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

Drug Registration and Regulatory Affairs (DR&R) Directorate

Guidelines for Registration of Software as a Medical Device (SaMD) in Nigeria

1.0. General

1.1. These Guidelines are for the interest of the general public and in particular, importers of Medical Devices in 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 Legislations 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.

2.0. Application

2.1. The Application for the registration of all Medical Devices products should be submitted and processed on the NAFDAC Automated Product Administration and Monitoring System (NAPAMS) portal www.napams.org or 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.

2.3. **Definitions**

2.3.1. Software as a Medical Device

The term "Software as a Medical Device" (SaMD) is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.

NOTES:

i. SaMD is a medical device and includes in-vitro diagnostic (IVD) medical device.

ii. SaMD is capable of running on general purpose (non-medical purpose) computing platforms without being part of" means software not necessary for a hardware medical device to achieve its intended medical purpose.

iii. Software does not meet the definition of SaMD if its intended purpose is to drive a hardware medical device.

iv. SaMD may be used in combination (e.g., as a module) with other products including medical devices.

v. SaMD may be interfaced with other medical devices, including hardware medical devices and other SaMD software, as well as general purpose software.

Mobile apps that meet the definition above are considered SaMD.

2.3.2. Intended use / Intended Purpose

The term "intended use / intended purpose" is 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.

2.4. 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. 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)

c. IEC 62304:2006 - Medical device software -- Software life cycle processes IEC 62304:2006 - Medical device software — Software life cycle processes (iso.org)

d. IMDRF SaMD WG N10 / Software as a Medical Device: Key Definitions https://www.imdrf.org/documents/software-medical-device-samd-key-definitions

e. ISO/IEC/IEEE 14764:2022 Software Engineering— Software Life Cycle Processes — Maintenance ISO/IEC/IEEE 14764:2022 - Software engineering — Software life cycle processes — Maintenance

2.5. Categorization of SaMD

The following principles are necessary in the categorization approach of SaMD.

a. The categorization relies on an accurate and complete SaMD definition statement.

b. The determination of the categories is the combination of the significance of the information provided by the SaMD to the healthcare decision and the healthcare situation or condition.

c. The four categories (I, II, III, IV) are based on the levels of impact on the patient or public health where accurate information provided by the SaMD to treat or diagnose, drive or inform clinical management is vital to avoid death, long-term disability or other serious deterioration of health, mitigating public health.

d. The categories are in relative significance to each other. Category IV has the highest level of impact, Category I the lowest.
e. When a manufacturer's SaMD definition statement states that the SaMD can be used across multiple healthcare situations or conditions it is categorized at the highest category according to the information included in the SaMD definition statement.
f. When a manufacturer makes changes to SaMD, during the lifecycle that results in the change of the definition statement, the categorization of SaMD should be reevaluated appropriately. The SaMD is categorized according to the information included in the changed (new) SaMD definition statement.
g. SaMD will have its own category according to its SaMD definition statement even when a SaMD is interfaced with other SaMD, other hardware medical devices, or used as a module in a larger system.

2.6. SaMD Categories State of the Healthcare or Significance of information provided by SaMD to healthcare decision

2.6.1 Summary Table for SaMD Categories

State of the Healthcare situation/ condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

3.0. Steps to Registration of SaMD

3.1. Documentations

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

3.2. The application letter addressed to the Director-General (NAFDAC), Attention:
Director, Drug Registration & Regulatory Affairs Directorate,
Ground Floor, NAFDAC Office Complex,
Oshodi-Apapa Express Way, Isolo, Lagos State.

3.3. End User License Agreement (EULA)
3.4. Notarized Declaration (Appendix 1). To be completed (typed), signed by Declarant and notarized by a Notary Public in Nigeria.
3.5. Notarized by a Notary Public in the country of manufacture.
3.6. 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.
3.7. 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.
3.8. Product Labels/artwork should be in line with the labelling requirement in Section 7.0

4.0. Technical Documents
4.1. Clinical Evaluation of a SaMD for the purposes of this document "Clinical evaluation of a SaMD" is defined as a set of ongoing activities conducted in the assessment and analysis of a SaMD's clinical safety, effectiveness and performance as intended by the manufacturer in the SaMD's definition statement.
4.1.1. Clinical evaluation landscape

S/N	Requirement	Information Required	Specification
1	Valid Clinical Association (scientific validity)	Valid clinical association between the SaMD output and the SaMD's targeted clinical conditions	Literature searches, original clinical report, professional society guidelines, secondary data analysis, clinical trials
3	Analytical/Technical Validation	Data/information to verify that the SaMD correctly processes input data to generate accurate, reliable and precise output data	Accuracy, Reliability, Precision
3	Clinical Validation	Data/information to verify that the SaMD is accurate, reliable and precise output data achieve the intended purpose in the target population in the context of clinical care	Sensitivity, Specificity, Odd ratio

4.2. Evidence of approval by other NRAs (if available)

5.0. Product Approval meeting

5.1. Upon satisfactory Documentation review and evaluation report of product are presented for the Food and Drug Registration Committee (FDRC) Approval Meetings.

STEP V

6.0. Issuance of Registration Certificate

6.1. Upon the FDRC, meeting, an electronic Certificate of Product Registration is issued to the Applicant via the NAPAMS platform.

7.0. Labelling Guidelines for Imported Medical Devices

7.1. Labelling should be informative, accurate and in conformance with the Agency's Medical Devices Labelling Regulations and any other relevant Regulations.

7.2. All imported 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
d. of a system, test kit, medical device group, medical device
e. Family or medical device group family (where applicable)

8.0. **Tariff**

8.1. The tariff for registration of medical devices applies. See NAFDAC Tariff section https://nafdac.gov.ng/regulatory-resources/nafdac-tariff/

9.0. **Note**

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

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

9.3. 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 Advert

9.4. NAFDAC reserves the right to revoke, suspend or vary a certificate during its validity period.
9.5. Filing an application and/or paying an application fee does not confer registration status.
9.6. Failure to respond promptly to queries or inquiries raised by NAFDAC on the application (within 90 working days) will automatically lead to the closure of the application.
9.7. The timeline for product registration from acceptance of submissions to issuance of Registration number is one hundred and twenty (120) working days.
9.8. Please note that the process clock stops once compliance directives are issued.

All correspondences should be addressed to: -

Director-General (NAFDAC),
Attn: The Director
Registration and Regulatory Affairs Directorate,
National Agency for Food and Drug Administration and Control,
Ground Floor, NAFDAC Office Complex
Isolo Industrial Estate, Apapa-Oshodi Expressway, Isolo, Lagos

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

APPENDIX I

NOTARIZED DECLARATION

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
   b. 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: _____