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 IN NIGERIA

1.0 General

1.1 These Guidelines are for the interest of the general public, manufacturers of medical devices in Nigeria, and importers of Medical Devices into Nigeria.

1.2. It is necessary to emphasize that, no Medical Device 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 application 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 Device' and 'In Vitro Diagnostic (IVD) Medical Device" GHTF SG1 Definition of the Terms 'Medical Device' and 'In Vitro Diagnostics' Medical Device's (imdrf.org)

b. In Vitro Diagnostic Medical Device 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" GHTF SG1 - Label and Instructions for Use for Medical Devices - 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 Application

2.1. The Application for the registration or renewal of registration of all Medical Devices products required for each single medical device, medical device group, medical device

family or medical device system 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

2.2. A separate application form shall be submitted for each product.

Step 1

3.0 Documentations

The following documents are uploaded on the NAPAMS portal. After successful submission, all original documents will be presented upon request.

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

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

3.3 Power of Attorney or Contract Manufacturing Agreement. An applicant on behalf of a manufacturer outside Nigeria must file evidence of 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 shall (be):

3.3.1 Issued by the manufacturer of the product.

3.3.2 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 shall also indicate 'Authority to register product with NAFDAC'.

3.3.3 State ownership of Brand name(s)/Trademark.

3.3.4 Notarized by a Notary Public in the country of manufacture.

3.3.5 Valid for at least five (5) years.

3.4 Contract Manufacturing Agreement: An applicant filing an application and being the owner of Brand name/Trademark, shall provide a Contract Manufacturing Agreement, which shall be signed by the applicant and the manufacturer. The Agreement shall be

3.4.1 Notarized by a Notary Public in the country of manufacture.

3.4.2 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.

3.5 Certificate of Manufacture and Free Sale (for imported medical devices). The manufacturer must show evidence that the company is licensed to manufacture medical devices and that the sale of the product does not constitute a contravention of the laws of that country, i.e., Free Sale Certificate (Certificate of Manufacture and Free Sale). The Free Sale Certificate should:

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

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

3.5.3 Be authenticated by the Nigerian Embassy or High Commission in the country of origin. In countries where no Nigerian Embassy exists, any Commonwealth or ECOWAS country can authenticate the document.

3.6 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 the under listed information:

3.6.1 The brand name of the product

3.6.2 The batch number of the product

3.6.3 The manufacturing and expiry dates

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

3.7 Evidence of Business Incorporation by the Corporate Affairs Commission.

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

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

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

3.10.1 MANUFACTURER INFORMATION: Name of Company, full location address of factory (not administrative office address), e-mail, and current phone no. Details (name, phone number and email) of contact person overseas.

3.10.2 LOCAL AGENT INFORMATION: Name of company, full location address, functional phone number. and e-mail address. Details (name, phone number and email) of contact person. Names(s) of product(s) for registration.

4.0 Technical Documents

4.1 Declaration of Conformity

4.1.1 The manufacturer should attest that its medical device complies 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:

a. A statement that each device that is the subject of the declaration–

i. complies with the applicable Essential Principles for Safety and Performance,

ii. has been classified according to the classification rules, and,

iii. has met all the applicable conformity assessment elements.

b. A Global Medical Device code and term for the device(s).

c. Date from which the Declaration of Conformity is valid.

d. Name and address of the device manufacturer; and,

e. The name, position, and signature of the responsible person who has been authorized to complete the Declaration of Conformity on behalf of the manufacturer.

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

4.3 Product Dossier for In-vitro Diagnostics (see NAFDAC guidance for compilation of a product Dossier for Registration of In-vitro Diagnostics (IVD ToC)

4.4 Product Dossier for Non In-vitro Diagnostics (see NAFDAC guidance for compilation of a product Dossier for Registration of In-vitro Diagnostics (nIVD ToC)

4.5 Clinical Evaluation Report with Statistical Data for Novel Medical Devices including In-vitro diagnostics.

4.6 In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IVD MA ToC), IMDRF/RPS WG/N13(Edition 2) FINAL:2019

4.7 Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVDMAToC), IMDRF/RPS WG/N9(Edition 3) FINAL:2019

Note: All technical documents must be submitted in electronic format e.g., Flash drive

5.0. GMP Inspection

5.1 Applicant should visit the Drug Evaluation and Research (DER) Directorate section of the Agency's website for more Information on the Inspection of manufacturing facility (for both imported and locally manufactured medical devices)

Step II

6.0 Import Permit (for imported medical devices)

6.1 Upon successful screening of documentation and review of supporting documents, a Permit to Import shall be issued electronically via the NAPAMS Portal to the applicant for the importation of Registration samples for Laboratory testing.

Step III

7.0 Submission of Products for Laboratory Analysis

7.1 Upon importation of Registration Samples (for imported medical devices), applicants are expected to submit same to the division for onward submission to the Laboratory for analysis. The following documents are expected to accompany the samples.

7.1.1 Letter for submission of Laboratory Samples

7.1.2 Evidence of payment to the Agency

7.1.3 Certificate of analysis

7.1.4 Evidence of submission for vetting

While registration samples for locally manufactured medical devices will be drawn by Drug Evaluation and Research (DER) Directorate.

Step IV

8.0 Product Approval Meeting

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

STEP V

9.0 Labelling Guidelines and Instruction for Use for Medical Devices

9.1 Labelling should be informative, accurate and in conformance with the Agency's Medical Devices, in vitro diagnostic and other related products Labelling Regulations and any other relevant Regulations.

9.2 All imported and locally manufactured medical devices should bear the following minimum information on the label:

a. Name of the device

b. Name and address of the manufacturer

c. The identifier of the device, including the identifier of a device that is part of a system, test kit, medical device group, medical device

d. Family or medical device group family (where applicable)

e. Batch or lot number

f. 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

g. The words "sterile" if the manufacturer intends to sale the device in a sterile condition

h. The words "for single use only" if the device is intended for that purpose

i. 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

k. the directions for use, unless directions are not required for the device to be used safely and effectively and

l. any special storage conditions applicable to the device

m. where a package that contains a device is too small to display all

the information in accordance with (a-k) above, the directions for use shall accompany the device but need not be set out on the outside of the package or be visible under normal conditions of sell.

9.3 Instruction For Use (IFU)

9.3.1 The following minimum information should be contained in the IFU:

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

i. what the IVD medical device measures or detects;
ii. its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic);
iii. the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;
iv. whether or not it includes automated components or is intended to be used with automated instruments;
v. what the IVD medical device reports (e.g., qualitative test, semi-quantitative, quantitative test);
vi. 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); and
vii. target population (on whom the IVD medical device is used).

b. 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 IVD medical device is based. Proprietary information need not be disclosed, but should provide enough detail to allow the user to understand how the IVD medical device is able to carry out its function.
c. 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 this situation, where appropriate, these IVD medical devices should comply with the instructions for use content in this section.
d. The instructions for use should include a list of materials provided and a list of any materials required but not provided.
e. 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.

f. The instructions for use should list the included and excluded conditions for collection, shipping, handling, and preparation of the specimen.
g. 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 reference measurement procedures of higher order.
h. 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, if any confirmatory testing should be considered.
i. The instructions for use should list the analytical performance characteristics, such as precision, accuracy, sensitivity, and specificity.
j. 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).
k. Where relevant, the instructions for use should include the reference intervals in normal and affected populations.
l. 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.
m. Where relevant, the instructions for use should include a bibliography or references section.

10.0 Tariff

10.1 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 Advertising 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 timelines for product registration from acceptance of submissions to issuance of Registration number is one hundred and twenty (120) working days.

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

12.0 PLAN FOR POST MARKETING SURVEILLANCE

12.1 The post market surveillance plan should be developed in accordance with the Section 4.8 (Medical Devices Vigilance System) of the NAFDAC Guidelines for Detecting and Reporting of Adverse Reactions for Pharmaceutical products and Medical Devices

13.0 APPENDICES

All correspondences should be addressed to: -

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

APPENDIX I

NOTARIZED DECLARATION (for imported medical devices)

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: _____