.4 NOTE: These Guidelines should be read in conjunction with all relevant IMDRF guidance documents, including the following;

a. GHTF/SG1/N71:2012 "Definition of the Terms 'Medical devices including IVDs' and 'In Vitro Diagnostic (IVD) Medical devices including IVDs" GHTF SG1 Definition of the Terms 'Medical Device' and 'In Vitro Diagnostics' Medical devices including IVDs' s (imdrf.org)

b. In Vitro Diagnostic Medical devices including IVDs Market Authorization Table of Contents (IVD MA ToC), IMDRF/RPS WG/N13(Edition 2) FINAL:2019
https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-190321-ivd-mdma-toc-n13.docx

c. GHTF/SG1/N70:2011 "Label and Instructions for Use for Medical devices including IVDss" GHTF SG1 - Label and Instructions for Use for Medical devices including IVDss - September 2011 (imdrf.org)

d. Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVDMAToC), IMDRF/RPS WG/N9(Edition 3) FINAL: 2019
Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC) (imdrf.org)

2.0 Classification

2.1 The classification of medical devices and related products is as stated below according to their level of risk: -

(a) Class A is low risk,
(b) Class B is low to moderate risk,
(c) Class C is moderate to high-risk,
(d) Class D is high risk, or
(e) any other class as the Agency may deem fit.

Where a medical device and related products belongs to more than one class, the class representing the higher risk shall apply.

2.2 Classification of In Vitro Diagnostics

The classification of IVDs is as stated below

(a) Class A is low individual risk and low public health risk,
(b) Class B is low to moderate individual risk and/or low public health risk,
(c) Class C is high individual risk and/or moderate public health risk,
(d) Class D is high individual risk and high public health risk.

3.0 Application

3.1 A Dossier Screening Clearance is a prerequisite for submitting applications for the registration of moderate and high-risk IVD and non-IVD medical devices on the NAFDAC Automated Products Administration and Monitoring System (NAPAMS) platform.

3.2 To initiate the registration process for an IVD or non-IVD medical device product, the applicant is required to send an email to md.vbmrr@nafdac.gov.ng requesting access to submit the product dossier. Upon receipt of the email, a unique link will be generated and communicated to the applicant, facilitating the submission of their dossier (For video description of the upload process, please click on this Link).

3.3 A separate application is required for each medical device, IVD, related product, medical device group, IVD group, medical device family, IVD family, or medical device system.

3.4 The application should be submitted and processed on the NAFDAC Automated Product Administration and Monitoring System (NAPAMS) portal - https://registration.nafdac.gov.ng. For more information, see the NAPAMS User Manual.

3.5 A separate application form should be submitted for each product, product group, product family, or system.

3.6 Applications for Class A medical devices, including IVDs, and related products are to be processed within a maximum of 120 workdays.

3.7 Applications for Classes B, C, and D medical devices, including IVDs and related products, will be processed within a maximum of 240 workdays.

3.8 The timeline for processing is suspended when there is a Compliance Directive.

Step 1

4.0 Documentation

The following documents should be uploaded to the NAPAMS portal.

4.1 Dossier Screening Clearance.

4.2 The application letter should be addressed to the Director-General (NAFDAC), Attention: Director, Vaccines, Biologics and Medical Devices Registration & Regulatory Affairs Directorate, NAFDAC Office Complex, Oshodi-Apapa Expressway, Isolo, Lagos State.

4.3 Notarized Declaration (Appendix 1). To be completed (typed), signed by the Declarant and notarized by a Notary Public in Nigeria (for imported medical devices and IVDs)

4.4 A Power of Attorney (where the applicant does not own the product brand name) or Contract Manufacturing Agreement (where the applicant owns the Brand name).

4.5 An applicant should, on behalf of a manufacturer outside Nigeria**,** file evidence of a Power of Attorney from the manufacturer, which authorizes him to speak for his principal on all matters relating to the latter's specialties. The Power of Attorney should:

- 4.5.1 Be issued by the manufacturer of the product.
- 4.5.2 Be signed by the Managing Director, General Manager, Chairman, or President of the company, stating the names of the products to be registered. The power of attorney should also indicate 'Authority to register product with NAFDAC.
- 4.5.3 State ownership of Brand name(s)/Trademark
- 4.5.4 Be notarized by a Notary Public in the country of manufacture
- 4.5.5 Be valid for at least five (5) years

4.6 Contract Manufacturing Agreement: A company filing an application and being the owner of the brand name/trademark shall provide a Contract Manufacturing Agreement, which shall be signed by the applicant and the manufacturer. The Agreement shall be

- 4.6.1 Notarized by a Notary Public in the country of manufacture.
- 4.6.2 Signed by both parties, stating names and designations of the signatories, with the names of all the products to be registered and other relevant clauses clearly explained in an unambiguous language.

4.7 Certificate of Manufacture and Free Sale/Free Sale Certificate (for imported medical devices and IVDs). The manufacturer must show evidence that the company is

licensed to manufacture medical devices and/or IVDs and that the sale of the product does not constitute a contravention of the laws of that country. The Certificate of Manufacture and Free Sale/Free Sale Certificate should:

4.7.1 Be issued by a relevant Health/Regulatory body in the country of manufacture.

4.7.2 Indicate the name of the manufacturer and the products to be registered.

4.7.3 Be authenticated by the Nigerian Embassy or High Commission in the country of origin. However, any Commonwealth or ECOWAS country can authenticate the document in countries without a Nigerian Embassy.

4.8 Comprehensive Certificate of Analysis. The certificate of analysis must be presented on a letter-headed paper of the Quality Control Laboratory where the sample was tested/evaluated and should contain all relevant technical parameters of interest in addition to the underlisted information:

4.8.1 The brand name of the product

4.8.2 The batch number of the product

4.8.3 The manufacturing and expiry dates

4.8.4 The name, designation, and signature of the analyst.

4.9 Evidence of Business Incorporation by the Corporate Affairs Commission.

4.10 Evidence of Registration of Brand Name with Trademark Registry in the Ministry of Industry, Trade and Investment. This should be registered under the name of the owner of the trademark/brand.

4.11 Product Labels/artwork should be in line with the labelling requirement in Section 10.0

4.12 Letter of Invitation for Good Manufacturing Practice (GMP) Inspection (for imported medical devices, including IVDs): A letter of invitation to inspect the factory abroad shall be written by the manufacturer and shall state the following:

4.12.1 **Manufacturer Information**: The name of the Company, the full location address of the factory (not the administrative office address), the e-mail, and the current phone number. The details (name, phone number, and email) of the contact person overseas.

4.12.2 **Local Agent Information**: Name of company, full location address, functional phone number, and e-mail address. Details (name, phone number, and email) of the contact person. Names(s) of product(s) for registration.

4.13 **Technical Documents**

4.13.1 Quality Management System Compliance - Submission of evidence of quality management system certification by the manufacturer.

4.14 **Declaration of Conformity**

The manufacturer should attest that its medical devices, including IVDs, comply fully with all applicable Essential Principles for Safety and Performance as documented in a written "Declaration of Conformity" (DOC). At a minimum, this declaration should contain the following information:

4.14.1 A statement that each device that is the subject of the declaration
- (a) complies with the applicable Essential Principles for Safety and Performance
- (b) has been classified according to the classification rules, and;
- (c) has met all the applicable conformity assessment elements.

4.14.2 A Global Medical Devices (including IVDs) code and term for the device(s), where available.

4.14.3 Date from which the Declaration of Conformity is valid.

4.14.4 Name and address of the device manufacturer; and,

4.14.5 The name, position, and signature of the responsible person authorized to complete the Declaration of Conformity on behalf of the manufacturer.

4.14.6 Certificate of Compliance with Recognized Standards (where available) should be submitted.

4.14.7 Product Dossier for In-vitro Diagnostics (see NAFDAC guidelines for compilation of a product Dossier for Registration of In-vitro Diagnostics (IVD ToC) (Applicable to Classes C and D).

4.14.8 Product Dossier for Non-In Vitro Diagnostics (see NAFDAC guidelines for compilation of a product Dossier for Registration of Non-In Vitro Diagnostics (nIVD ToC) (Applicable to Classes C and D)

Note:

(a) All technical documents must be submitted in electronic format.

(b) After successfully submitting the application on the NAPAMS platform, original copies of all documents will be presented upon request.

(c) The applicant must notify the Directorate of the submission via email at md.vbmrr@nafdac.gov.ng, stating the application number for class C and D medical devices, including IVDs. This notification is necessary to facilitate the progression of the product dossier to full review.

Step II

5.0 **Import Permit (for imported medical devices, including IVDs)**

Upon successful screening of documentation and review of supporting documents, a Permit to Import will be issued electronically via the NAPAMS Portal to the applicant to

import registration samples for laboratory testing/evaluation.

Step III

6.0 GMP Inspection

The applicant should visit the Drug Evaluation and Research (DER) Directorate section of the Agency's website for more information on the manufacturing facility inspection (for both imported and locally manufactured medical devices, including IVDs)

Step IV

7.0 Labelling Guidelines and Instruction for Use for Medical devices including IVDs

7.1 Labelling should be informative, accurate, and in conformance with the Agency's Medical devices, including IVDs, and other related products Labelling Regulations and any other relevant Regulations.

7.2 All imported and locally manufactured medical devices, including IVDs, should bear the following minimum information on the label:

- 7.2.1 Name of the device
- 7.2.2 Name and address of the manufacturer
- 7.2.3 The identifier of the device, including the identifier of a device that is part of a system, test kit, medical devices, including IVDs group, and medical devices, including IVDs family
- 7.2.4 Medical devices, including IVDs group or family (where applicable)
- 7.2.5 Batch or lot number
- 7.2.6 If the contents are not readily apparent, an indication of what the package contains, expressed in terms appropriate to the device, such as size, net weight, length, volume, or number of units
- 7.2.7 The word "sterile" if the manufacturer intends to sell the device in a sterile condition
- 7.2.8 The words "for single use only" if the device is intended for that purpose
- 7.2.9 The manufacturing and expiry date of the device expressed in month and year (where applicable) unless self-evident to the intended user, the medical conditions, purposes, and uses for which the device is manufactured, sold, or represented, including the performance specifications of the device if those specifications are necessary for proper use.
- 7.2.10 The directions for use, unless directions are not required for the device to be

used safely and effectively.

7.2.11 Any special storage conditions applicable to the device

7.2.12 Where a package containing a device is too small to display all the information in accordance with (7.2.1-7.2.11) above, the directions for use shall accompany the device but need not be set out on the outside of the package or visible under normal conditions of sale.

7.3 Instructions for Use (IFU)

The following minimum information should be contained in the IFU:

7.3.1 The description of the intended use should include the following, where applicable:

a. what the medical device or IVD, measures or detects;
b. its function (e.g., screening, monitoring, diagnosis, or aid to diagnosis, prognosis, prediction, companion diagnostic);
c. the specific disorder, condition, or risk factor of interest that it is intended to detect, define, or differentiate;
d. whether or not it includes automated components or is intended to be used with automated instruments;
e. what the medical device or IVD reports (e.g., qualitative test, semi-quantitative, quantitative test);
f. the type of specimen(s) (e.g., serum, plasma, whole blood, tissue biopsy, urine) required, including the specimen source(s) (e.g., capillary whole blood from arm), matrix (e.g., EDTA tube), time (e.g., 8 hours after injury), and collection method (e.g., self-collected urine);
g. target population (on whom the medical device or IVD is used).

7.3.2 The instructions for use should include a statement of the test principle(s), such as the general biological, chemical, microbiological, immunochemical, and other principles on which the medical device or IVD is based. Proprietary information need not be disclosed, but should provide enough detail to allow the user to understand how the medical devices or IVD is able to carry out its function.

7.3.3 The instructions for use should include a description and the amount of the reagent, calibrators, and controls, and any limitation upon their use (e.g., suitable for a dedicated instrument only).

NOTE: IVD medical device kits include individual reagents and articles that may be made available as separate IVD medical devices. In such situations, these IVD medical devices should comply with the requirements for instructions for use as stated in this section.

7.3.4 The instructions for use should include a list of materials provided and a list of any materials required but not provided.

7.3.5 The instructions for use should include a description of in-use stability. This may include the storage conditions prior to opening and shelf-life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant.

7.3.6 The instructions for use should list the included and excluded conditions for collection, shipping, handling, and preparation of the specimen.

7.3.7 Where relevant, the instructions for use should include the traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials and/or higher-order reference measurement procedures.

7.3.8 The instructions for use should describe the assay procedure, including calculations and interpretation of results, any additional software or reference database required, and, where relevant, whether any confirmatory testing should be considered.

7.3.9 The instructions for use should list the analytical performance characteristics, such as precision, accuracy, sensitivity, and specificity.

7.3.10 Where relevant, the instructions for use should list the clinical performance characteristics (e.g., diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations).

7.3.11 Where relevant, the instructions for use should include the reference intervals in normal and affected populations.

7.3.12 The instructions for use should include information on any interfering substances or limitations (e.g., visual evidence of hyperlipidemia or hemolysis, age of specimen/sample) that may affect the performance of the assay.

7.3.13 Where relevant, the instructions for use should include a bibliography or references section.

Step V

8.0 Submission of Products for Laboratory Analysis

8.1 Upon importation of registration samples (for imported medical devices, including IVDs), applicants are expected to submit the same to the Vaccines, Biologics and Medical Devices Directorate for onward submission to the Laboratory for analysis. The following documents are expected to accompany the samples:

8.1.1 Letter for Submission of Laboratory Samples
8.1.2 Evidence of payment of processing fees to the Agency
8.1.3 Certificate of analysis
8.1.4 Evidence of submission of samples for vetting

8.2 The Drug Evaluation and Research (DER) Directorate will draw registration samples for locally manufactured medical devices, including IVDs.

Step VI

9.0 **Product Approval Meeting**

Upon satisfactory documentation review, GMP inspection of the production facility and laboratory analysis of the product (where applicable), the products are presented to the Food and Drug Registration Committee (FDRC) for approval.

10.0 **Tariff**

10.0 See NAFDAC Tariff section.

11.0 **Note**

11.1 Failure to comply with these requirements may result in the rejection of the application or lead to considerable delay in the processing of registration.

11.2 A successful application will be issued a Certificate of Registration with a validity period of five (5) years.

11.3 Registration of a product does not automatically confer Advertisement Permit. A separate application and subsequent approval by the Agency shall be required if the product is to be advertised. For further information on advert approvals, see NAFDAC Guidelines on Advertisement.

11.4 NAFDAC reserves the right to revoke, suspend or vary a certificate during its validity period.

11.5 Filing an application and/or paying an application fee does not confer registration status.

11.6 Failure to respond promptly to queries or enquiries raised by NAFDAC on the application (**within ninety (90) days) will automatically lead to the closure of the Application.**

11.7 The timeline for product registration from acceptance of submissions to issuance of the Registration number is a maximum of two hundred and forty (240) work days.

11.8 Please **note that the clock stops once compliances are issued.**

12.0 PLAN FOR POST MARKETING SURVEILLANCE

The post market surveillance plan should be developed in accordance with the NAFDAC Guidelines for Detecting and Reporting Adverse Reactions for Pharmaceutical Products and Medical Devices including IVDs

All correspondences should be addressed to:
The Director-General (NAFDAC),
Attn: The Director (Vaccines, Biologics and Medical Devices Registration and Regulatory Affairs Directorate)
National Agency for Food and Drug Administration and Control
NAFDAC Office Complex
Isolo Industrial Estate
Apapa-Oshodi Expressway, Isolo, Lagos

NAFDAC website: www.nafdac.gov.ng
E-mail: bvmregistration@nafdac.gov.ng

13.0 **APPENDICES**

APPENDIX I

NOTARIZED DECLARATION (for imported medical devices including IVDs)

I **Applicant's Name** the Managing Director of **Applicant's Company Name** hereby declare on oath and state as follows:

1. That **Applicant's Company Name** of **Applicant's Company Address** forwarded an application to the National Agency for Food and Drug Administration and Control for the Registration of regulated products hereinafter listed:
   a. **List of Products (Product Names)**
   b. _____

   Pursuant to the provisions of Food and Drugs and Regulated Products (REG etc.) Act Cap F33 LFN 2004 and all relevant Regulations as representatives of **Manufacturer's Company Name.**

2. That the said application before the National Agency for Food and Drug Administration and Control for the registration of the above listed Products, the application No: **Applicant Form No** thereof and the attached documents viz:

   a. Power of attorney / Contract Manufacturing Agreement and notarization thereof
   b. Certificates of Pharmaceutical Product/ Certificate of Manufacture and/or Free Sale and the authentication thereof by the Nigerian Mission in the country of origin
   c. Manufacturing license / Certificate for companies from India and China and the authentication thereof by the Nigerian Mission in the country of origin

d. Certificate of Good Manufacturing Practice (GMP) and the authentication thereof by the Nigerian Mission in the country of origin
e. Certificate of Analysis of product
f. Evidence of Registration of Trademark and the information contained in all the above referred documents is true and correct.

3. a. That the manufacturer **Manufacturer's Company Name** is or is not the owner of the trademark
   c. The product _____is generic.

4. a. That **Applicant's Company Name** of **Applicant's Company Address** is or is not the owner of the Trademark.
   b. The product _____is generic

5. That **Applicant's Company Name** and the declarant shall indemnify the National Agency for Food and Drug Administration and Control against any suit, claim, damages or liability arising from the use of all documents submitted and information declared by us in the processing, approval and grant of any certificate of registration in respect of **Product Name(s)**

6. We agree to be held criminally liable for any false declaration made herein and forged documents submitted to the National Agency for Food and Drug Administration and Control in respect of the application for the registration of **Product Name(s)**

Signature & Date

DECLARANT (Applicant)

BEFORE ME

NOTARY PUBLIC (NBA Seal)

NAME: _____
ADDRESS: _____
SIGNATURE: _____
DATE: _____