PHARMACY COUNCIL OF NIGERIA (ESTABLISHMENT) ACT NO. 31, 2022

INSPECTION, REGISTRATION AND LICENSING OF MEDICAL DEVICE FACILITY REGULATIONS, 2026

ARRANGEMENT OF REGULATIONS

Regulation:

LICENSING

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MISCELLANEOUS PROVISIONS

REGISTRATION AND LICENSING OF MEDICAL DEVICES FACILITIES REGULATIONS, 2025

[ ] Commencement

In exercise of the powers conferred upon the Pharmacy Council of Nigeria by section 64 of the Pharmacy Council of Nigeria (Establishment) Act, No. 31, 2022, section 52 (2), Poisons and Pharmacy Act, Cap 535 LFN 1990 and all other powers enabling the Council in that behalf, the Council with the approval of the Honourable Coordinating Minister of Health and Social Welfare, makes the following Regulations-

PART I
OBJECTIVE AND APPLICATION

1. Objective

The objective of these Regulations is to ensure that Medical Devices Facilities in Nigeria are inspected, registered and licensed with the Pharmacy Council of Nigeria so as to protect Public Health and reduce the risk of medical device-related adverse events.

2. Application

These Regulations shall apply to Medical Devices Facilities in Nigeria.

3. Definition

(i) Medical device in these Regulations means any device, instrument, apparatus, implement, for in vitro use, 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;
- treatment, alleviation of injury;
- Medical life support;
- control of conception;

- cleaning, disinfection or sterilization of medical devices;

and which 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.

(ii) Notwithstanding the provisions above, Medical Devices regulated by the Council shall be only those under the Pharmacy Council of Nigeria's mandate as identified in the classification below.

4. Classification of Medical Devices

Class A (Low Risk): Non-invasive devices intended to be used as a mechanical barrier, for compression or for the absorption of exudates only.

Class B (Low–moderate Risk): Devices intended to be used principally with wounds which have breached the dermis, including devices used for removal or delivery of medications, fluids and nutrition from or into the body.

Class C (Moderate–high Risk)

This classification is in line with their risk level as specified under the First Schedule to these Regulations in accordance with the World Health Organisation (WHO) Global Model Regulatory framework for Medical Devices.

Class	Risk	Examples
A	Low	Examination gloves, bandages, gauze, cotton wool, surgical masks, protective gowns, bouffant caps, cleanroom shoe covers, compression sleeves, adhesive wound strips, thermometers, urine bag joint support, cervical collar etc
B	Low–moderate	Surgical gloves, infusion sets, syringes, hypodermic needles, iv cannulas, Nasogastric tubes, suction catheters, diagnostic test kits etc
C	Moderate–high	Condoms – unless with spermicide (in which case, Class D)
D	High	Condoms with spermicide.

Where a medical device belongs to more than one class, the class of the medical device that has the higher risk shall apply.

PART II
INSPECTION AND MONITORING OF MEDICAL DEVICES FACILITIES

5. Inspection of Medical Devices Facilities

Notwithstanding the class of medical devices in these Regulations, the Pharmacy Council of Nigeria shall:

(i) Carry out various kinds of inspections including location or site approval inspection, pre-registration of facility inspection, routine facility inspection, investigative or for-cause inspection, inspection due to change or variation.

(ii) Conduct GXP inspection in the Medical Devices Facility prior to license issuance or renewal of license.

(iii) Carry out regular GXP inspections of Medical Device Facility; manufacturing, importation, warehousing, storage, distribution, wholesaling, and retailing.

(iv) Through Inspection Officers, appointed by the Council, have the power while carrying out the duties at reasonable times and on production of their identity cards if so required to:

(a) enter any Facility in which they reasonably believe or suspect that a medical device to which these Regulations apply is manufactured, prepared, packaged, warehoused, distributed, stored and sold therein;

(b) examine such medical device or records in the Facility to which these Regulations apply which they reasonably believe, or suspect is used or is capable of being used for the manufacturing, importation, warehousing, distribution, wholesaling, retailing or sale of any such device;

(c) take sample of such medical device to which these Regulations apply;

(d) examine while on the Facility any medical device which they reasonably believe or suspect that these Regulations apply and would help in their investigations;

(e) examine any books, documents or other records found on the Facility which they reasonably believe or suspect may contain information relevant to the enforcement of these Regulations and make copies thereof; and;

(f) seize and detain as may be necessary, any medical device by means of which they reasonably believe or suspect any provision of these Regulations have been contravened.

6. Structure of Medical Device Facilities

Medical Devices Facilities shall be located in an approved location and such size shall be as prescribed by the Council from time to time to ensure good and healthy business practice.

7. Monitoring of Medical Devices Facilities

The Council shall monitor the operation of the Medical Devices Facilities to ensure best practices and compliance with these Regulations.

8. Enforcement of Medical Devices Facilities

PCN Inspection Officers shall have the powers to:

(i) Conduct surveillance visits on Medical Devices Facilities and

(ii) Seal any Medical Devices Facility where any part of these Regulations have been breached.

9. Timelines for Inspections of Medical Devices Facilities

(i) Location Approval Inspections

(a) For Retail, Wholesale/Distribution and Importation Facilities of Medical Devices, location approval inspection shall be conducted within two (2) weeks on receipt of the

application for inspection at Zonal/State offices if all conditions precedent are met.

(b) For manufacturing facilities, the location approval inspection shall be conducted within four (4) weeks on receipt of the application by the PCN Registry.

(ii) Pre-registration inspections

(a) For Retail, Wholesale/Distribution and Importation, the pre-registration inspection shall be conducted within two (2) weeks after the Responsible/Authorised personnel has applied for the inspection.

(b) The report of the inspection and recommendations shall be forwarded to the Registrar within two (2) weeks after the inspection.

(c) For Manufacturing facilities, the Pre-registration inspection shall be conducted within four (4) weeks after the premises has applied for the inspection and have met all the requirements for the inspection.

(iii) Routine inspections of Medical Devices Retail, Wholesale, Distribution and Importation Facilities and Re-granting of License Inspection for Medical Devices Manufacturing Facilities

The time frame for all routine inspections and re-granting of license inspection (manufacturing facility) shall be based on the risk rating of the facility as determined from the facility's last inspection outcome.

(iv) **Investigative Inspection**

Action shall be taken as soon as the petition is received. However, resolution time varies depending on the nature of the petition.

PART III
REGISTRATION OF MEDICAL DEVICES FACILITIES

10. **Registration Authority**

The Pharmacy Council of Nigeria shall;

(1) register and license Medical Devices Facilities in Nigeria throughout the supply chain.

(2) establish and maintain a register of premises used for the manufacture, importation, warehouse, distribution, wholesale, retail and sale of medical devices and accessories in Nigeria;

(3) approve or acknowledge the appointment of the operator or authorised personnels appointed by the Medical Devices Facility upon provision of the following requirement;

a. Relevant Degree certificate such as Pharmacy, Medicine, Biomedical Engineering, Microbiology, Chemistry, Medical Laboratory Science, and any other scientific discipline.
b. Registration with recognized professional bodies
c. Current practicing licence where applicable
d. Certification in GMP, Quality Management, in the case of a medical devices facility engaged in manufacturing, regardless of the class of medical devices.

(4) grant and issue approvals to the authorised personnelnel upon fulfilment of the above requirements.

11. **Procedure for Registration of Medical Devices Facilities**

(1) An application for registration of Medical Devices Facility shall be made-

(a) to the Registrar, Pharmacy Council of Nigeria; and

(b) by obtaining and completing the relevant application or renewal form as prescribed by the Council.

(2) Regardless of the class of medical devices in these Regulations to be manufactured, imported, warehoused, distributed, wholesale, retail or sold, the applicant shall complete the relevant form in duplicate and submit the form to the Zonal or State office of the Council.

(3) Regardless of the class of medical devices in these Regulations, an application for renewal of Medical Devices Facility Certificate shall be made by obtaining and completing the relevant form, as prescribed by the Council, addressed to the Registrar, Pharmacy Council of Nigeria and submitting same.

(4) The applicant shall complete the relevant form in duplicate and submit the form to the Zonal or State office of the Council with:

(a) an application letter to register the Facility;
(b) current annual licence to practice pharmacy of the Superintendent Pharmacist where applicable;
(c) Current practicing licence of the operator from professional body where applicable;
(d) evidence of payment of the prescribed fees to the Council;
(e) Company certificate of incorporation or evidence of registration of business name, is acceptable;
(f) Copy of Memorandum and Articles of Association of the company;
(g) Certified true copies of Corporate Affairs Commission documents showing names and particulars of Directors where applicable;
(h) Current Annual License to practice as a Pharmacist Director where applicable;
(i) Certificate of National Service or Certificate of Exemption where applicable; and
(j) Where applicable submit-

(i) letter of resignation from previous employment,
(ii) letter of acceptance of resignation,

(iii) letter of appointment as the Operator of Medical Device Facility,
(iv) any other document as the Council may prescribe and

12. **Application for Registration of Medical Devices Manufacturing Facilities**

(1) Where the Medical Devices Facility sought to be registered is a manufacturing facility, in addition to the documents listed in section 11 (4) of these Regulations, the application shall be accompanied with -

(a) list of Medical Devices to be manufactured;

(b) list of equipment for Production and Quality Control Departments;

(c) list and sources of suppliers of raw and packaging materials;

(d) Standard Operating Procedures;

(e) factory layout;

(f) production flow chart;

(g) list of key staff showing qualifications and job descriptions;

(h) organogram of the Company.

(2) The overall quality assurance of the facility shall be the responsibility of the Authorised personnel.

(3) The Production and Quality Control Managers shall report to the Authourised Personnel.

PART IV
LICENSING

12. Licensing

(1) The Council shall issue Facility Certificate for all Medical Devices Facilities in Nigeria throughout the supply chain.

(2) A person shall not operate facility where medical devices and medical accessories are manufactured, imported, warehoused, distributed, wholesale, retail or sold unless he has paid the prescribed fees and is duly licensed by the Council.

(3) The Council may issue or grant Facility Certificates to all registered Medical Devices Facilities in Nigeria in line with GXP

14. Renewal of Facility Certificate

(1) A Facility Certificate shall expire on the 31st day of December of each year and be due for renewal on the 1st day of January every year.

(2) The renewal of Facility Certificate after the 31st day of March shall be considered as late renewal and shall attract such administrative charges as prescribed by the Council.

(3) An application for renewal of Medical Devices Facility Certificate shall be made by obtaining and completing the relevant form, as prescribed by the Council, addressed to the Registrar, Pharmacy Council of Nigeria and submitting same.

(4) The online application procedure for renewal of Medical Devices Facility Certificate shall be in accordance with the Guidelines for Registration and Licensing of Medical Devices Facilities, 2026.

(5) The processing of the application for renewal of facility certificate shall be within seven working days from the date of receipt of application.

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(6) The procedure for renewal of Facility Certificate shall be in accordance with the Guidelines for Inspection, Registration and Licensing of Medical Devices Facilities, 2026.

15. **Change, Variation or Modification of Facility Certificate**

(1) An Authorised personnel of a licensed Medical Devices Facility shall notify the Registrar of any major/minor changes, variation or modification to the original certificate of the facility.

(2) The procedures and instructions for application for change, variation or modification in a Facility Certificate shall be in accordance with the Guidelines for Inspection, Registration and Licensing of Medical Device Facilities.

16. **Suspension, Revocation, Withdrawal or Cancellation of Facility Certificate**

(1) Where there is a breach of any of the provisions of these Regulations or the Act by the holder of a facility certificate, the Council is empowered to suspend, revoke, withdraw, or cancel the Facility Certificate.

(2) Notice shall be given to the holder of a facility certificate where the Registrar is of the view that the facility certificate should be suspended, revoked, withdrawn, or canceled.

(3) The holder of a Certificate to be suspended, revoked, withdrawn, or canceled shall within 14 days of receipt of the notice as provided in sub regulation (2) of these regulations be required to give reasons why the Facility Certificate should not be suspended, revoked, withdrawn or cancelled and where the-

(a) Registrar is satisfied by the reasons given, such Certificate shall not be suspended, revoked, withdrawn or cancelled; or

(b) reason given is not satisfactory, the Registrar shall notify the holder of the decision to suspend, revoke, withdraw or cancel the Certificate in which case, the holder of the certificate may appeal to the Council within 14 days.

(4) The Council shall make and keep an update of any alteration to the issued Certificate.

(5) The Council shall make information with respect to the status of the registration of the Medical Device Facilities and other relevant information publicly available on the PCN website, official bulletins, or other legal publications.

17. **Right of appeal**

(1) Regulatory decision taken or rendered in the course of administering the provisions of these Regulations, may be appealed against by the aggrieved person in writing within 14 working days of such decision stating the substance of the complaint and the reliefs sought.

(2) The steps and procedures for making appeals shall be in line with the Pharmacy Council of Nigeria Guidelines for Complaints and Appeals Against Regulatory Decisions.

PART V
MISCELLANEOUS PROVISIONS

18. **General Provisions**

(1) An Operator of Medical Device Facility shall not use any name other than that registered with the Council on the signpost of the facility.

(2) A request for temporary closure of the Facility shall be for a maximum period of two years and renewal fees shall be paid for the period of the closure after which further request for renewal may not be granted.

(3) The failure, refusal or negligence to renew facility certificate of Facilities for a maximum period of two years is deemed to be notice to the Council of permanent closure of the Medical Devices Facility.

(4) The Council shall prescribe or review the fees payable in respect of the registration of facilities.

19. **Penalties for Late Payment of Fees**

(1) A Medical Devices Facility that fails, refuses or neglects to renew its Facility Certificate by the 31st day of March of every year shall, in addition to paying the prescribed renewal fee, pay 50% of the applicable fee as late payment.

(2) Where a Medical Devices Facility fails to renew its Facility Certificate by the 31st day of March each year, the Medical Devices Facilities may be sealed.

20**.** **Offences and Penalties**

(1) An unregistered Medical Devices Facility operates in breach of these Regulations and is liable to be sealed.

(2) An operator of a Medical Devices Facility found guilty of a criminal offence by a Court of competent jurisdiction or tribunal shall not be registered or licenced to operate same until the Council decides otherwise.

(3) A person who willfully makes a false statement for the purpose of procuring the registration of a name, facility, qualification or any other matter under these Regulations, commits an offence and is liable on conviction, to a fine not less than N500,000.00 or to imprisonment for a term not exceeding one year or both.

(4) A person who is not a registered operator of a Medical Devices Facility, under these Regulations, but operates as such, holds himself out as being so registered, or takes or uses a name, title,

addition or description implying that he is so registered and authorised by law to so operate, commits an offence under these Regulations and is liable on conviction, to a fine not less than N1,000,000.00 or to imprisonment for a term not exceeding two years, or both.

(5) A Medical Devices Facility that violates the provisions of these Regulation commits an offence and is liable on conviction, in the case of —

(a) subregulation (1), to a fine of not less than N2,000,000.00 and the directors or principal officers of the body corporate are liable to a fine of not less than N250,000.00 or to imprisonment for a term not exceeding two years or both; or

(b) subregulation (2), to a fine of not less than N5,000,000.00 and the directors or principal officers of the body corporate are liable to a fine of not less than N500,000.00 or to imprisonment for a term not exceeding three years or both.

(6) Where an offence under these Regulations has been committed by a body corporate and the offence is proved to have been committed with the consent, connivance or collusion of or attributable to any neglect on the part of a director, manager, secretary or any other officer of the body corporate or any person who was purporting to act in such capacity, the officer and the body corporate commits an offence and are liable to be proceeded against and punished accordingly.

(7) In relation to a body corporate carrying on business on medical devices, subregulation (3) shall have effect to a person who, not being an officer of the body corporate at the time of the commission of the offence is the—

(a) Operator; or
(b) authourised person who acts under the directions of the Operator, or as if he were such an officer of the body corporate.

(8) A person or body corporate that owns, operates, maintains, establishes or has charge of, either alone or with another person, an facilities which is not registered under these Regulations, commits an offence and is liable on conviction to a fine of N2,500,000.00 or to imprisonment for a term of two years or both.

(9) A person or body corporate that owns, operates, maintains, establishes or has charge of, either alone or with another person, a pharmacy in which a person not certificate as an operator commits an offence and is liable on conviction to a fine of N2,500,000.00 or to imprisonment for a term of two years or both.

(10) A person or body corporate that owns, operates, maintains, establishes or has charge of, either alone or with another person, or patent and patent medicine shop which is not registered under these Regulations, but operate or deals in Medical Device commits an offence and is liable on conviction to a fine of N500,000.00 or to imprisonment for a term not less than six months or both.

(11) A person who willfully and with intent to defraud-

(a) makes a false or fraudulent claim, for himself or another person, in any application, affidavit or statement presented to the Council or any proceeding before the Council, commits an offence and is liable on conviction to a fine of N250,000.00 or to imprisonment for a term of one year or both.

(12) A person who commits an offence under these Regulations for which no specific penalty is provided is liable on conviction to a fine of not less than N500,000.00 or to imprisonment for a term of two years or both.

(13) A body corporate that commits an offence under these Regulations for which no specific penalty is provided is liable on conviction to a fine not less than N2,000,000.00

21. **Interpretation**

In these Regulations -

"*Act*" means Pharmacy Council of Nigeria (*Establishment*) Act, 2022;
"*Authourised person*" means a qualified person in charge of the overall operations of the Medical Devices Facility;
"Certification" the PCN process of providing an official certificate, permit or licence which attest to the registration status or level of any individual;
"*Community Pharmacy*" means a healthcare facility that provides pharmaceutical services, including storage and dispensing of medicines to a specific community;
"*Council*" means the Pharmacy Council of Nigeria;
"*Disciplinary Tribunal*" means the Tribunal established in accordance with the provision of Section 17 of the PCN Act;
"Ethical Products" means products that are prescription-only;
"GMP" means good manufacturing practice in this context as it applies to licensure and revalidation of such licences;
"GPP" means good pharmaceutical practice in accordance with best global practices;
"GSDP" means Good Storage and Distribution Practice;
"GXP" means *G – Good, X - Pharmacy, Distribution, Warehousing, Manufacturing, Dispensing, or Storage, P – Practice;*
"*Licensing" means the official authorization, granted by the Pharmacy Council of Nigeria to a stakeholder to engage in any of its regulated activity;*
"*Licensing" also refer to the PCN official process in granting approval to a applicants for the purpose of engaging in sales, distribution, importation, exportation, third party to use, make, or sell something. It allows the owner of an asset (the licensor) to authorize another party (the licensee) to use their property, typically in exchange for a fee*

"PCN" means Pharmacy Council of Nigeria
"*Prescribed fees*" means fees as approved by the Council;

Medical Device: Medical device in these Regulations means any device, instrument, apparatus, implement, for in vitro use, 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;*
- *treatment, alleviation of injury;*
- *Medical life support;*
- *control of conception;*
- *cleaning, disinfection or sterilization of medical devices;*

and which 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 Devices Facility: Any licensed facility regulated by PCN for the, manufacture, importation, warehousing, distribution, and sale medical devices

***In vitro diagnostic medical device (IVD)**:*
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. (e.g., blood glucose test kits, HIV rapid test kits).

Retailer/Wholesaler: Any person or entity licensed by PCN to distribute or sell medical devices to end-users or other licensed facilities.

22 Citation

These Regulations may be cited as the Inspection, Registration and Licensing of Medical Devices Facility Regulations, 2026.

Inspection, Registration and Licensing of Medical Devices Facility Regulations, 2026