

NIGERIA IVD NATIONAL REGULATORY AUTHORITY (MLSCN)
PRODUCT REGISTRATION FILE (PRF)

1. Executive summary: Commercial marketing history and post-market information and if appropriate a risk/benefit assessment.
2. Documentation on conformity with essential principles of safety and performance.
3. Device description, including intended use and any warnings/precautions.
4. Design verification and validation: preclinical studies and clinical evidence (if required).
5. Labelling, instructions for use and promotional materials
6. Risk management
7. Manufacturer's information: quality management certification and manufacturing process

1. Executive Summary:

- i. An overview: introductory descriptive information on the device, the intended uses and indications for use, novel features and a synopsis of the content of the Product Registration File.
- ii. Commercial marketing history, list of countries where the IVD device is marketed and dates of introduction into each country
- iii. Intended uses and indications in labelling
- iv. List of regulatory approval or marketing clearance obtained
- v. Status of any pending request for market clearance
- vi. Important safety/performance related information

2. Documentation demonstrating conformity with essential principles

Devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety or health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

- i. General requirements of QMS, risk management and technical tests to provide for high level of protection of health and safety for intended use
- ii. Conformance to safety and risk hazard control
- iii. Designed, manufactured and packaged to meet intended function and performance
- iv. Characteristics and performance should not be adversely affected under stress conditions during normal conditions of use.
- v. Characteristics and performances should not be adversely affected under transport and storage conditions
- vi. The benefits to outweigh undesirable side effects
- vii. Chemical, physical and biological properties
- viii. Infection and microbial contamination
- ix. Manufacturing and environmental properties
- x. Requirements for device connected to or equipped with an energy source

- xi. Protection against mechanical risks, protection against risks posed by supplied energy or substances
- xii. Protection against risks posed to the patient for devices for self-testing or self-administration
- xiii. Performance evaluation and clinical evaluation where appropriate

3. Device description

- i. Indicate whether the IVD device consists of reagent(s), control material(s), calibrator(s) or other components, or any of their combinations
- ii. List all accessories for the device to be used in accordance with its intended purpose
- iii. Short description of how the components are used together to achieve the intended purpose
- iv. Identify how components and accessories are intended to work together to achieve the intended use

4. Design verification and validation

- The depth and details of the documentation required depends on the classification of the device
- Manufacturers may be asked by the national regulatory authority(MLSCN)to submit related information on performance characteristics of the device.
- Under an effective QMS, at the stage of design control, the manufacturer should have completed product verification and validation
 - i. Analytical performance data
 - ii. Clinical performance data
 - iii. Traceability of calibrators and control materials
 - iv. Stability

NB: Software verification and validation is required.

Different intended use may have different requirements. (e.g. qualitative, quantitative, POC, over the counter).

If a recognized standard including specific acceptance criteria is used, declaration of conformity could be accepted.

If a recognized standard without specific acceptance criteria is used, justification of using that standard should be submitted.

If a professional guideline/standard or in-house standard is used, the rationale of using the standard, method of the experiment.

- Performance evaluation report of the IVD device
- Demonstration of equivalence to another IVD
- Published method of diagnosis where safety and efficacy of which are well established.
 - i. Study design
 - ii. Methods, procedure, including acceptance criteria
 - iii. Study report including arranged and analysed data (where appropriate, the report should include raw data/line listing)
 - iv. Conclusion of the study
 - v. All claims (e.g. intended use and performance characteristic) mentioned in the submission should be verified and validated

5. Labelling, information for users and promotional materials

- i. Specific characteristics, including single use, sterility, intended users (healthcare professionals only, or laypersons) and whether for self-use
- ii. Instruction for use available in a suitable language(s)
- iii. All labelling including instructions, manuals, device and package labels and special listing information

- iv. Device brochures, demonstration video clips and/or animation clips illustrating the usage and applications of the device
- v. Indications for use, intended locations of use, contraindications against use, cleaning, disinfection and/or sterilization procedures, user precautions and disposal precautions

6. Risk management

- i. International or national standard with which the IVD complies such as ISO14971; EN13612:2002; ISO18113:2009
- ii. Risk analysis conducted with report or summary
- iii. Type of test performed with report or test certificate

7. Manufacturer's information

- i. Each manufacturing site shall be specified
- ii. Manufacturing sites or sub-contractors not engaged for production of the whole device but just a part of or some constituting components need not be included
- iii. Copies of ISO13485 certificates covering the manufacturing sites shall be provided
- iv. The name and address of the manufacturing sites shall be the same as those stipulated in the ISO13485 certificates