NAFDAC Medical Devices, including In-vitro Diagnostics and Related Products Regulations, 2025

Comments are welcomed from Stakeholders within 60 calendar days (ending 20th September 2025). Please send all comments/input/feedback to regulatoryaffairs@nafdac.gov.ng

NAFDAC Medical Devices, including In-vitro Diagnostics and Related Products Regulations, 2025

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NAFDAC Medical Devices, including In-vitro Diagnostics and Related Products Regulations, 2025

[ ] Commencement

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control ('the Governing Council') by Section 30 of the National Agency for Food and Drug Administration and Control Act, Cap. N1, LFN, 2004 and Section 12 of the Food, Drugs and Related Products (Registration, Etc.) Act. Cap. F33. LFN, 2004 and of all the powers enabling it in that behalf, the Governing Council with the approval of the Minister makes the following Regulations: -

Part 1
Objective And Application

149. **Objective**

The objective of these Regulations is to provide a regulatory framework for the regulation of medical devices including in vitro diagnostics (IVDs), and related products manufactured, imported, exported, advertised, sold, displayed for sale, distributed, or used in Nigeria.

150. **Application**

These Regulations shall apply to clinical investigation, manufacture, registration, labelling, advertisement, post market surveillance, vigilance, recall, handling and disposal of medical devices including IVDs and related products manufactured, imported, exported, advertised, sold, distributed, displayed for sale, or used in Nigeria.

Part 2
Clinical Investigation for Medical Devices including IVDs and Related Products

151. **General**

(a) These Regulations shall describe the good clinical practice requirements for the conduct of clinical investigations involving medical devices including IVDs to ensure that:
  (i) the right, safety and well-being of trial participants are protected; and
  (ii) the result or outcome of a clinical investigation are credible

(b) Except as provided by these Regulations, failure to comply with any provision set forth in these Regulations in respect of Clinical Investigation shall render such clinical investigation illegal, the reports from it shall be invalid, and the medical devices including IVDs, as well as the person, who is responsible for the non-compliance shall be liable to the penalty set out in this Regulations.

152. (1) **Good Clinical Practice for Medical Devices including IVDs and Related Products**

(a) Clinical investigation for a medical device including IVD studies shall be:
  (i) designed, conducted, recorded, and reported in accordance with these Regulations;
  (ii) conducted in accordance with good clinical practice principles and ethical principles that have their origin in the Declaration of Helsinki and are consistent with Good Clinical Practices (GCP).

(b) The right and safety of the trial participant shall prevail over the interest of science and society.

(c) Manufactured investigational medical devices including IVDs, and related products shall be handled and stored in accordance with applicable Good Manufacturing Practices (GMP) and used in accordance with the approved protocol.
(d) Systems with procedures that assure the quality of every aspect of a trial shall be implemented.
(e) Amendments relating to the conduct, design, and methodology of the clinical investigation of medical devices including IVDs or the investigator or site of the clinical investigation, which may have a substantial impact on the safety of the participants and credibility of the data shall be approved by the Agency.
(f) A person involved in conducting a clinical investigation shall be qualified by education, training, and experience to perform the assigned task.
(g) Informed consent shall be obtained from every participant prior to Clinical investigation enrollment.
(h) The confidentiality of records that could identify participants shall be protected, respecting the confidentiality rules in accordance with the applicable regulatory requirement.
(i) A person involved in the conduct of a clinical investigation shall provide complete and accurate information attesting to the absence of conflict of interest in the clinical investigation.
(j) A sponsor or investigator shall
  (i) submit a study report as prescribed by the Agency.
  (ii) register all clinical investigations with the clinical trial registry as prescribed by the Agency before submission of an application to the Agency for approval.
(k) The Agency shall inspect every approved trial site and facility used or is being used for the purpose of clinical investigation.
(l) Notwithstanding the provisions of regulation 4 (1) (c) of this regulation, the assembly of an investigational medical product in a hospital or health center which is a clinical investigation site shall not be required to meet GMP requirements provided the assembling and use are in that site.

(2) An investigational medical product shall:
(a) be labeled to ensure the protection of the participant, identification of the product, and facilitate proper use of the investigational medical product;
(b) be traceable, stored, returned, or destroyed as approved by the Agency.
(c) have written or electronic records of destruction submitted to the Agency.
(d) be retrieved from the individual investigator where
  (i) the product is unused or expired,
  (ii) a participant in the investigation is discontinued or terminated.
(e) be labelled in a manner that complies with the requirements of the Agency.

153. **Ethics Committee**
(a) An applicant for a clinical investigation shall obtain a favourable opinion from the Ethics Committee.
(b) The Agency may refuse the favorable opinion of an Ethics Committee, where there are grounds to believe that the Ethics Committee:
  (i) was not composed of members with requisite qualifications and experience to review and evaluate the science, medical aspect, and the ethics of the proposed clinical investigation;
  (ii) has not established, documented and followed its procedures; and
  (iii) does not have a valid registration certificate issued by the National Health Research Ethics Committee (NHREC).

(c) The Ethics Committee shall;
  (i) carry out its task without any influence or bias from those conducting the clinical investigation; and
  (ii) declare any potential conflict of interest with respect to the clinical investigation
(d) Any member of the Ethics Committee having an interest in the clinical investigation, shall not participate in the review of the clinical investigation, except by providing information as may be requested by the Ethics Committee.

154. **Obligations of Sponsor of Clinical Investigation**
(1) A sponsor or his representative shall be domiciled in Nigeria.
(2) The sponsor of a clinical investigation shall be responsible for;
  (a) selecting qualified investigators;
  (b) providing the investigators with the requisite information that is necessary for conducting an investigation effectively;
  (c) ensuring that the investigation is conducted in accordance with the general investigational plan and protocols for the study;
  (d) ensuring proper monitoring of the investigation;
  (e) maintaining effective control with respect to the investigations;
  (f) ensuring that the Agency and participating clinical investigators are promptly informed of significant new adverse effects or risks with respect to the medical devices including IVDs and related products.
  (g) ensuring the establishment of appropriate compensation mechanisms to the participants or investigators arising from the clinical investigation; and
  (h) ensuring the supply of investigational medical devices including IVDs and related products that conform with good manufacturing practice principles.
(3) A sponsor may delegate its function to a person, provided that the sponsor shall be responsible for the clinical investigation.
(4) A sponsor shall ensure that data generated from the clinical investigation complies with the requirements of the Agency.
(5) Every essential document relating to the clinical investigation shall be archived by the sponsor as prescribed by the Agency and made available and accessible upon request by the Agency.
(6) Any transfer of ownership of the content of the Clinical Investigation Master File by the sponsor or his representative to the new owner shall be documented and the new owner shall assume the responsibilities set out in these Regulations.

155. **Clinical Investigator**
(1) An Investigator shall have requisite qualifications in terms of education, training, and experience to assume the responsibility for the proper conduct of the clinical investigation in compliance with Good Clinical Practice and other applicable requirements as may be prescribed by the Agency.
(2) Where a clinical investigation is conducted with more than one investigator, the sponsor shall appoint a Principal Investigator among the investigators, who shall coordinate and ensure that the clinical investigation complies with the requirements of these Regulations.
(3) The Principal Investigator or an Investigator shall provide progress reports and close-out notification at the end of a clinical investigation as prescribed by the Agency to the sponsor and the Agency.

156. **Safety Report**

(1) The sponsor shall review information relevant to the safety of an investigational medical product received from any source, foreign or domestic, including
   (a) information derived from any clinical or epidemiological investigations,
   (b) animal investigations,
   (c) commercial marketing experience,
   (d) reports in the scientific literature and unpublished scientific papers,
   (e) reports from foreign regulatory authorities that have not been previously reported to the Agency.

(2) The sponsor shall
   (a) upon receipt of any safety information, notify the Agency in writing.
   (b) within the stipulated period report to the Agency any unexpected fatal or life-threatening experience associated with the use of the medical product after initial receipt of the information.

(3) The sponsor of a clinical investigation shall within the stipulated period report to the Agency, any suspected or unexpected Serious Adverse Reactions which occur outside the particular clinical investigation at the sponsor's first knowledge.

(4) The sponsor shall within the stipulated period report to the Agency after the sponsor has first knowledge of safety issues, which might materially alter the current benefit-risk assessment of the investigational medical product or that would be sufficient to consider changes in the investigational Medical Products administration or in the overall conduct of the clinical investigation.

157. **Inactive Status of a Clinical Investigation**

(1) The Agency may, in its opinion or upon request by the sponsor, place a clinical investigation on inactive status, where there is no progress report sent to the Agency by the investigator for a period as may be prescribed by the Agency.

(2) To restart a clinical investigation after a temporary halt shall be deemed as a substantial amendment.

(3) An investigation that remains on inactive status for a period such as may be prescribed by the agency, shall be terminated.

(4) Where an investigation is placed on inactive status, investigators shall be notified and stocks of investigational medical devices including IVDs and related products shall be returned or disposed of, in accordance with the requirements of the Agency.

158. **Data and Safety Monitoring Board**

(1) The Agency may impose a condition for the establishment of a Data and Safety Monitoring Board.

(2) Pursuant to regulation 11(1) of this Regulations, the establishment of a Data and Safety Monitoring Board may depend on any of the following—
   (a) the design and scientific background of the clinical investigation.
   (b) the benefit and risk assessment of the clinical investigation; or
   (c) any other reason as may be prescribed by the Agency.

(3) Where the Data and Safety Monitoring Board is involved in monitoring a clinical investigation, the Agency shall require the following—
   (a) a broad statement of the aims and objectives of the clinical investigation.
   (b) terms of reference.
   (c) composition of members, at least one member from the country or region, conducting the clinical investigation.
   (d) qualifications of members.
   (e) specific roles including responsibility of statistician.

(f) the role of statistical stopping rules.
(g) relationship between the principal investigator and clinical investigation management team.
(h) decision-making process.
(i) meeting arrangement.
(j) whether the members will be blinded to the investigation of medical devices including IVDs and related products; and what options can be recommended;
(k) in what form and to whom the decisions shall be conveyed;
(l) a person whom the Data and Safety Monitoring Board shall report to;
(m) the role of the Data and Safety Monitoring Board in the publication of the outcome of the medical devices including IVDs and related products clinical investigation ; and
(n) disclosure of conflict of interest of any of the Board members.

159. **NAFDAC Expert Advisory Committee**

(1) The Agency shall;
(a) constitute an Expert Advisory Committee, comprising experts from different fields of relevant professions; and
(b) define the Terms of Reference for the Expert Advisory Committee.
(2) The Expert Advisory Committee shall be a standing committee, and its role remains advisory to the Agency.

160. **Insurance and Indemnity**

(1) A clinical investigation shall not be conducted unless the sponsor provides insurance cover for participants in the clinical investigation from a registered insurance company in Nigeria against any related injuries or harms that may arise in the course of such clinical investigation.
(2) Pursuant to regulation 12 (1) of this regulations, the sponsor shall indemnify an investigator against claims arising from the clinical investigation, except for claims on malpractice or negligence
(3) The insurance cover for participants and investigators referred to in regulation 13 (1) of this Regulation, shall be in accordance with the applicable insurance law in Nigeria.

161. **Good Clinical Practice Inspection**

(1) The Agency shall conduct good clinical practice inspections to any site or facilities related to the investigational study to determine whether the study is in compliance with the provisions of these Regulations and other statutory requirements of the Agency.
(2) Investigators shall allow the Agency to copy, verify and evaluate participants' medical records and any other record or report made relating to the handling, storage, usage and disposal of unnecessary medical devices including IVDs and related products in compliance with Good Clinical Practice.
(3) The Agency may not give notice of inspection to a Sponsor or Investigator before conducting an inspection.

162. **Foreign Clinical Investigations**

(1) The Agency may rely on data obtained from foreign clinical investigation studies to form its decision, provided the studies are designed, conducted, and performed by qualified investigators in accordance with good clinical practice guidelines and Declaration of Helsinki guideline.
(2) Studies meeting these criteria may be utilized to support clinical investigations in Nigeria or registration provided that, an application based solely on foreign clinical data, meeting Nigeria criteria for registration —

(a) foreign data are applicable to the Nigerian population and Nigeria medical practice;
(b) studies were performed by competent investigators;
(c) data may be considered valid without the need for an on-site inspection by the Agency; and
(d) Agency considers such an inspection to be necessary and shall validate the data through an on-site inspection or other appropriate means.

(3) The Agency may rely on information or regulatory decisions of well-resourced regulatory authorities, regional or international bodies, to form its regulatory decisions.

163. **Registry of Clinical Investigation Information**

An applicant for Clinical investigation shall register in a registry as may be prescribed by the Agency.

164. **Revocation or Cancellation of Approval**

(1) The Agency, by a notice in writing may suspend or revoke the licence or permit for a clinical investigation for such period as may be determined by the Agency due to non-compliance with these Regulations.

(2) The Agency may disqualify or suspend an Investigator, where it has information indicating that the Investigator, failed to comply with the requirements of these Regulations or submitted to the Agency or the sponsor, false information in any required report.

PART 3
Manufacture of Medical Devices, In Vitro Diagnostics and Related Products

165. **General**

(1) A manufacturer of medical device, including IVD, or related product shall ensure the product is;
(a) consistently manufactured in conformance with quality standards;
(b) consistently designed, developed, produced, stored, and distributed as prescribed by this Regulations,
(c) is safe, effective, and of good performance.

(2) Premises for the manufacture of medical devices including IVDs and related product shall be inspected in accordance with current applicable standards.

166. **Quality System**

(1) A manufacturer of medical devices including IVDs and related product shall establish and maintain a quality system:
(a) that is appropriate for the specific medical device, IVD or related product designed or manufactured.
(b) which shall cover organizational structure, responsibilities, policies, procedures, processes, and application of the principles of risk management, as well as appropriate resource, compliance and records management.

(2) Top management of the organization shall have the responsibility to ensure that an effective quality system is in place, adequately resourced, the effectiveness continually improved, and roles, responsibilities, and authorities are defined, communicated, and implemented throughout the organization.

(3) The organizational structure shall clearly define the responsibilities, authorities, interrelationships and qualifications of all personnel in the organization as well as its place in the parent organization, where applicable.

(4) The manufacturer shall consider the quality, safety, and performance of the medical devices including

167. **IVDs and related products at all stages of production**

(1) Manufacturer of medical device including IVD and related product shall ensure that the finished medical devices including IVD or related products are safe, effective, and of good performance.

(2) Manufacturer of medical devices including IVDs and related products shall establish a Risk Management System (RMS) establishing policies and principles for effective implementation as prescribed by the provisions of these Regulations

(3) A system for regular updates of the RMS shall be put in place and be applied throughout the lifecycle of the medical device including IVD or related product.

(4) The RMS shall cover:

(a) identification of potential risks

(b) assessment of risks during intended use and foreseeable misuse

(c) controlling risks through design, manufacture, and protection

(d) continuous monitoring and updating of risk management plans

(5) Safety measures shall be put in place at every phase of the Quality Management System (QMS) to identify and mitigate potential risks to the effectiveness of the product.

(6) Records from the risk management shall be documented, maintained and made available upon request by the Agency.

168. **Personnel**

(1) A manufacturer shall have sufficient number of competent and appropriately qualified personnel to perform assigned functions and achieve the quality management objectives.

(2) Initial and continuing training shall be in the particular operations that the employee performs and in good manufacturing practices as they relate to the employee's functions. The training effectiveness shall be verified, and records of training shall be kept.

(3) Personnel performing verification and validation activities shall be trained on defects and errors that may occur during the production process.

(4) Experts advising on the manufacture, processing, packaging, or holding of medical device including IVD or related products shall have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Records shall be maintained stating the name, address, and qualifications of the consultants and the type of service they provide.

(5) Hygiene programs adapted to the activities to be carried out shall be established and observed. These programs shall include procedures relating to health, hygiene practice and clothing of personnel.

169. **Premises and Equipment**

(1) Building and equipment used in the manufacture, processing, packaging, or holding of medical devices, including IVDs and related products shall be adequately located, designed, constructed, adapted, maintained and of suitable size as appropriate to the type and stage of manufacture.

(2) Buildings shall have adequate space for the orderly placement of equipment and materials and shall have orderly flow of personnel, materials and processes through the building to prevent mix-ups, contamination, cross contamination. and any adverse effect on the quality of the product.

(3) There shall be dedicated and self-contained facilities for the production of different classes of medical devices, IVDs, and related products to minimize the risk of serious medical hazards due to cross-contamination, where applicable.

(4) The manufacturer shall establish a program for preventive and breakdown maintenance of all

equipment and instrument inclusive of GMP support facilities.

(5) Records for calibration of instruments and equipment requiring calibration shall be maintained and updated periodically.

170. **Design Controls**

Manufacturer of medical devices including IVDs and related products shall:

(1) create and maintain plans that outline design and development activities. Input and output shall be documented and reviewed.

(2) ensure that design outputs align with design inputs and that devices conform to intended uses.

(3) conduct clinical or performance evaluations as applicable in line with the provisions of this Regulations.

(4) put in place a Device History File to document and demonstrate that each manufactured product was designed and developed following the approved design plan.

(5) put in place procedures for design transfer and design changes to identify, document, validate or verify, review, and approve design changes before implementation.

171. **Qualification and validation**

(1) Premises and equipment to be used for manufacturing and testing operations, which are critical to the quality of the products, shall be subjected to appropriate qualification and validation.

(2) Critical processes and GMP support systems shall be validated, continually monitored, and periodically re-validated.

(3) Changes to processes, systems, equipment, or materials that may affect product quality or process reproducibility shall be requalified or re-validated prior to routine implementation.

172. **Documentation**

(1) Manufacturer of medical devices including IVDs, or related products shall;

(a) ensure adherence to good documentation practice.

(b) establish and maintain a documentation system based on instructions, records, and reports covering the various manufacturing and control operations and all activities performed as appropriate to the quality system.

(2) Procedures and records shall be maintained for all processes that impact the quality, safety, and performance of the medical devices including IVDs and related products.

(3) Pre-established procedures for general manufacturing operations and conditions shall be kept available together with specific documents for the manufacture and control of each batch or lot and the documents shall enable the history of the manufacture of each batch or lot of medical devices including IVD or related products traced.

(4) Manufacturing records pertaining to medical devices including IVDs and related products shall be maintained for at least 1 year after the expiration date of the product.

(5) Data may be stored by means of electronic, photographic or other data processing systems which shall first be validated to ensure that the data will be appropriately stored during the anticipated period of storage.

(6) Data stored by as specified in regulations (5) to this Regulations shall be made readily available in legible form and shall be provided to the Agency on request.

(7) The electronically stored data shall be protected by methods such as duplication or back-up and transfer on to another storage system, against loss or damage of data, and audit trails shall be maintained.

(8) Adequate measures to ensure data integrity, confidentiality, and security shall be established, implemented, and maintained.

173. **Production**

(1) Procedures and instructions shall be established for production and process control to ensure that a medical device including IVD or related product has the identity, safety, performance, and reliability it purports or is represented to possess, and the procedures and instructions shall be followed, and records maintained.

(2) Any deviation from the procedures and instructions shall be reported, investigated, recorded, and justified.

(3) Medical device including IVD or related product defects shall be documented and thoroughly investigated for determination of root cause and appropriate corrective and preventive actions.

(4) There shall be adequate in-process control for production operations which shall be sufficiently resourced.

(5) Measures shall be taken to mitigate risks of contamination and mix-ups.

(6) Procedures for rework or reprocessing of medical devices, IVDs, and related products shall be established and detailed records maintained, including retesting and re-evaluation of the nonconforming product after rework or reprocessing to ensure it meets approved specifications.

(7) The manufacturer shall maintain Device History Records (DHRs) for each batch, lot, or unit to demonstrate compliance with the Device Master Record (DMR) procedure.

174. **Purchasing and Materials management**

(1) A manufacturer shall establish a system for evaluation and selection of suppliers based on their ability to meet quality requirements and maintain a list of approved suppliers from whom it shall source materials and services.

(2) Adequate measures shall be taken to ensure that materials meet established specifications before use. Only materials released by the quality unit and within their shelf-life, where applicable, shall be used for manufacturing and control activities.

(3) Materials and products shall be stored under the appropriate conditions established by the manufacturer, and in an orderly manner, to permit batch segregation and stock rotation.

(4) Cleaning, lubricating, fumigating, sanitizing, and pest control materials shall not contaminate equipment and materials.

175. **Quality Assurance & Quality Control**

(1) Manufacturer of medical devices including IVDs, or related products shall establish and maintain a;

(a) quality assurance department which shall be a distinct organizational unit that functions and reports to management independently of any other functional unit.

(b) quality control department under the authority of a person with appropriate qualifications and experience having at his disposal or have access to one or more control laboratories, which are adequately resourced to carry out the necessary examinations and testing of materials.

(2) Materials shall not be released for use or finished products released for sale or distribution unless their quality has been adjudged satisfactory and approved by the authorized person.

(3) The manufacturer shall retain an appropriate number of samples of each batch of finished medical device including IVD or related products for at least one year after the expiry date.

176. **Contract manufacture and analysis**

(1) Where the whole or a part of the manufacturing process or analysis of materials or products is contracted, the contract shall be in written form, clearly spelling out the responsibilities of each party.

(2) The observance of good manufacturing practices and other relevant requirements to be followed by the contract acceptor and the manner in which each batch is to be released by the authorized person shall be clearly stated in the contract.

(3) The contract acceptor shall be subject to inspections by the Agency and the contract giver.

(4) The contract acceptor shall not subcontract any of the work entrusted to him under the contract without written authorization from the contract-giver.

177. **Complaints and product recall**

(1) Complaints and other information concerning potentially defective products shall be carefully investigated, recorded, and reviewed according to written procedures by the manufacturer.

(2) A manufacturer of medical devices including IVDs, or related products shall

(a) establish and maintain a system to recall from the market, promptly and effectively, products known or suspected to be defective.

(b) inform the Agency of any defect that could result in the recall or abnormal restriction on the supply of a medical device including IVD or related product within and outside the country as well as any regulatory action taken against the company by relevant authorities due to non-compliance with requirements.

178. **Quality Audit**

(1) The manufacturer shall establish a routinely implemented quality audit program designed to monitor the implementation of GMP, assess the effectiveness as well as compliance of the quality system with established requirements.

(2) The recommended corrective and preventive actions shall be implemented, and records maintained.

179. **Non-compliance with GMP requirements**

The Agency may as part of control measures withdraw, cancel, or suspend the manufacturing authorization of any company that contravenes the provisions of these Regulations.

Part 4
Registration of Medical Devices including IVDs and Related Products

180. **Classification**

(1) The classification of medical devices including IVDs and related products shall be in accordance with the First Schedule to these Regulations and categorized 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.

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

(3) The classification of IVDs shall be as stated below with details in the Second Schedule to this Regulations:

(1) Class A is low individual risk and low public health risk,

(2) Class B is low to moderate individual risk and/or low public health risk,
(3) Class C is high individual risk and/or moderate public health risk,
(4) Class D is high individual risk and high public health risk.

181. **Application for Registration**

(1) Application for registration of medical device including IVDs and related products shall be;
(a) required for each single medical device including IVDs and related product, a group system or family;
(b) made by submitting an application accompanied by relevant documents prescribed by the Agency.

(2) The medical device including IVDs and related product submitted for registration under these Regulations shall be designed and manufactured to be safe and perform as intended throughout its life cycle.

(3) The particulars and description of the medical device including IVDs and related products referred to in regulation 33 (1) (b) to this regulation shall contain administrative and technical information to allow the Agency to make informed decision about the product.

(4) Notwithstanding the provisions of regulation 18 of these Regulations, manufacturers of medical devices including IVDs, and related products shall:
(a) establish and maintain a Quality Management System (QMS) including the requirements for a declaration of conformity to the Essential Principles of Safety and Performance.
(b) submit the declaration of conformity to the Essential Principles of Safety and Performance and QMS Certificate, to fulfil the technical and legal requirements of this Regulations.
(c) manufacture in accordance with good manufacturing practices and any requirements issued by the Agency

(5) The Agency, in considering an application;
(a) may request the applicant to make available such other information as it may require to enable it reach a decision on the application;
(b) shall satisfy itself that there is need to have the medical device or related products registered in Nigeria; and
(c) may register the medical device including IVDs and related products in accordance with the provisions of Food, Drug and Related Products (Registration etc.) Act, Cap. F33, LFN 2004.

182. **Refusal of application for registration**

The Agency may refuse an application for registration where;
(a) documentation as required by the Agency is incomplete;
(b) it is discovered that the method, facility or control used in the manufacture, processing, and packaging of the medical device and related product is inadequate to ensure and consistently preserve its identity, performance, safety, quality, and purity;
(c) laboratory report for the product is unsatisfactory;
(d) quality management system or good manufacturing practice inspection report is unsatisfactory;
(e) product labeling contravenes the provisions of these Regulations.
(f) medical devices, including IVD or related products do not meet other requirements of the Agency, or
(g) Any other reason as may be determined by the Agency.

183. **Issuance of Certificate of Registration**

(1) Where the Agency considers an application for registration to be satisfactory, the applicant shall be issued a Certificate of Registration.

(2) Notwithstanding the provision of regulation (1) to this regulation, the Agency may withhold the issuance of certificate of registration if: -
   (a) The applicant does not comply with these Regulations or relevant provisions of the Food, Drug and Related Products (Registration etc.) Act cap F33 LFN 2004;
   (b) the applicant has made a false or misleading statement in the application;
   (c) the medical device including IVD or related products does not comply with the labelling requirements set out in these Regulations; and
   (d) the applicant has not fulfilled a request for supplementary information set by these Regulations.

(3) Where the application for registration is unsatisfactory, the Agency shall refuse the application and inform the applicant in writing stating the reason for the refusal.

184. **Validity of Registration**

The registration of medical devices including IVD or related products under these Regulations shall, unless it is cancelled, be valid for a period of five years and may be renewed.

185. **Suspension, withdrawal or cancellation of Certificate of Registration**

(1) The Agency may suspend or cancel the registration of a medical device including IVDs and related product, where;
   (a) the grounds on which the medical device including IVDs and related products were registered is false or incomplete,
   (b) any of the conditions under which the medical device including IVDs and related products was registered has been contravened,
   (c) standard of quality, performance, safety or purity as prescribed in the documentation for registration is not being complied with,
   (d) the product has proven to be ineffective for the approved intended use;
   (e) the premises in which the medical device including IVDs and related products, are manufactured, assembled, or stored are not in compliance with the requirements of Good Manufacturing Practice (GMP), Good Distribution Practice (GDP) and Good Warehouse Practice (GWP) as may be determined by the Agency; or
   (f) holder of Certificate of Registration has given a notice to the Agency in writing of intention to suspend product registration for a period not exceeding the validity of the Certificate of Registration.

(2) Where the registration of medical device including IVDs and related product is suspended or cancelled, the Agency shall order the withdrawal from circulation of such medical device including IVDs and related product and shall accordingly cause the suspension, cancellation or withdrawal to be published.

(3) Where a Certificate of Registration is suspended or cancelled pursuant to the provisions in regulation 37 (1) of this regulation, a holder of Certificate of Registration shall notify the Agency of the intention to resume marketing of a registered medical device including IVDs and related product and shall submit relevant document and pay the prescribed renewal fee for product registration, where the Certificate of Registration has expired.

186. **Publication of Registered medical device including IVDs and related product**

The Agency shall, from time to time, publish on its official website or any other medium as deemed fit, the list of registered medical devices including IVDs and related products registered by the Agency.

187. **Registration of novel devices**

The registration of a novel medical devices including IVDs and related products shall be subject to a satisfactory performance evaluation study conducted by the Agency.

188. **Post- registration changes**

(1) Change to a registered medical device including IVDs and related shall not be carried out on medical devices including IVDs and related products without notification to the Agency, except as prescribed in these Regulations.

(2) Any changes that may likely impact on the quality, safety and performance of a product shall require prior approval of the Agency.

(3) Every application for change to an approved product shall be submitted to the Agency describing in detail the changes to be carried out.

(4) Where a change is required to be effected, the holder of Certificate of Registration shall not distribute the medical devices including IVDs and related products unless the —

(a) effect of the change is duly assessed and approved by the Agency; and

(b) product label is revised to reflect the change, where applicable.

(5) Payment for variation applications shall be as prescribed by the Agency

189. **Renewal of Certificate of Registration**

Application for renewal of Certificate of Registration of medical devices including IVDs and related products shall be;

(a) initiated before the expiration of the Certificate of Registration

(b) made by submitting application including;

(i) particulars and description of the medical device including IVDs and related products,

(ii) name of the medical devices including IVDs and related products,

(iii) class of the medical devices including IVDs and related products,

(iv) identification of the medical devices including IVDs and related products

(v) the manufacturer's "Declaration of No Change" since the product's last approval by the Agency

(vi) provision of detailed information on any changes made and their potential impact on the product's safety, quality or performance. considering the

(c) post-market surveillance and vigilance report conducted by the manufacturer.

(d) market history of the product in the country since its last approval including sales quantity, safety or performance related complaints, adverse event/incidents report, recall rates.

(e) any other document as may be prescribed by the Agency.

190. **Establishment of Expert Advisory Committee**

(1) The Agency shall establish an expert advisory committee for the purpose of advising on specific issues related to the registration of medical devices including IVDs and related products.

(2) The committee established under regulation (1) to this regulation shall execute its functions based on the terms of reference as may be prescribed by the Agency.

191. **Obligations of the Holder of Certificate of Registration**

(1) **Monitoring products in the supply chain**

(a) Holder of Certificate of Registration shall:

(i) monitor the medical devices including IVDs and related products on the market and inform the Agency immediately after the detection of any problem relating to a registered medical device, IVDs and related products which may endanger public health;

(ii) maintain communication with the Agency on matters relating to the medical devices including IVDs and related products;

(iii) handle medical device recalls including IVDs and related products; and

(iv) provide technical support and services to users of registered medical devices, including IVDs and related products

(2) **Distribution Records**

(a) The Holder of Certificate of Registration shall maintain a distribution record in respect of each medical device including IVDs and related products manufactured, imported, exported, distributed, displayed for sale, sold or used.

(b) Put in place a post-market surveillance system as prescribed by the Agency

(c) The holder of Certificate of Registration shall provide the distribution records as specified in regulation 43 (2)(a) to this regulation, to the Agency upon request.

(3) **Post-market surveillance and vigilance**

(a) The Holder of Certificate of Registration shall monitor the safety and performance of the medical device including IVDs and related products manufactured, imported, exported distributed, displayed for sale, sold or used and put in place a post-market surveillance system as prescribed by the agency.

(b) The Holder of Certificate of Registration shall ensure that any vigilance report of adverse incident involving medical device including IVDs and related products in the market is properly recorded and fully evaluated.

(4) **Complaint Handling**

The Holder of Certificate of Registration shall establish and implement documented procedures and maintain records of reported problems or complaints relating to the safety and the performance characteristics of medical device including IVDs and related products.

(5) **Mandatory problem reporting**

The holder of Certificate of Registration shall report to the Agency any incident that comes to the establishment's attention occurring inside or outside Nigeria that:

(a) is related to the failure of the medical device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its instructions for use and such report shall be made within required timeline as specified by the Agency;

(b) has led to the death or serious deterioration in the state of health of a patient, user or other person, or if the incident were to reoccur and such report shall be made within required timeline as specified by the Agency; or

(c) is a serious threat to public health and such report shall be made immediately upon the discovery.

(6) **Field Safety Corrective Action**

The Holder of Certificate of Registration shall undertake corrective or preventive action in relation to a medical device including IVDs and related products manufactured, imported, exported distributed, displayed for sale, sold or used in the market which may include:

(a) the return of the medical device including IVDs and related products to the Holder of Certificate of Registration.

(b) modification of the medical device including IVDs and related products;
(c) exchange of the medical device including IVDs and related products;
(d) destruction of the medical device including IVDs and related products; or
(e) specific advice on the use of the medical device including IVDs and related products.

(7) **Recall**

(a) The Holder of Certificate of Registration shall:
(i) recall any defective medical device including IVDs and related products at any time.
(ii) provide information as may be specified by the Agency before undertaking a recall of the medical device including IVDs and related products.
(iii) report to the Agency the results of the recall and any action taken to prevent a recurrence of the problem upon completion of the recall.

(b) Notwithstanding regulation (7) (a) to this regulation, the Agency shall request the establishment to recall any medical device including IVDs and related product at any time due to patient safety and public health.

(8) **Disposal**

A holder of Certificate of Registration and the user of medical devices including IVDs and related products shall ensure that the disposal of expired, degraded or obsolete medical device and related product shall be carried out in a manner prescribed by the competent authority and under the supervision of the Agency.

192. **Reprocessing of Single-Use Medical Device**

The reprocessing of a Single Use Medical devices (SUMD) as labelled by its manufacturer is not permitted.

193. **Refurbishment of Medical devices**

(1) A person that intends to undertake refurbishment of medical devices with the intention of making it available on the market, shall seek and obtain approval from the Agency
(2) A refurbished medical device shall meet the same requirements for safety and performance as applied to the original medical device.
(3) A refurbishment process carried out on a medical device shall be done in accordance with the Principles of Good Refurbishment practice (GRP).
(4) The label of a refurbished medical device shall indicate that it is refurbished. The refurbishment date shall also be indicated, with other labelling requirements as prescribed by the Agency.
(5) The person refurbishing the medical device shall assume the obligations of the manufacturer.
(6) The elements of regulatory control for refurbished medical devices shall include:
(a) Quality Management System (QMS)
(b) Post Market Surveillance
(c) Declaration of conformity with the Essential Principles of Safety and Performance
(d) Technical documentation

194. **Registration of Establishment**

An Applicant or manufacturer for the registration of medical devices including, IVDs and related products shall submit an establishment license issued by the relevant authority in Nigeria.

195. **Disclosure of information supplied by applicant**

A person shall not disclose information supplied to the Agency in pursuance of regulation 33 of

these Regulations, except –

(a) with the written consent of the person who supplied the information;

(b) in accordance with the directive of the Agency; or

(c) for the purpose of a proceeding under these Regulations.

Part 5
Labelling of Medical Devices including IVDs and Related Product Labelling Information

196. **Labelling information**

(1) Information required to be indicated on the label of medical device including IVDs and related product shall;

(a) be informative, accurate, prominent, legible and distinct;

(b) appear in font size and style type, adequate for clarity and on sufficient contrasting background without obscuring designs or vignettes or crowding within written, printed, or graphic matter;

(c) be in English Language and may include any other languages

(d) indicate the letters of the name of the medical device including IVDs and related product and the net content or net weight in a size reasonably related to the predominant character on the label.

(e) not be false or misleading, deceptive or likely to create an erroneous impression regarding its character, quality, quantity and origin; and

(f) have required information and statements on the part or panel of the label, which is presented or displayed under customary conditions of purchase.

(2) The medical device including IVDs and related product label space shall not be used to present information, statement or graphics not required by these Regulations in such a manner as to make the label space insufficient for the prominent placing of such information or statements required under these Regulations.

(3) Medical device including IVDs and related product label shall state the following;

(a) the brand name, where applicable;

(b) the product's statement of identity;

(c) batch or lot number;

(d) net content or net weight;

(e) manufacture date and expiry date, where applicable;

(f) manufacturer's name and manufacturing address including country of origin;

(g) NAFDAC registration number assigned by the Agency in the manner prescribed;

(h) warnings and cautions

(i) instruction for use of the medical device, including IVDs and related product;

(j) storage conditions; and

(k) any other information as may be prescribed by the Agency.

(4) Notwithstanding the provisions of regulation 48 (3) of this regulation, a medical device including IVDs and related product in a container having inadequate space shall indicate the following;

(a) brand name, where applicable;

(b) product statement of identity;

(c) lot or batch number;

(d) net content or net weight;

(e) expiry date, where applicable;

(f) manufacturer's name and facility address; and

(g) NAFDAC registration number in the manner prescribed.

(5) Where a medical device including IVD and related product container is covered with a packaging

material, the label shall be made legible through the outer packaging material and shall not be obscured by it.

(6) Labels of medical device including IVD and related product shall be affixed in a manner that is not removable from the medical device including IVD or related product container.

(7) Label shall not bear words, pictorial or other means, which refers to any other product or falsely suggests either directly or indirectly, that the medical device including IVDs and related product is connected with such other product.

(8) Information and statements required under these Regulations shall appear on the part or panel of the label which is presented or displayed under customary conditions of purchase.

(9) A claim on the medical device including IVDs and related product shall be substantiated.

(10) Special labelling requirements and product safety information shall be clearly stated.

(11) Any other information as may be prescribed by the Agency.

197. **Expiry Date**

(1) Medical devices including IVDs and related product label shall indicate the expiry date of the product as prescribed in regulation 48 (3) and (4) of this Regulations.

(2) Notwithstanding regulation 49 (1) of these Regulation for Medical devices including IVDs and related product for continuous use, the manufacture date shall suffice.

198. **Name and address of Manufacturer, Holder of Certificate of Registration, Packer on Label**

(1) The label of a medical device including IVDs and related product shall be conspicuous, indicating the name and manufacturing address of the manufacturer.

(2) Where a medical device including IVDs and related product is manufactured under a contract manufacturing arrangement, the name and manufacturing address shall be indicated by a phrase that reveals the connection with the entity such as "Manufactured by ....., for ……. "., 'Manufactured for by……", or any other wording that expresses the facts.

(3) The name and address of the manufacturer and packer of a medical device including IVDs and related product shall be specified on the packaging component label, where present, in such a manner that is easily readable.

(4) Where a medical device including IVDs and related product undergoes any processing in another country which affects its contents, such country shall be considered as the country of manufacture for the purpose of labeling.

(5) Where a medical device including IVDs and related product undergoes any processing in another country which does not affect its contents, such a country shall be considered as the country of packaging for the purpose of labeling.

(6) The address of the manufacturer of a medical device including IVDs and related product shall be complete on the label of the primary, secondary and tertiary packaging where applicable, unless the primary packaging of the medical device including IVDs and related product is inadequate, in which case the address is to be displayed on the primary label.

199. **Product Identification**

(1) A trademark or brand name shall be displayed on the label without giving a wrong impression of the nature or quality of the medical devices including IVDs and related product;

(2) Where the brand name or trademark is in conflict with any Regulations or requirements of the Agency, the latter shall supersede and prevail; and

(3) The brand name of a medical device including IVDs and related product shall not be a sound or

look alike to an already registered medical device or related product

200. **Statement of Identity**

(1) Statement of identity label of a medical device including IVDs and related product , shall —

(a) bear the name of the medical device including IVDs and related product and indicate the accurate nature of the medical device including IVDs and related product;

(b) where a common name or statement of identity has been established for the medical device including IVDs and related product, it shall be used in conjunction with the brand name of the medical device and related product;

(c) where no common name or statement of identity exists for a medical device including IVDs and related product, an appropriate descriptive name shall be affixed to it; and

(d) where a coined or fanciful name is used for the medical device including IVDs and related product, the name shall not be misleading and be accompanied by an appropriate descriptive term.

(2) Medical device and related product shall have product specific identifier-

(a) such as batch number, lot number, batch code, lot code, serial number, control number or version number and barcode, where applicable;

(b) indicated on all packaging components of medical device including IVDs and related product or primary packaging.

(3) Where it is impossible, for reasons of size, for details of the product identifier to appear on all packaging components of medical device including IVDs and related product, the details shall be given on the primary packaging

201. **Composition and components**

(1) A complete list of composition or components of the medical device including IVDs and related product shall be indicated on the primary and secondary label, where applicable, in decreasing order of predominance.

(2) Where there is no secondary packaging, the list of composition or components shall be indicated on the primary label.

(3) Composition or components in concentrations of less than 1% may be listed in any order after those concentrations of 1% or more.

(4) Where the composition or components of a medical device including IVDs and related product have more than one composition or component, the name of the composition or components shall be included in the list of composition or components.

(5) The declaration of composition or components shall be made prominent, readable and understandable under normal conditions of purchase.

(6) Where a medical device including IVDs and related product contains a pharmaceutically active composition or components, the declaration of composition or components shall indicate the active pharmaceutical composition or components in accordance with provisions of the Agency's Drug and Related Products Labelling Regulations.

(7) Where a composition or components of a medical device including IVDs and related product is known to cause hypersensitivity, such shall be declared on the label.

(8) Where multi-packs are involved, the following shall apply —

(a) where the composition or components labelling is on the secondary packaging, the composition or components for each product may be separately listed or combined into one list;

(b) where labelling on the secondary packaging is impossible for practical reasons or impracticable for

reasons of size or shape, the list shall be given on a leaflet, label, tag, tape or card enclosed with the product and the consumer shall be referred to the text either by abbreviated information or by a special symbol on the outer pack;

(c) where the products within a multi-pack have containers which are individually labelled or printed with a composition or components list, there shall be no need for a separate leaflet, label, tape, tag or card; and

(d) in the case of transparent packaging, where the composition or components labelling of the products is clearly visible, separate labelling is not required.

202. **Date marking instruction**

(1) The date marking shall be stated for medical device including IVDs and related product and indicated on the primary, secondary and tertiary packaging, where present.

(2) The batch number and date markings shall not be pre-printed on the label.

203. **Storage Condition**

The required storage condition shall be specified on the primary, secondary and tertiary packaging where applicable.

204. **Registration number assigned by the Agency**

(1) The primary, secondary and tertiary packaging of a medical device including IVDs and related product shall clearly show the registration number (NAFDAC REG. NO.) of the product assigned to it by the Agency as indicated on the Certificate of Registration in a manner prescribed by the Agency.

(2) Where a medical device including IVDs, has tertiary, secondary and primary packaging materials and the content of a unit pack is considered to be dispensed or sold to an end-user as a whole or is for a single use, the NAFDAC REG. No. shall be shown on the tertiary and secondary packaging materials.

(3) Where the primary package is a Trade Item, NAFDAC REG. NO shall be assigned to the primary package.

205. **Instruction for Use**

Instruction for use shall be included on the label to ensure correct utilization of the medical device including IVDs and related product. Where this is not possible, Instruction for use shall be made on the leaflet and be included in the product pack

206. **Warnings and Cautions**

The label of medical device including IVDs and related product shall carry clear and adequate warning to prevent any danger arising from the usage of the product.

207. **Displayed information etc.**

(1) Any information displayed on a label which misleads or deceives a consumer in anyway shall constitute an offence under these Regulations.

(2) A person shall not remove, add to, alter, deface or render illegible any statement on a label printed on or attached to the packaging or container in pursuance of these Regulations.

208. **Net Content**

(1) The accurate average net content or net weight of medical device including IVDs correlated product shall be declared on the primary, secondary and tertiary packaging label in the metric system.

(2) Medical device including IVDs and related product that have only primary packaging label shall meet the same requirements as those for the secondary or tertiary packaging label of products having primary, secondary and tertiary packaging labels.

PART 6
Advertisement of Medical Device, IVDs and Related Products

209. **Application for the approval of advertisement**

(1) Advertisement materials including scripts, storyboard, artwork, radio scripts and any other advertisement material shall be submitted along with an application and other accompanying documents in a manner prescribed by the Agency.

(2) Advertisement materials submitted under these Regulations shall be authenticated by the Chief Executive or the appropriate technical person of the medical device including IVDs and related product company sponsoring the advertisement.

(3) Application submitted by an advertising agent, distributor, manufacturer or the sponsor of the advert shall contain the following information —

(a) the brand name of the medical device including IVDs and related product, if any;
(b) place of importation or local manufacturer
(c) the name and address of the manufacturer;
(d) the name and address of the local distributor;
(e) the name and address of the advertising company;
(f) the date of first introduction of the medical devices including IVDs and related products to the Nigerian market, for new products;
(g) information about any previous advertisement of the medical devices including IVDs and related products in Nigeria, where necessary;
(h) the proposed media of the advertisement;
(i) evidence of current product registration;
(j) a justification for any special claims on the medical devices including IVDs and related products;
(k) scripts and recordings; and
(l) such other materials as may be required by the Agency from time to time

210. **Nature of advertisement**

(1) Advertisements of medical devices including IVDs and related products shall be precise, accurate, complete, clear and designed to promote credibility and trust by the general public.

(2) Statements or illustrations contained on the packaging or advertisement material shall not mislead directly or indirectly.

211. **Non referential advertisement**

Advertisement of medical devices including IVDs and related products shall not —

(a) imitate the general layout, text, slogan or visual presentation of another medical device including IVDs and related product in a manner likely to mislead or confuse the consumer; or
(b) be stated in such a manner to induce fear among users leading to the purchase of medical device including IVDs and related products.

212. **Validity of approval**

(1) An approval for advertisement of medical device including IVDs and related product shall be valid for

a period of one year at first instance from the date of the approval.

(2) Subsequent advertisement applications shall be valid for two years provided that no alteration is made and conditions of renewal approval remain the same.

(3) Notwithstanding regulation 64 (1) of this regulation, consumer promotions shall have validity period of 15 weeks.

213. **Alteration in approved Advertisement material**

Any alteration in the format of the approved script or recording without the approval of the Agency shall render the approval invalid.

214. **Withdrawal of approval within the validity period**

The Agency may withdraw the approval for an advertisement —

(a) where the grounds on which an approval is granted is found to be false or incomplete;

(b) where any of the conditions under which the approval is granted has been contravened; or

(c) for any reasons of new scientific evidence.

215. **Reference to professional bodies or associations, etc.**

Advertisement of medical device including IVDs and related product shall not refer, or lay claim to an endorsement, directly or indirectly, to a national or international body, except as prescribed by the Agency.

216. **Advertisement not to prejudice public confidence**

A person shall not advertise medical device including IVDs and related product in a manner that brings the industry to disrepute or prejudice public confidence in the medical devices including IVDs and related products.

217. **Accurate** interpretation of research findings

(1) Every advertisement shall be written as to accurately interpret valid and representative research findings.

(2) Statistics in an advertisement shall be written to reflect only their true validity and significance.

218. **Scientific articles and literature**

(1) A claim or quotation shall contain both the negative and positive findings and shall be readily verifiable by the Agency.

(2) A claim based on, or quotation that has been selected from a scientific article or series of articles, which emphasis only the positive features while ignoring negative findings, shall not be acceptable.

219. **Contravention of ethical standards**

Advertisement of medical devices including IVDs and related products shall not contravene the ethical standard of the health care profession.

220. **Unfairly disparage competition**

Advertisement of medical devices and related products shall not contravene the ethical standard of the health care profession.

221. **Claims**

(1) Advertisement for medical device including IVDs and related product shall not state, imply in absolute terms or by quotations taken out of context, that any medical device including IVDs and related product is "safest", has "guaranteed effectiveness" or special status.

(2) Any statement claiming or implying a superlative function such as "most effective", "least toxic", "best tolerated", or special status such as "the medical device including IVDs and related product of choice", or any such statements, for a medical device including IVDs and related product shall not be used unless it can be adequately substantiated and shall not imply superior effectiveness to other products in the same category.

(3) "Best-selling" claims when used shall not imply superior effectiveness to other products in the same category.

(4) Where an advertisement portrays a medical device including IVDs and related product as "fast", "immediate" "instant" or "rapid" in action, or any similar descriptions, such claims shall be substantiated using studies based on the performance of the medical device including IVDs and related products.

(5) "Duration of action" claims in medical device including IVDs and related product advertisements is allowed provided the claims can be supported by performance studies.

(6) Where claims on performance are made in the advertisement of a medical device including IVDs and related product, such claims shall be substantiated using performance studies carried out in actual patients.

(7) Top parity claims and 'Natural' claims may be permitted provided they are adequately substantiated.

222. **Restrictions**

(1) Advertisement of a medical device including IVDs and related product shall not contain —

(a) false or misleading information.

(b) incomplete truths, inadequate qualification and limitations regarding safety or effectiveness of the medical device including IVDs and related product;

(c) vague, unsubstantiated statements, or suggestions of superiority over competing medical device including IVDs and related product; and

(d) false impression that the advertised medical device including IVDs and related products is for universal purpose or shall be regarded as a more effective and safer alternative to another medical device including IVDs and related product in the same category.

(2) Medical device including IVDs and related product advertisement shall not —

(a) contain such word as "magic" "miracle", least harmful", "best tolerated" or description such as "most effective" or any other words as to induce the daily or continuous use of the medical device including IVDs and related product outside of its intended use;

(b) contain a message that if the reader, viewer or listener does not use a particular medical device or related products the user may not get the best result; and

(c) disparage or attack unfairly any competitive brand of medical device including IVDs and related products.

223. **Prohibition of misleading comparison**

(1) Comparison in an advertisement shall not mislead the public either directly or indirectly and where there is comparison, it shall be supported by reliable current scientific data.

(2) A reference to a competitive manufacturer or its specialties in an advertisement shall be restricted to factual comparison without the use of identifiable regulated product or brand name.

(3) Data illustrations including charts and graphs, tables extracted from reference studies or other sources or reproduced by artwork, presented in an advertisement, shall —

(a) be accurate, complete and clear, with their source specifically identified; and

(b) not be misleading or ambiguous or distort the original intended meaning or interpretation either directly or by implication.

224. **Labelling and advertisement for medical devices including IVDs and related product**

Medical devices including IVDs and related products not for lay users shall be advertised in accordance with the provisions of these Regulations via scientific and medical journals, "Leave Behinds", pamphlets or scientific literature or health newsletters, which shall be used for distribution to healthcare professionals only, provided that such materials have been vetted and approved by the Agency.

225. **Accurate interpretation of research findings for Medical Devices including IVDs and Related products advertisement**

(1) Advertisement materials including scripts, story-boards, artwork, radio scripts and any other advertisement material for medical device and related product shall be written as to accurately interpret valid and representative research findings.

(2) Statistics in an advertisement of medical device and related product shall be written as to reflect only their true validity and significance.

(3) Copy of any reference cited by an applicant in the advertisement of medical device including IVDs and related product shall be provided to the Agency for verification.

226. **Product launch and press release for medical devices including IVDs and related products**

(1) The material approved by the Agency for medical devices including IVDs and related products shall be the same for product launch or press release.

(2) Where there is a change in the material for the product launch or press release, the change shall be approved by the Agency.

Part 7
Good Storage and Distribution Practice for Medical Devices Including IVDS and Related Products

227. **Application**

The regulations establish minimum requirements for good storage and distribution practices in both the public and private sectors with respect to medical devices, including in vitro diagnostics (IVDs) and related products:

(1) a person involved in any aspect of the distribution of medical devices, including IVDs, from the manufacturing site to the point of use; and

(2) governments at all levels, public and private health institutions and storage facilities, manufacturers of medical devices, including IVDs, importers, exporters, distributors, wholesalers, suppliers, retailers, freighters, forwarding agents, and transporters.

228. **Distribution authorization:**

A Distributor, holder of Certificate of Registration, Importer or Wholesaler shall-

(a) be an entity that is authorized by the Pharmacy Council of Nigeria (PCN) to perform extended functions and shall be held accountable for its activities;

(b) obtain a supply of medical devices, including IVDs, only from people or organizations who are themselves in possession of appropriate distribution authorization issued by the PCN; and

(c) Supply medical devices, including IVDs, to distributors, retailers, hospitals or dispensaries, and organizations that have the necessary distribution or sale authorization.
(d) A distributor or transferor cannot receive, store, warehouse, handle, offer, market, display, or transport any medical device, including IVDs, without a valid marketing authorization issued by the Agency for that product.

229. **Inspection:**

The Agency shall inspect the premises and delivery vehicle of distributor, holder of Certificate of Registration, importer or wholesaler.

230. **Organization and Personnel:**

(a) There shall be a clear organizational structure that defines the responsibility, authority, relationship, and qualification of all the personnel working in the organization.
(b) A qualified management representative shall be appointed at each distribution point and have clearly defined authority and responsibility for ensuring that a quality system is implemented and maintained.
(c) Person engaged in the distribution of medical devices, including IVDs and related product shall have the necessary education, training, and experience to perform the assigned function.
(d) There shall be an adequate number of qualified personnel to perform and supervise the distribution of medical devices, including IVDs and related product; and
(e) Personnel engaged in the distribution of medical devices, including IVDs and related product, should wear clothing appropriate for the duties they perform.

231. **Location, design, and construction of building facilities:**

Location where medical devices, including IVDs and related products, are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported shall;
(a) appropriately located and constructed, of suitable size to facilitate cleaning, maintenance, and proper operation as appropriate.
(b) have defined areas of adequate size and fit for purpose.
(c) have storage areas suitable for intended use.
(d) be maintained in clean and orderly condition.

232. **Documentation or Record Keeping:**

(1) Distributors of medical devices, including IVDs and related products, shall establish and maintain records of all transactions relating to the receipt, distribution or disposal of medical devices, including IVDs and related products.
(2) The records referred to in sub-regulation (1) of this regulation shall contain information, including-
  (a) the source of the medical devices, including IVDs and related products, the name and principal address of all distributors or transferors, or the address of the location from which the medical devices, including IVDs, were shipped.
  (b) The identity and quantity of the medical devices including IVDs and related products, received and distributed, or disposed off.
  (c) the date and time of receipt and distribution or disposal of the medical devices including IVDs and related products; and
  (d) the name, address and professional license number of the business, licensed by the regulatory authority as appropriate, or the licensed practitioner.
  (e) any other information as may be required by the Agency.
(3) Inventories, records, and logs shall be made available for inspection and copying by the Agency and be retained for a duration of 5 years.
(4) Records shall-

(a) be kept at the inspection site or retrievable from an electronic means and made readily available at the time of inspection; or
(b) be made available for inspection within 48 hours of a request by the Agency, if kept at a central location and not electronically retrievable at the inspection site.

(5) The distributor shall obtain written authorization from the Agency to store the required records outside the inspection site and provide the Agency, in writing, with the name, address, and all the necessary contact information of the custodian.

(6) All facilities shall have adequate backup systems to protect against inadvertent loss or deliberate destruction of data.

(7) The facility shall provide and maintain appropriate inventory controls to detect and document any theft, counterfeiting, or diversion of medical devices, including IVDs and related products.

233. **Written policies and procedures:**

(1) A distributor shall-
(a) establish, maintain, and adhere to policies and procedures to be followed for the receipt of complaints.
(b) provide security, storage, inventory, and distribution of medical devices, including IVDs and related products,
(c) establish policy and procedure for identifying, recording, and reporting losses or thefts at the facility; and
(d) ensure protection against crisis that may constitute a security threat to the operation of the facility.

(2) There shall be written policies and procedures;
(a) for managing and correcting all errors or inaccuracies in inventories.
(b) to ensure that expired medical device including IVDs and related product are segregated from other stock and be returned to the source of supply or otherwise destroyed and be documented.
(c) that adopts the practice of First Expiry First Out (FEFO) for the distribution of medical device, including IVDs.

234. **Storage condition:**

(1) Medical devices including IVDs and related product shall be stored at appropriate temperature and conditions as specified on product labeling of the Instruction for Use (IFU).

(2) Where there is no specific storage requirement for a medical device including IVDs and related product, it may be held at a controlled room temperature, as defined in the current edition of a recognized compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(3) Appropriate conditions of temperature, humidity, and light recording equipment, or logs shall be utilized to document proper storage of medical devices, including IVDs and related product, and the record shall be kept as prescribed in regulation 84 of these Regulations.

235. **Examination of shipments:**

(1) A shipment shall be visually examined to determine the identity, the state of damage, prohibition, or its status, whether suspected of being contaminated, counterfeited, or otherwise unfit for distribution.

(2) Appropriate measures shall be put in place to check that shipments have not been held under improper transit conditions.

(3) A distributor shall review records for accuracy, completeness, and the integrity of the medical device, including IVDs, considering the total facts and circumstances surrounding the transactions and the distributors involved.

236. **Returned, damaged, and expired medical devices, including IVDs:**

(1) A distributor shall maintain and follow a written procedure to ensure the proper handling and disposal of returned goods.

(2) When conditions under which a medical device including IVDs and related product has been returned, cast doubt on the safety, identity, quality, purity or performance of the medical device including IVDs and related product, the product shall be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the medical device including IVDs meets appropriate standards of safety, identity, quality, purity or performance.

(3) In investigating the conditions which cast doubt on the safety, identity, strength, quality, or purity of the medical device including IVDs and related product, the distributor shall consider, among other things, the conditions under which the product has been held, stored, or shipped before or during its return and the condition of the product and its container, carton, or labeling, as a result of storage or shipping.

237. **Vehicles and equipment:**

(1) Vehicles and equipment used in the distribution of medical devices, including IVDs and related product, shall be suitable for the intended use and appropriately equipped.

(2) Monitoring equipment shall be qualified or calibrated as required.

238. **Shipment containers and container labelling:**

(1) A medical device including IVDs and related product shall be stored and distributed in shipment containers, which do not have an adverse effect on the quality and safety of the products and which offer adequate protection from external influences, including contamination.

(2) Only internationally or nationally accepted abbreviations, names, or codes shall be used in the labelling of containers.

Part 8
Vigilance Practice Regulations

239. **The Role of the Manufacturer:**

(1) The manufacturer or holder of certificate of registration shall notify the Agency about incidents and field safety corrective actions.

(2) The Manufacturer or holder of certificate of registration has the responsibility for investigating incidents and for taking any corrective actions necessary.

(3) The manufacturer, holder of certificate shall ensure that the provisions of these Regulations are made known to the distributor.

(4) The manufacturer or holder of certificate of registration shall ensure that the distributor is kept informed of incident reports as appropriate.

(5) Where an incident occurs as a consequence of the combined use of two or more separate medical devices including IVDs and related products or accessories made by different manufacturers, each manufacturer shall submit a report to the Agency.

(6) When placing on the market of a particular model of medical device including IVDs and related products ceases, the manufacturer's vigilance reporting obligations under the medical device directives remain.

(7) Where the vigilance and other post market surveillance obligations are being transferred to another legal entity it is important that post market surveillance activities continue and that the Agency notified.

240. **Vigilance System for Manufacturers or Authorized Representatives/Certificate of Registration Holders:**

(1) Without prejudice to regulation 91 of these Regulations, the manufacturer, holder of certificate of registration Holder, or distributor shall,

(a) operate a vigilance system for the fulfilment of vigilance activities and regulatory responsibilities;

(b) have the responsibility to ensure that the vigilance system is in place, is adequately resourced, the effectiveness continually improved, and that roles, responsibilities, and authorities are defined, communicated, and implemented; and

(c) have permanently and continuously at its disposal an appropriately Person Responsible for Regulatory Compliance (PRRC) responsible for its vigilance system, who shall reside in Nigeria;

(d) have sufficient number of competent and appropriately qualified personnel to perform vigilance activities.

(2) The vigilance system shall cover organisational structure, responsibilities, procedures, processes, and resources as well as appropriate resource management, compliance management and record management.

(3) Where the Manufacturer, holder of Certificate of Registration or distributor of medical device including IVDs and related products, subcontracts any vigilance activities to another organization, the arrangement shall be subject to a written contract and the Manufacturer, holder of Certificate of Registration or distributor retain the responsibility for ensuring that an effective quality system is applied in relation to those activities.

241. **Good Vigilance Practice for Manufacturer**

Manufacturer or holder of Certificate of Registration shall comply with the following Good Vigilance Practice requirements-

(a) establish and implement a quality system;

(b) continuously monitor vigilance data;

(c) perform scientific evaluation of products risks;

(d) submission of accurate and verifiable data on serious and non-serious adverse event or incidents, FSCAs and the monitoring of trends of expected side effects to the Agency;

(e) updating of product information and communication relevant safety information to healthcare professionals and patients;

(f) assign task and responsibility to persons involved in the implementation of the vigilance system.

(g) Continuously monitor product performance and provision of new safety information to the Agency, healthcare professionals, patients, and the public in relation to the safety of medical devices including IVDs and related products;

(h) Manufacturer and holder of certificate of registration shall conduct trend analysis of non-serious incidents and report any statistically significant increase in their frequency or severity that has a significant impact on the benefit-risk profile of the device that may result in actual or potential unacceptable risks. Appropriate baselines and thresholds must be established by the manufacturer to allow systematic trending.

(i) Co-ordination and maintenance of continuous quality improvement by all parties implementing the vigilance system;

(j) Allocation of resources and tasks to support proactive, risk-proportionate, continuous and integrated conduct of vigilance;

(k) Seek evidence on the risk-benefit balance of medical devices including IVDs and related products in relevant aspects, which could impact on the risk-benefit balance and the use of these products, and provide this evidence as a guide into decision-making; and

(l) any other requirements as may be prescribed by the Agency.

242. **Good Vigilance Practice for** Medical Devices Including IVDS And Related Products **User Facilities**

Medical devices including IVDS and related products user facilities shall -

(a) establish and implement quality system;
(b) continuously monitor vigilance data;
(c) perform scientific evaluation of product risk;
(d) submission of accurate and verifiable data on serious and non-serious adverse event or incidents to the Manufacturer, holder of Certificate of Registration or distributor and the Agency.
(e) assign task and responsibility to person involved in the implementation of the vigilance system.

243. **Training of Personnel for Vigilance**

(1) Manufacturer, holder of Certificate of Registration, distributor or device user facilities shall ensure there is initial and continuous training of an employee in the operations that the employee performs and in good vigilance practices.
(2) Training effectiveness shall be verified, and records of training shall be kept.

244. **Facilities and Equipment for Vigilance**

Facilities and equipment for the conduct of vigilance shall be subject to checks, qualification, and validation as appropriate, to prove their suitability for the intended purpose.

245. **Record Management and Documentation**

(1) **General Provisions**

The Manufacturer shall;

(a) maintain and control comprehensive, up-to-date, appropriately authorized, retrievable, and traceable written instructions, records and reports of all activities relating to vigilance operations.
(b) ensure that the documentation system is traceable, retrievable, secure and access restricted only to authorized personnel. Management of records of adverse events or incidents shall ensure that the right to privacy is fully and effectively guaranteed.

(2) **Specific Provisions**

Notwithstanding the provisions of regulation 97 (1) to this regulation, the manufacturer, holder Certificate of Registration or distributor of a medical device including IVDS and related products shall each maintain records of the following:

(a) reported problems relating to the performance characteristics or safety of the device, including any consumer complaints, received by the manufacturer, importer or distributor after the device was first sold in Nigeria; and
(b) actions taken by the manufacturer holder Certificate of Registration or distributor in response to the problems referred to in regulation 97 (2) (a).

246. **Vigilance System File**

Manufacturers or holder Certificate of Registration or distributor shall -

(a) maintain Vigilance System File (VSF); and
(b) make a copy of the VSF available upon request by the Agency.

247. **Vigilance inspection and audit**

(1) The Agency shall at any time it deems fit conduct a vigilance inspection to determine if the Manufacturer, Certificate of Registration Holder or distributor is operating in compliance with the provisions of these Regulations and other requirements of the Agency.

(2) Manufacturer, Certificate of Registration Holder or distributor shall -

(a) permit the Agency to access, copy, and verify any records or reports made with regard to vigilance activities;

(b) carry out a self-audit and the records shall be kept.

(c) develop and implement appropriate corrective and preventive actions based on audit findings.

248. **Incidents Reporting**

(1) Manufacturers, holder Certification of Registration, distributor or device user facility shall establish a system that ensures the prompt identification, timely investigation, reporting, documentation, and filing of death, serious injury, and malfunction related to medical devices including IVDs and related products.

(2) Only incidents that occur in Nigeria are shall be reported to the Agency.

(3) Incidents for Class A and B medical devices that occur outside of Nigeria for devices supplied in Nigeria may not need to be reported to the Agency. However, records of these events should be available if requested.

(4) Also, any remedial action that arises outside of Nigeria for Class C and D medical devices supplied in Nigeria shall be reported.

(5) The manufacturer holder Certificate of Registration, distributor a medical device shall each make a preliminary and a final report to Agency concerning any incident that comes to their attention occurring in Nigeria that involves the device if

(a) the device is sold in Nigeria; and

(b) the incident

(i) is related to a failure of the device or a deterioration in its effectiveness or any inadequacy in its labelling or in its directions for use, and

(ii) has led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so were the incident to recur.

(6) Subject to regulation 100 (2) of this regulation, the manufacturer holder Certificate of Registration, distributor a Class C or Class D medical device including IVDS and related products shall each make a preliminary and a final report to the Agency concerning any incident that comes to their attention occurring outside Nigeria that involves the device if the conditions in regulation 100 (5)(a) and (b) of this regulation are met.

(7) The requirement to report an incident that occurs outside Nigeria does not apply unless the manufacturer has indicated, to a regulatory agency of the country in which the incident occurred, the manufacturer's intention to take corrective action, or unless the regulatory agency has required the manufacturer to take corrective action.

249. **Preliminary Report**

(1) A preliminary report shall be submitted to the Agency:

(a) in respect of an incident that occurs in Nigeria

(i) within 2 calendar days after the manufacturer or importer of a medical device including IVDS and related products becomes aware of an incident, if the incident has led to the death or a serious deterioration in the state of health of a patient, user or other person, or

(ii) within 10 days after the manufacturer or importer of a medical device including IVDS and related products becomes aware of an incident, if the incident has not led to the death or a serious deterioration in the state of health of a patient, user or other person, but could do so were it to recur; and

(iii) if the information relates to an event or other occurrence that represents a serious threat to public health within 48 hours after the person becomes aware of the event or occurrence and

(iv) if the information relates to an event or other occurrence a recurrence of which might lead to the death, or a serious deterioration in the state of health, of a patient, a user of the medical device

including IVDS and related products, or another person within 15 days after the person becomes aware of the event or occurrence

(b) in respect of an incident that occurs outside Nigeria, as soon as possible after the manufacturer has indicated, to the regulatory Agency referred to in Regulation 100 (5) (2), the manufacturer's intention to take corrective action, or after the regulatory Agency has required the manufacturer to take corrective action.

(2) The preliminary report shall contain the following information:

(a) the name of the medical device including IVDS and related products and its identifier, including the identifier of any medical device including IVDS and related products that is part of a system, test kit, medical device group, medical device family or medical device group family;

(b) if the report is made by

(i) the manufacturer, the name and address of that manufacturer and of any known importer, and the name, designation and telephone and email address of a representative of the manufacturer to contact for any information concerning the incident, or

(ii) the importer of the device, the name and address of the importer and of the manufacturer, and the name, designation, telephone number and email address of a representative of the importer to contact for any information concerning the incident;

(c) the date on which the incident came to the attention of the manufacturer or importer;

(d) the details known in respect of the incident, including the date on which the incident occurred and the consequences for the patient, user or other person;

(e) the name, address and telephone number, if known, of the person who reported the incident to the manufacturer or importer;

(f) the identity of any other medical device, including IVDs and related products or accessory involved in the incident, if known;

(g) the manufacturer's or importer's preliminary comments with respect to the incident;

(h) the course of action, including an investigation, that the manufacturer or importer proposes to follow in respect of the incident and a timetable for carrying out any proposed action and for submitting a final report; and

(i) a statement indicating whether a previous report has been made to the Agency with respect to the device and, if so, the date of the report.

250. **Final Report**

(1) After the preliminary report is made in accordance with Regulation 101, a final report shall be submitted to the Agency in accordance with the timetable established under Regulation 101(2)(h).

(2) The final report shall contain the following information:

(a) a description of the incident, including the number of persons who have experienced a serious deterioration in the state of their health or who have died;

(b) a detailed explanation of the cause of the incident and a justification for the actions taken in respect of the incident; and

(c) any actions taken as a result of the investigation referred to in paragraph 14(2)(h), which may include

(i) increased post-market surveillance of the device,

(ii) corrective and preventive action regarding the design and manufacture of the device, and

(iii) recall of the device.

251. **Delegation of Reporting responsibilities**

(1) Notwithstanding the provisions of regulation Despite subsection 100 (5), the manufacturer of a medical device may permit the importer of the device to prepare and submit the preliminary and final reports on the manufacturer's behalf if the information that the manufacturer and the importer must include is identical.

(2) The manufacturer shall notify the Agency in writing if the manufacturer has permitted the importer to prepare and submit the reports on the manufacturer's behalf.

252. **Trend reporting**

(1) Manufacturers shall report, by means specified or prescribed by the Agency any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side- effects that could have a significant impact on the benefit-risk analysis and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits.

(2) The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents in respect of the device, or category or group of devices, in question during a specific period as specified in the technical documentation and product information.

(3) The manufacturer shall specify how to manage the incidents and the methodology used for determining any statistically significant increase in the frequency or severity of such incidents, as well as the observation period.

(4) The Agency may conduct its own assessments on the trend reports referred to in regulation 104 (1) to this regulation and require the manufacturer to adopt appropriate measures in accordance with this Regulation in order to ensure the protection of public health and patient safety.

253. **Analysis of serious incidents and Field Safety Corrective Actions (FSCA)**

(1) Following the reporting of a serious incident pursuant to Regulation 100 (2), the manufacturer shall, without delay, perform the necessary investigations in relation to the serious incident and the medical devices including IVD and related product concerned.

(2) The manufacturer shall not perform any investigation which involves altering the medical devices including IVD and related product or a sample of the relevant batch in a way which may affect any subsequent evaluation of the causes of the incident, without informing the Agency.

(3) The Agency shall take the necessary steps to ensure that information about a serious incident that has occurred within Nigeria, or a field safety corrective action that has been or is to be undertaken within Nigeria, and that is brought to the knowledge of the Agency in accordance with Regulations 101 and 101 is evaluated centrally at national level, if possible together with the manufacturer.

(4) The Agency shall evaluate the risks arising from the reported serious incident and evaluate any related field safety corrective actions.

(5) The manufacturer shall provide all documents necessary for risk assessment upon request from the Agency.

(6) The Agency may monitor the manufacturer's investigation of a serious incident and may intervene or initiate an independent investigation.

(7) The manufacturer shall provide a final report to the Agency setting out its findings from the investigation in a manner prescribed by Agency.

(8) The Agency may notify the general public and other relevant organizations of the outcome of the evaluation conducted.

(9) The manufacturer shall ensure that information about the field safety corrective action taken is brought without delay to the attention of users of the device in question by means of a field safety notice. Except in cases when it is urgent, the content of the draft field safety notice shall be submitted to the Agency.

(10) The field safety notice shall information on Unique Device Identifier (UDI) of relevant medical devices including IVDs and related products and manufacturer details.

(11) The field safety notice shall explain, in a clear manner, without understating the level of risk, the reasons for the field safety corrective action with reference to the device malfunction and associated risks for patients, users or other persons, and shall clearly indicate all the actions to be taken by users.

254. **Analysis of Vigilance Data**

(1) The Agency shall
   (a) establish a national database for collecting adverse events or incidents occurring in Nigeria.
   (b) put in place systems and processes to actively monitor the data available in the national database in order to identify trends, patterns or signals in the data that may reveal new risks or safety concerns.

(2) Where a previously unknown risk is identified or the frequency of an anticipated risk significantly and adversely changes the benefit-risk determination, the Agency shall inform the manufacturer, or where applicable the authorized representative, which shall then take the necessary corrective actions.

255. **Risk Management Responsibilities of the Manufacturer**

A medical device shall be designed and manufactured to be safe, and the manufacturer, take reasonable measures to;

(1) identify the risks inherent in the device;
(2) if the risks can be eliminated, eliminate them;
(3) if the risks cannot be eliminated,
   (a) reduce the risks to the extent possible,
   (b) provide for protection appropriate to those risks, including the provision of alarms,
   (c) provide, with the device, information relative to the risks that remain; and
   (d) minimize the hazard from potential failures during the projected useful life of the device.

256. **Risk Management System**

Pursuant to Regulation 107 to these Regulations, The Manufacturer or holder of Certificate of Registration shall-

(1) establish vigilance plan for collection of data relevant to the safety profile of medical devices and in vitro diagnostics medical devices as well as identifying the risks from continuous evaluation of safety signals from within and outside Nigeria;
(2) monitor the outcome of risk minimization measures which are contained in the risk management plan and take appropriate measures as necessary;
(3) submit the Risk Management Plan (RMP) in a format as approved by the Agency for conditions such as -
   (a) new submissions on medical devices and in vitro diagnostics that incorporate new technology,
   (b) any medical device including IVDs and related product that is coming back to the market that was previously withdrawn due to a serious safety issue,
   (c) medical devices and in vitro medical devices with a significant modification/ change in design and purpose,
   (d) medical devices including IVDs and related products under the Public Health Programmes,
   (e) medical device including IVDs and related products for which a serious safety issue has been identified,
   (f) a previously acceptable RMP which has undergone significant changes,

(g) medical devices including IVDs and related products new to a class for which a serious or potentially serious safety issue is identified,
(h) safety issues associated with a generic devices and in vitro diagnostics,
(i) part of an ongoing review or other situations to support informed regulatory decision making about the device and in vitro diagnostics, and
(j) for a marketed medical device including IVDs and related product the Certificate of Registration Holder identifies that there has been a significant change to what is known about the benefits, harms, or uncertainties associated with the product, an RMP or an update to the Safety Management Plan (SMP) shall be submitted to the Agency.
(k) The provisions of regulations 108 (1) (c) of this regulation applies to cases where no previous RMP exists or when an update is needed to a previously acceptable RMP.

257. **Serious Risk of Injury to Human Health**

(1) This regulation applies to a holder of one of the following:
(a) a medical device including IVDs and related product manufacturing licence; and
(b) a licence to import Class B, C or D medical devices.
(2) The holder of a Certificate of Registration or import permit issued in respect of a medical device shall submit to the Agency information in respect of any serious risk of injury to human health that the holder receives or becomes aware of and that is relevant to the safety of the device, regarding
(a) risks that have been communicated by any regulatory agency or by any person who is authorized to manufacture or sell a medical device within the jurisdiction of such a regulatory agency, and the manner of the communication;
(b) changes that have been made to the labelling of any medical device and that have been communicated to or requested by any regulatory agency and
(c) recalls, reassessments and suspensions or revocations of authorizations, including licences, in respect of any medical device, that have taken place within the jurisdiction of any regulatory agency.
(3) The information shall be submitted to the Agency within 72 hours after the holder of a Certificate of Registration or import permit receives or becomes aware of it, whichever occurs first.

258. **Periodic Safety Update Report**

(1) The holder of a medical device licence shall prepare
(a) in the case of a Class B medical device, on a biennial basis, a periodic safety update report of the information referred to in subsection (2) that the holder received or became aware of during the previous 24 months; and
(b) in the case of a Class C or D medical device, on an annual basis, a periodic safety update report of the information referred to in subsection (2) that the holder received or became aware of during the previous 12 months.
(c) The reporting period is not tied to the anniversary date of a medical device licence or authorization. Certificate of Authorization Holders may choose the reporting period for the report as long as the report falls within the required reporting timeframe.
(d) Holders of Certificates of registration are required to prepare periodic safety update reports for as long as their device is licensed or authorized in Nigeria.
(2) The information to be covered by the periodic safety update report is in respect of;
(a) adverse effects;

(b) problems relating to the performance characteristics or safety of the device, including any consumer complaints, received by the manufacturer, importer or distributor after the device was first sold in Nigeria; and
(c) incidents referred to in sub-regulation 101(1); and
(d) serious risks of injury to human health that are relevant to the safety of the medical device and are referred to in regulation 109 (2) of these Regulations.

(3) The periodic safety report shall contain a concise critical analysis of the information referred to in regulation (2) of this regulation.

(4) In preparing the periodic safety report, the holder shall determine, on the basis of the critical analysis, whether what is known about the benefits and risks associated with the medical device has changed in any of the following ways:
(a) the potential benefits for patients through the use of the device may be less;
(b) in respect of each of the risks,
(i) the harm associated with the risk is more likely to occur, or
(ii) if the harm associated with the risk occurs, the consequences for the health or safety of patients, users or other persons could be more serious; and
(c) a new risk has been identified.

(5) The holder shall include the conclusions they reach under sub-regulation (4) in the periodic safety report.

(6) If, in preparing the periodic safety update report, the holder concludes that what is known about the benefits and risks associated with the medical device has changed in any of the ways referred to in sub-regulations (4)(a) to (c), they shall notify the Agency, in writing, within 72 hours after having reached the conclusion, unless that has already been done.

(7) The holder of a medical device licence shall maintain records of the periodic safety update reports and the information on the basis of which those reports were prepared.

(8) The Certificate of Registration holder shall submit to the Agency Periodic Safety Update Reports from within and outside Nigeria based on all available data, including Identification and evaluation of changes of the benefit-risk profile, Field Safety Corrective Actions, clinical trials data in unauthorized off label use of the medical device.

(9) The PSUR shall be as specified by the Agency.

(10) PSUR for novel technology or model device in Nigeria shall be submitted within the first (1) year of registration, at least every six (6) months for the first two (2) years, annually for the three (3) following years, and every five (5) years at the time of renewal of license.

(11) Where a novel technology or model device is already being marketed elsewhere, existing PSUR shall be submitted to the Agency not later than thirty (30) days after submission of documents requesting for registration in Nigeria.

(12) Where a device is Listed, the holder of Certificate of Registration shall submit a PSUR every six (6) months for the two (2) year Listing period (Provisional Registration).

259. **Incident Reporting by Device User Facility**

(1) The following prescribed information about a medical device incident that is in Device User Facility control shall be provided to the Agency in writing within 30 days after the day on which the medical device incident is first documented within the facility:
(a) the name of the facility and the contact information of a representative of that facility;
(b) the name or identifier of the medical device;
(c) the date on which the medical device incident was first documented;
(d) the name of the manufacturer of the medical device;

(e) a description of the medical device incident;
(f) the lot number of the device or its serial number;
(g) any contributing factors to the medical device including IVDs and related product incident, including any medical condition of the patient that directly relates to the medical device including IVDs and related incident; and
(h) the effect of the medical device incident on the patient's health.

(2) A Device User Facility is exempt reporting of information referred to in subsection (2) if;
(a) the Device User Facility does not have in its control all of the information referred to in paragraphs (2)(b) and (e) in respect of the medical device incident; or
(b) the medical device including IVDs and related product incident involves only a medical device that is the subject of an authorization issued under special considerations such as investigational testing.

260. **Access to Medical Devices including IVDs and related product incident involved in Adverse Events**

(1) The manufacturer, the holder of Certificate of Registration or distributor, shall where possible consult with the medical device including IVDs and related product incident user about the event before a report is submitted to the Agency.
(2) The medical device including IVDs and related product user may grant the manufacturer, holder of Certificate of Registration or distributor access to medical device including IVDs and related product involved in the event to determine if the event should be reported to the Regulatory Authority.
(3) The access specified in regulation (2) of this regulation shall be at the discretion of the device user who may be advised to assist the manufacturer, holder of Certificate of Registration or distributor to determine the root cause of the incident.
(4) If the manufacturer, holder of Certificate of Registration or distributor has access to the medical device including IVDs and related product incident, and the initial assessment or cleaning or decontamination process will involve altering the device in a way that may affect subsequent analysis, the holder of Certificate of Registration or manufacturer or distributor shall inform the Agency before proceeding.
(5) The Agency shall advise the release of the medical device to the manufacturer, holder of Certificate of Registration or distributor so that they can complete their analysis, which may require the assistance of the primary manufacturer.

261. **Adverse Events Reporting**

The Holder of Certificate of Registration shall -
(1) take appropriate measures to collect and collate all reports of suspected adverse events associated with its own products originating from unsolicited or solicited sources;
(2) ensure the collection and recording of all reports of suspected adverse events or incidents brought to its attention by health care professionals, user or occurring in the context of post-approval study;
(3) not refuse to consider reports of suspected adverse events received from patients and healthcare professionals.
(4) establish procedures in order to obtain accurate and verifiable data for the scientific evaluation of suspected adverse events reports of its own products;
(5) maintain detailed records of all suspected adverse events relating to its products occurring within and outside Nigeria;
(6) maintain records of all suspected serious adverse events which have occurred

(a) within Nigeria and report same to the Agency not later than 48 hours following the receipt of information;
(b) outside Nigeria and report same to the Agency not later than 15 calendar days following the receipt of information;
(c) within Nigeria and report same to the Agency not later than 90 calendar days following the receipt of information while non-serious adverse events occurring outside Nigeria shall be contained or reported within the Periodic Safety Update Report;

(7) report to the Agency any action relating to their product safety that has been taken by a regulatory authority outside Nigeria, including the basis for such action not later than 2 working days of first knowledge; and
(8) release all necessary information including confidential information to the Agency on request.

262. **Safety communication**

(1) The Certificate of Registration Holder shall –
(a) obtain approval from the Agency on any information intended for the health practitioner and public on Vigilance concerns in relation to the safety, quality, and rational use of a medical devices or in vitro diagnostic device; and
(b) ensure that information to the public is presented objectively and is not misleading.
(2) Field Safety Corrective Action shall be notified to the customers via a FIELD SAFETY NOTICE.

263. **Field Safety Corrective Action**

The Manufacturer shall report to the Agency any technical or medical reason leading to a systematic recall of devices of the same type by the Manufacturer. These reasons may be:
(a) any malfunction or deterioration in the characteristics or performance of a device,
(b) any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health.

264. **Post Authorization Safety Study**

(1) The Manufacturer or holder of Certificate of Registration shall -
(a) conduct Post Authorization Safety Study in pursuance to obligations by the Agency for the purpose of identifying, characterising, or quantifying a safety hazard, confirming the safety profile of the medical device including IVDs and related product or measuring the effectiveness of risk management measures;
(b) submit the Post Authorization Safety Study (PASS) protocol to the Agency for approval before conducting the study in Nigeria;
(c) submit any substantial amendments to the protocol to the Agency for approval before implementation, or after a PASS has commenced;
(d) monitor the data generated from a PASS and consider its implications for the benefit-risk balance of the medical device including IVDs and related product concerned and any new information which might influence the evaluation of the benefit-risk balance of the medicinal product shall be immediately communicated to the Agency;
(e) submit the final report of the PASS within 6 months of completion of data collection; and
(f) not promote the use of the medical device or in vitro diagnostic device during PASS.
(2) All Adverse Events observed during Post Approval Study shall be reported to Agency.

265. **Signal detection, Identification and management**

Certificate of Registration holder shall have mechanisms in place for signal detection and investigation

including the following-

(1) have a system in place for detecting and investigating safety issues or signals that may arise at any stage in the life cycle of a medical devices including IVDs and related products, including the clinical development, manufacturing or in the post-market setting in a timely manner;
(2) have written procedures in place that adequately describes the way in which signal detection be performed;
(3) roles and responsibilities of each person involved in the signal detection process shall be clearly identified and documented;
(4) the source of the information, the analysis and the method used for signal detection be documented;
(5) actions taken based on the outcome generated from the signal detection activities be documented adequately;
(6) data regarding changes of what is known about the risks and benefits of the medical device including IVDs and related product ug shall be sent to the Agency and be documented; and
(7) safety monitoring activities include a review of cumulative cases in order to allow for a comprehensive review of potential safety issues.

266. **Reporting of counterfeit, unregistered, substandard, and falsified medical devices**

Manufacturer or holder of Certificate of Registration shall report to the Agency any medical device, IVDs and related product or in vitro diagnostics medical device suspected to be counterfeit, unregistered, substandard or falsified.

267. **Clinical Trials involving Medical Devices**

Adverse events or incidents observed during clinical trials conducted in Nigeria must be reported to the Agency in accordance with established procedures and timelines.

268. **Investigational Testing of Medical Devices:**

(1) Only holders of certificate of Registration and distributors may apply for investigational testing of medical devices.
(2) Adverse events or incidents observed during investigational testing of any medical device must be reported to the Agency in line with the reporting procedures and timelines.

269. **Post Market Clinical Follow-up (PMCF)**

(1) Manufacturer shall conduct Post Market Clinical Follow up which should run on a continuous basis throughout the life cycle of all medical devices marketed in Nigeria regardless of risk classification.
(2) Findings from the PMCF shall be incorporated into the PSUR
(3) The design of PMCF studies and surveys should be documented in a PMCF Plan and results must be collated in a PMCF Report that forms an important input to the Clinical Evaluation Report (CER) for the device.
(4) The PMCF Plan and PMCF Report shall be submitted along with the marketing authorization application
(5) The PMCF Report shall be in the format and content prescribed by the Agency.

270. **Vigilance system**

(1) The National Vigilance Centre shall:
  (a) be domiciled in the Agency and shall co-ordinate all vigilance activities in Nigeria
  (b) maintain all vigilance information and database
  (c) carry out any other activity as the Agency may from time to time deem fit.

(2) The National Drug Safety Advisory Committee (NDSAC) of the Agency shall assess safety issues on medical devices, IVDs and related products.

271. **Non-compliance with Vigilance requirements**

The Agency may as part of control measures place on hold, recall, destroy, seal manufacturing line or facility, withdraw registration certificate of products not in compliance with this Regulation.

Part 9
Recall, Handling and Disposal of Medical Devices including IVDs and Related Products

272. **Reasons for recall**

The reasons for the recall of medical devices including IVDs and related products shall include-

(a) design deficiencies;
(b) component defect or failures;
(c) labelling and packaging deficiencies
(d) manufacturing defect;
(e) software errors;
(f) improper shipping installation or servicing;
(g) inappropriate storage, transport
(h) unfit medical devices including IVDs and related products
(i) any other reason as may be determined by the Agency.

273. **Classification of recall**

(1) Recall shall be classified depending on the nature of the health risk or adverse events as:
   (a) Class I is for defective, dangerous or potentially life-threatening medical devices that predictably or probably could result into serious health risk or adverse events or death;
   (b) Class II is for medical devices that possibly could cause temporary or medically reversible adverse health problem or mistreatment;
   (c) Class III is for medical devices that are defective and are unlikely to cause any adverse health reaction or which do not comply with the requirements of these regulations.

(2) The maximum time for recalling class I, II and III shall be as prescribed by the Agency.

(3) Notwithstanding the provisions of regulation (2) of this regulation, the Agency reserves the right to determine the maximum time for recall depending on the urgency and health risk involved.

(4) The Agency shall assess the performance of the recall and take necessary action as it may so determine.

274. **Initiation of voluntary recall**

(1) A holder of certificate of registration shall initiate the voluntary recall of medical devices including IVDs and related products if such medical devices including IVDs and related product has caused or is about to cause injury to the health or safety of patients, users or other person.

(2) The holder of certificate of registration shall notify the Agency in writing stating the reason for of the voluntary recall of the product and shall include-
   (a) product name;
   (b) batch number;
   (c) manufacturing date;
   (d) expiry date;
   (e) identified defect;
   (f) recall protocol; and
   (g) other information as may be determined by the Agency to make informed decision.

(3) The holder of certificate of registration shall notify all the distributors of the product recall, reason for recall and the recall structures.
(4) The Agency shall participate in the recall exercise.
(5) A certificate of registration holder shall bear the cost of the voluntary recall of medical devices including IVDs and related products

275. **Initiation of non-voluntary recall.**

(1) The Agency shall initiate the non-voluntary recall of medical devices including IVDs and related products at any time it is of the opinion that medical devices including IVDs and related products may cause injury to the health or safety of patients, users or other persons.
(2) The Agency upon the establishment of the reason for recall of medical devices including IVDs and related products shall notify the holder of certificate of registration.
(3) The notification referred to in regulation (2) of this regulation shall include the following details of the product
   (a) name of the medical devices including IVDs and related products and its identification, including identification of any medical devices including IVDs and related products that is part of a system, test kit, medical devices group, medical devices family or medical devices group family;
   (b) name and address of the holder of certificate of registration, and the name and address of the premises where the medical devices including IVDs and related products was manufactured;
   (c) reason for the recall,
   (d) nature of the defective or possible defective and the date on and circumstances under which the defective or possible defective was discovered;
   (e) number of affected units of the medical devices including IVDs and related products devices;
   (f) period during which the affected units of the medical devices including IVDs and related products were distributed in Nigeria by the holder of certificate of registration
   (g) name of each person to whom the affected medical devices including IVDs and related products was sold to by the holder of certificate of registration and the number of units of the device sold to each person;
   (h) copy of any communication issued with respect to the recall;
   (i) proposed strategy for conducting the recall, including the date for beginning the recall, information as to how and when the Authority will be informed of the progress of the recall and the proposed date for its completion; and
   (j) any other information that may be prescribed by the Agency;
(4) Where there is no identifiable person responsible for the presence of the medical devices including IVDs and related products in Nigeria, the Agency shall request any outlet and the person in possession of the medical devices including IVDs and related products to report to the nearest office of the Agency.
(5) The holder of a certificate of registration shall bear the cost of the recall of medical devices including IVDs and related products.

276. **Recall strategy**

(1) The holder of a certificate of registration shall prepare and obtain approval for the recall strategy.
(2) The recall strategy shall include-
   (a) the duration for the recall;
   (b) the key personnel appointed to coordinate the recall and provide feedback to the Agency at intervals until the completion of the exercise; and
   (c) any other strategy as the Agency may determine.

277. **Notification and public announcement.**

Upon the Agency's approval for the recall of the medical devices including IVDs and related products, the Agency shall publicize it at the expense of the holder of a certificate of registration.

278. **Submission of report after recall**

(1) The holder of certificate of registration of medical devices including IVDs and related products shall submit detailed documented evidence at the completion of a recall process.

(2) The Agency shall assess the performance of the recall, and the necessary actions as may be determined by the Agency.

279. **Storage**

(1) The recalled medical devices, including IVDs and related products shall be transferred to the Agency's storage facility and inventories shall be taken.

(2) The product shall be appropriately stacked and stored until disposal exercise is scheduled.

(3) The Agency shall determine the action to be taken on the recalled product to reduce the risk of death or serious deterioration in the state of health associated with the use of medical devices including IVDs and related products including;

(a) replacement or destruction of the medical devices including IVDs and related products

(b) modification of the medical devices including IVDs and related products

(c) retrofitting the medical devices including IVDs and related products in accordance with any modification to it or any change to its design.

(d) making of any permanent or temporary change to the labelling or instructions for use of the medical devices including IVDs and related products.

(e) any upgrade to any software used with the medical devices including IVDs and related products carried out by remote access.

280. **Decision to initiate disposal of unfit medical devices including IVDs and related products**

A person shall not dispose of any unfit medical devices unless as approved by the Agency.

281. **Request for disposal of unfit medical devices**

(1) The decision to initiate disposal of unfit medical devices shall be made by the Agency, Certificate of Registration Holder or Authorized person of facility or premises.

(2) The Agency, upon receipt of request for disposal, shall verify the information submitted in relation to the consignment to be disposed.

(3) Verification referred to in regulation (2) to this regulation shall be made in the form as may be prescribed by the Agency

(4) Upon completion of the verification process, the Agency shall inform the applicant of the proposed mode of destruction.

(5) The holder of a certificate of registration shall bear the cost of the disposal of medical devices including IVDs and related products**.**

282. **Planning for disposal of unfit medical devices including IVDs and related products**

For the purpose of effective disposal of the medical devices including IVDs and related products, the following shall be identified-

(a) quantity and presentation of the medical devices including IVDs and related products.

(b) the respective disposal methods for the medical devices including IVDs and related products

(c) the required human resources;

(d) the location, space, equipment, materials and logistics for the volume of medical devices including IVDs and related products; and

(e) the estimated cost of the disposal exercise.

283. **Health and safety.**

The Agency shall provide appropriate safety gears and sanitary provision on the site.

284. **Transfer of recalled unfit medical devices including IVDs and related products to disposal site.**

The recalled medical devices including IVDs and related products shall be transported to the disposal site in a secured manner and in the company of regulatory officer and security personnel.

285. **Sorting at the disposal site.**

(1) The recalled medical devices including IVDs and related products shall be sorted at the disposal site according to the identified method of disposal pursuant to regulation 134 (b) of these Regulations.

(2) The recalled and sorted medical devices, in vitro diagnostics and related products shall be disposed of in accordance with the identified disposal method.

(3) The cost of the disposal of the medical devices, in vitro diagnostics and related product shall be borne by the Holder of a Certificate of Registration or any person found in possession of the medical devices, in vitro diagnostics and related product.

Part 10
General

286. **Regulatory reliance**

(1) The Agency shall adopt regulatory reliance mechanisms in making regulatory decisions, where;

(a) the quality, safety and performance of medical devices including IVDs and related product has been confirmed or approved in a jurisdiction with a well-resourced regulatory Agency; or

(b) the WHO listed Authority, Maturity Level 3 (ML3) National Regulatory Authority (NRA) or regional regulatory authority.

(2) The Agency shall maintain its right to its national decision without compromising the quality, safety and efficacy of the medical devices and related product.

(3) Safety information or reports shall be evidence based and verifiable.

287. **Donated Medical Devices including IVDs and related product**

Donated Medical Devices, including IVDs and related products, shall comply with the provisions of this Regulations and as may be required by the Agency.

288. **Medical Devices for Personal Use**

The Agency may, upon application by an individual, and in such amount to be determined by the Agency, authorize the importation of medical devices for personal use.

289. **Importation & Exportation of Medical Devices**

A person shall not import or export a medical device regulated under these Regulations unless they hold a valid permit issued by the Agency for that purpose or as may be prescribed by the Agency.

290. **Appeal**

(1) Any person aggrieved by a decision of the Agency may, within thirty (30) workdays, submit an appeal in writing to the Director General.

(2) Notwithstanding the provision of regulation (1) of this regulation, where a person has failed to submit an appeal within the prescribed time, may within fifteen (15) days apply to the Director General for

an extension of time to lodge an appeal.

(3) The Director General may for any good reason extend the time for the lodging of an appeal; or

(4) Failure to comply with the provisions of sub regulations (2) and (3) above, the person shall be barred from appealing.

(5) In determining an appeal under this regulation, the Director General may:

(a) form an expert committee to advise on the subject matter.

(b) allow or dismiss the appeal;

(c) reverse any refusal, revocation, or suspension and;

(d) require the person to make a new application

291. **Power to Seal Premises**

The Agency shall have power to seal up any premises used or being used in connection with an offence under these Regulations until such time as the regulated product is removed or such reasonable time as the Minister responsible for health may determine.

Part 10
Prohibition, Enforcement of these Regulations

292. **Prohibition**

A person shall not carry out clinical investigation, manufacture, registration, labelling, advertisement, post market surveillance, vigilance, recall, handling and disposal of medical devices including IVDs and related products manufactured, imported, exported, advertised, sold, distributed, displayed for sale, or used in Nigeria unless it is in accordance with the provisions of these Regulations.

293. **Enforcement of these Regulations**

The Agency shall be responsible for the enforcement of these Regulations.

Part 11
Offences and Penalty, Forfeiture after conviction

294. **Offences and Penalties**

(1) Any person who contravenes any of the provisions of these Regulations commits an offence and liable on conviction. In the case of: -

(a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding N800,000:00 or both,

(b) a body corporate, to a fine not exceeding N5,000, 000:00.

(2) Where an offence under these Regulations is committed by a body corporate, firm or any other association of individuals, every: -

(a) director, manager, secretary or other similar officer of the body corporate;

(b) partner or officer of the firm;

(c) trustee of the body concerned;

(d) person concerned in the management of the affairs of the association; or

(e) person who was purporting to act in a capacity referred to in paragraphs (a) to (d) of this regulation, commits an offence and liable to be proceeded against and punished in the same manner as if he had himself committed the offence, unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

295. **Forfeiture after conviction**

(1) A person convicted of an offence under these Regulations shall forfeit to the Federal Government: -

(a) any asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence; and

(b) any of the person's property or instruments used in any manner to commit or to facilitate the commission of the offence.

In this section, "proceeds" means any property derived or obtained, directly or indirectly, through the commission of the offence.

Part 12
Miscellaneous

296. **Interpretations**

In these Regulations, unless the context otherwise requires:

'Agency' means National Agency for Food and Drug Administration and Control;

'Address' means a place where the business of manufacture, sale, distribution, storage and display of medical devices is carried out which includes the house number, plot number, street name, town or city, state, country;

'Advertisement' means the publicity of medical device or related product, which includes any form of notices in circulars, handouts, labels, wrappers, catalogues and billboards, posters, newspapers, magazines, and any other documents, made orally or otherwise or by means of projected light; it also means a form of communication through the media about products, services or ideas by an identified

'Advertising' means the publicity of goods and description of all products, (which includes any form of notices in circulars, handouts, labels, wrappers, catalogues and price lists, billboards, posters, newspapers, magazines, digital and social media, and any other documents) made orally, online or otherwise or by means of projected light and sound recordings;

Applicant means a person or institution or company that applies formally to the Agency to obtain Certificate of Registration for a medical device

'Authorized person' means the person recognised by the Agency as having the necessary basic scientific and technical background and experience; and who is responsible for ensuring that each batch of finished product has been manufactured, tested and approved for release in compliance with regulations of the Agency;

'Batch' means a specific quantity of a medical device that is intended to have uniform character and quality, within specified limit, and is produced according to a single manufacturing order during the same cycle of manufacturing process;

'Claim' means any representation which states, suggests or implies that the medical device has particular qualities relating to its origin, nutritional properties, nature, processing, composition or any other quality;

"**Certificate of Registration**" means a document describing the particulars and conditions under which a product is registered and indicates the assigned NAFDAC Reg. No. for a product;

'Clinical investigation' means any investigation in participants intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more investigational medical devices including IVDs and related product, or to identify any adverse reactions to one or more investigational medical devices including IVDs and related product or to study absorption, distribution, metabolism and excretion of one or more investigational medical devices including IVDs and related product with the objective of ascertaining its safety or efficacy and this includes Clinical investigations carried out in either one site or multiple sites;

"**Competent Authority**" means a government agency or body statutorily authorised and responsible for carrying out the function;

'Contamination' means the undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or on to a starting material or intermediate during production, sampling, packaging or repackaging, storage or transport;

"**Expiry date**" means any date after which a medical device or related product is not recommended for use;

'Fast' means the claimed effect of medical device is demonstrated to be observed 'within 30 minutes;

Good Manufacturing Practice (GMP) means that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Certificate of Registration;

'Good Refurbishment Practice (GRP)': set of standard operating procedures and dedicated quality requirements that ensure a refurbished medical device is as safe and effective as when it was new

"**Immediate"** or **"Instant**" means there must be evidence of claimed effects "within 10 seconds";

'In-process control' means checks performed during production to monitor and, if necessary, to adjust the process to ensure that the product conforms to its specifications. The control of the environment or equipment may also be regarded as a part of in-process control;

"**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;

'Investigator' means the authorized health professional responsible for the conduct of Clinical investigation at a trial site and the leader is called the Principal Investigator (PI);

'Investigational medical device' means medical device that are being evaluated for safety or

performance in a clinical investigation.

"**Investigation Site**" means a hospital, health center, surgery or other establishment or facility at or from which a Clinical investigation, or any part of such an investigation, is conducted.

'Inspection' means the act by the Agency of conducting an official review of documents, facilities, records, quality assurance arrangements and any other resources that are deemed by the Agency to be related to the Clinical investigation and that may be located at the site of the trial, at the sponsor's or contract research organization's facilities or at other establishments which the Agency deems fit to inspect;

"**In vitro diagnostic (IVDs)"** means a medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. This includes reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles; "*Justification*" means written explanation in respect of any claim, which shall be in the light of current knowledge acceptable to the Agency;

"**Label**" means any tag, brand, mark, pictorial, or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on, or attached to a package or container of medical device or related product;

"**Labelling**" means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article;

'Lot' refer to a batch or a specific identified portion of a batch that has uniform character and quality within specified limit or a specific identified amount produced in a unit of time;

'Manufacture' means all operations of purchase of materials and products, production, quality control (QC), release, storage and distribution of medical devices or related products, and the related controls;

"Manufacture*r*" means any natural or legal person with responsibility for the design or manufacture of a medical device with the intention of making the medical device available for use, under its name; whether or not such a medical device is designed or manufactured by that person, or on that person's behalf, by another person;

'Manufacturer' means a company that carries out operations such as production, packaging, repackaging, labelling and re-labelling of medical devices and related products;

'Materials' means a general term used to denote design components, raw materials, process aids, intermediates, device containers, closures, packaging and labelling materials including finished devices.

'Media' means newspaper, magazine, medical journal, television, radio, the Internet; Out of home, vehicle branding, posters, handbills, cinema, point of sale material; online, digital and social media,

any form of projected light and sound recordings or any of such means of communication;

"**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:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- 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.

"**Medical device family"** means a group of medical devices that are made by the same manufacturer, that differ only in shape, colour, flavour, or size, that have the same design and manufacturing process and that have the same intended use;

"**Medical device group**" means medical devices comprising a collection of medical devices, such as a procedure pack or tray, that is sold under a single name;

"**Medical device group family**" means a collection of medical device groups that are made by the same manufacturer, that have the same generic name specifying their intended use, and that differ only in the number and combination of products that comprise each group;

"**Package**" means any suitable container in which a medical device or related is wholly or partly placed or packed;

'Packaging material' means any material employed in the packaging of a device product, excluding any outer packaging used for transportation or shipment and packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product;

"**Personalized Medical Device**" means any of the types of medical devices that are intended for a particular individual, which could be either a custom-made, patient-matched, or adaptable medical device;

"**Post Approval Variation**" means any change to a registered medical device including IVDs and related products

"**Primary packaging material**" means packaging material that come in direct contact with the product, e.g. bottle, blister, aluminum foils, etc.

"**Proceeds**" means any property derived or obtained, directly or indirectly, through the commission of the offence.

'Production' means all operations involved in the preparation of a medical device or related product, from receipt of materials, through processing and packaging, to its completion as a finished product;

"**Protocol**" means a document that describes the objective(s), design, methodology, statistical considerations and organization of a trial it also refers to the protocol, successive versions of the protocol and protocol amendments;

'Quality control (QC)' means the part of GMP that is concerned with sampling, specifications, testing, documentation, and release procedures which ensures that materials are not released for use, and that medical device and related products are not released for sale or supply, until their quality has been deemed satisfactory;

"**Qualified person**" means the holder of a certificate or other evidence of formal qualifications awarded on completion of a university or other higher education course of study in pharmacy, chemistry, medicine, biology or a related life science, which the Agency has stated to be qualifications sufficient for the purpose of performing the functions of a qualified person ;

"Recall" means the process for withdrawing or removing of medical devices, in vitro diagnostics and related products from the distribution chain.

'Refurbishment' means to restore a used medical devices, in vitro diagnostics and related products to manufacturer defined safety and performance standards, which include actions such as repair, recondition, rework, software updates, replacement of worn parts with original parts. All actions shall be performed in a manner consistent with product specifications and service procedures defined by the manufacturer without changing its intended use

'Regulatory action' means product hold, recall, forfeiture, or destruction, sealing of manufacturing line or facility, withdrawal of GMP certificate or product license or registration certificate, prosecution;

"**Secondary packaging material**" means packaging material in which primary packaging material is enclosed;

'Specifications' means a list of detailed requirements with which the products

"**Sponsor**" means an individual, company, institution or organization which takes responsibility for the initiation, management or financing of a Clinical investigation;

"**Test kit"** means an in vitro diagnostic medical device that consists of reagents or articles, or any combination of these Regulations, and that is intended to be used to conduct a specific test

"**Tertiary packaging material**" means outer carton in which multiples of saleable units are packed, *i.e.* shipper carton; and

"**Top Parity**" means a situation where several products within the same category are of equal efficacy and the evidence shows that no product is superior to the one being advertised; a top parity claim may be used. These Regulations shall be cited as the NAFDAC Medical Devices and Related Products (Registration, Labelling, Advertisement) Regulations, 2024

297. **Citation**

These Regulations may be cited as the NAFDAC Medical Devices, including In-vitro Diagnostics and Related Products Regulations, 2025

MADE at Abuja this ……day of ……2025.

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Chairman of the Governing Council
National Agency for Food and Drug Administration and Control (NAFDAC)