Nnamdi Azikiwe University Awka Journal of Private and Property Law, volume 3 (2) April, 2026

NAFDAC REGULATION OF AI-POWERED MEDICAL DEVICES IN NIGERIA: ADEQUACY AND REFORMS

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Abstract

AI-powered medical devices are being actively deployed across Nigerian hospitals, clinics, and telemedicine platforms, yet the National Agency for Food and Drug Administration and Control (NAFDAC) has not developed a regulatory framework specifically calibrated to their unique safety, accuracy, and accountability requirements. This article critically examines the adequacy of NAFDAC's existing medical device regulatory architecture — including the 2024 Regulations and the draft 2025 Regulations — for governing AI-powered medical devices. Drawing on doctrinal legal analysis and comparative insights from the United States FDA,, South Africa's SAHPRA, Kenya, and the IMDRF international standards framework, the article identifies critical regulatory gaps including the absence of AI-specific SaMD classification criteria, no mandatory pre-market AI accuracy validation, inadequate post-market surveillance for algorithmic drift, absent algorithmic transparency requirements, and no algorithmic bias assessment obligations. The article proposes a targeted reform agenda anchored in AI-specific SaMD regulations, mandatory pre-market validation, the establishment of an AI Medical Device Advisory Committee, enhanced post-market surveillance, and alignment with IMDRF international standards. It concludes that regulatory adequacy for AI medical devices is a patient safety and human rights imperative that NAFDAC must urgently address.

Keywords: AI in Healthcare, AI Medical Devices, Algorithmic Bias, Digital Health, Software as a Medical Device (SaMD), Patient Safety.

1.Introduction

Gradually, artificial intelligence (AI) has transformed medical device technology at a pace that has outrun the regulatory frameworks designed to govern it.[2] In Nigeria, AI-powered diagnostic tools, clinical decision support systems, and machine learning-based in-vitro diagnostics are being utilized in health facilities and telemedicine platforms without any specific legislative framework.[3] This means that there are no unique laws specifically governing the safety, accuracy, or accountability of these AI powered devices. Presently, the key regulator of medical devices is the National Agency for Food and Drug Administration and Control (NAFDAC). This is pursuant to commendable general frameworks provided by it in its 2024 Regulations and 2025 draft. None of these instruments properly addresses the peculiar legal challenges posed by the use of AI-powered medical devices. A careful look through them reveals this.

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[2] K Zhou and G Gattinger, 'The Evolving Regulatory Paradigm of AI in MedTech: A Review of Perspectives and Where We Are Today.' (2024) *Therapeutic Innovation & Regulatory Science*, 456.

[3] N E Emeka, 'Applicability of Artificial Intelligence in the Nigerian Healthcare Sector: An Imperative for a Legal Framework.' (2024) *Journal of Law and Clinical Legal Education*, 18.

This regulatory gap has grave consequences for Nigerian patients. AI diagnostic tools can produce errors, exhibit systematic bias against underrepresented populations, and degrade in performance over time without detection. None of these are addressed in the guidelines released by NAFDAC or any other law in Nigeria. The central question this article addresses is whether NAFDAC's existing and proposed framework is adequate for governing AI-powered medical devices, and if not, what targeted legal reforms are required.

The article adopts a doctrinal legal research methodology, combining analysis of Nigerian legislation and NAFDAC regulatory instruments with comparative review of AI medical device frameworks in the United States, South Africa, and Kenya, and engagement with the International Medical Device Regulators Forum (IMDRF) AI Software as a Medical Device (SaMD) international guidance framework. The article proceeds to clarifying pertinent concepts, an assessment of NAFDAC's existing framework, identification of critical gaps, then concluding with realistic recommendations.

2. Conceptual Clarifications

2.1 AI-Powered Medical Devices and SaMD

Contextually, artificial intelligence (AI) in medical devices integrates machine learning, deep learning, and other AI technologies into medical equipment and software to improve diagnostics, treatment planning, and patient care.[4] These devices analyze large amounts of medical data, recognize patterns that may be imperceptible to clinicians, and provide decision support or autonomous interventions. The international concept of Software as a Medical Device (SaMD), developed by the International Medical Device Regulators Forum (IMDRF), provides the foundational classification framework for such tools.[5] The IMDRF's AI SaMD guidance – developed collaboratively by regulators from the United States, EU, UK, Canada, Australia, Japan, and others – addresses AI-specific classification, pre-market evaluation, algorithmic transparency, and post-market surveillance. NAFDAC has engaged with the IMDRF framework through its participation in the IMDRF's 26th Session, yet has not operationalised the IMDRF's AI SaMD standards into binding domestic regulation.[6]

The defining characteristic that sets AI medical devices apart from conventional devices which renders existing frameworks inadequate – is their use of data-driven learning to generate random outputs that cannot be fully predicted, explained, or pre-specified. For instance, an AI tuberculosis screening tool does not apply a fixed diagnostic algorithm; it generates outputs based on patterns learned from training data that may be unrepresentative of Nigerian patients, and its performance may shift over time as data distributions evolve.[7] These characteristics demand regulatory solutions that go beyond the conventional static device evaluation model.

[4] Arterex, 'AI in Medical Devices: Applications, Benefits, Challenges, Regulations, and Future Trends.' https://arterexmedical.com/ai-in-medical-devices/#wiaimd retrieved on April 25, 2026.

[5] IMDRF, 'Software as a Medical Device.' https://www.imdrf.org/working-groups/software-medical-device-samd retrieved on April 25, 2026.

[6] IMDRF, 'Day 2 IMDRF Stakeholder Forum.' https://www.imdrf.org/sites/default/files/2026-03/Nigeria%20NAFDAC.pdf retrieved on April 25, 2026.

[7] U O Arama, *et al* 'Exploring the role of artificial intelligence toward management of HIV and TB co-infection in Nigeria: a comprehensive narrative review.' (2025)

2.2 The Legal Stakes: Patient Safety and Human Rights

The deployment of AI medical devices in Nigeria engages fundamental legal obligations. Nigeria's obligations under the African Charter on Human and Peoples' Rights — domesticated under the African Charter on Human and Peoples' Rights (Ratification and Enforcement) Act — include Article 16's right to the best attainable state of health. An AI diagnostic tool that systematically underperforms on Nigerian patients due to training data bias, or that degrades in accuracy without regulatory detection, directly violates this right.[8] The relevant laws that give health professionals a duty of care in handling patients,[9] obligate health professionals to seek and get informed consent and also consumer protection laws[10] regulating product liability all implicated by AI medical device failures – yet none of these existing legal frameworks adequately assigns responsibility when AI systems cause patient harm in the absence of a specific regulatory framework that defines the applicable standard of care and duty of oversight.

3. An Assessment of the NAFDAC's Regulatory Framework for the Use of Medical Devices

3.1 Statutory Foundation

NAFDAC's medical device regulatory mandate is embedded in section 30 of the NAFDAC Act,[11] and section 12 of the Food, Drugs and Related Products (Registration, Etc.) Act.[12] The statutory definition of 'medical device' which encompasses instruments manufactured, sold, or advertised for use in the diagnosis, treatment, or prevention of disease – is broad enough to capture AI-powered SaMD. NAFDAC requires registration of software as a medical device as a precondition for its marketing and use in Nigeria, and a successful registration is distinct from the advertising permit required before clinical claims can be made. This basic regulatory gateway, while commendable, is the limit of NAFDAC's specific engagement with AI medical tools under current law.

3.2 NAFDAC Medical Devices and Related Products (Registration, Labelling And Advertisement) Regulations, 2024[13]

The NAFDAC Medical Devices and Related Products (Registration, Labelling and Advertisement) Regulations[14] has the objective of providing a regulatory framework for the regulation of medical devices and related products manufactured, imported, advertised, sold, displayed for sale, distributed, or used in Nigeria.[15] The NAFDAC Medical Devices Regulations established a four-class risk-based classification system for medical devices aligned with the Global Medical Device Nomenclature, post-market surveillance obligations, adverse event

https://pmc.ncbi.nlm.nih.gov/articles/PMC12644435/pdf/10.1177_20499361251395916.pdf retrieved on April 25, 2026.

[8] N Sani *et al*, 'Harnessing the power of Artificial Intelligence for better health data management.' (2024) Intl J Health Recs & Info Mgt. 38-39.

[9] The National Health Act, 2014 and the Code of Ethics that regulate the various health professionals like the Code of Medical Ethics for medical and dental practitioners.

[10] Federal Competition and Consumer Protection Act.

[11] Cap. N1 LFN 2004.

[12] Cap. F33 LFN 2004.

[13] S.I. No. 42 of 2024

[14] Hereinafter referred to as NAFDAC Medical Devices Regulations.

[15] Section 1.

reporting requirements, and good clinical practice standards for device investigations.[16] A careful look through the NAFDAC Medical Devices Regulations reveals it focuses less on the legal implications on patients and more on registration, labelling and advertisement of medical devices and related products manufactured, imported, exported, advertised, sold, distributed, displayed for sale, or used in Nigeria.[17] There is total silence on informed consent, data privacy, responsibility for medically errors in diagnoses or processing patients' data by the use of AI.

On July 23, 2025, NAFDAC published a comprehensive draft of new Regulations open for public comment through September 20, 2025, proposing further enhancements to the registration, surveillance, and compliance framework.[18] These are meaningful regulatory developments that reflect NAFDAC's institutional commitment to modernising Nigeria's medical device governance.

However, a critical review of both instruments reveals a shared and fundamental deficiency: neither the 2024 Regulations nor the 2025 draft contains any provisions specifically addressing AI-powered medical devices. The four-class classification system does not incorporate AI-specific risk dimensions. The post-market surveillance framework relies on passive adverse event reporting ill-suited to detecting algorithmic performance degradation. The clinical investigation requirements do not address AI performance validation on Nigerian patient populations. The absence of AI-specific provisions in both instruments is not a minor technical gap — it is a systemic regulatory failure that leaves the fastest-growing category of medical technology entirely ungoverned by purpose-built legal standards.

4. Regulatory Frameworks in Selected Jurisdictions

The United States Food and Drug Agency's (FDA) Digital Health Centre of Excellence has developed the most comprehensive AI SaMD framework currently in existence.[19] It combines pre-market performance validation requirements[20] with a Predetermined Change Control Plan framework enabling adaptive AI updates within pre-approved parameters, mandatory algorithmic transparency in device labelling, and a public AI-enabled device registry.[21] The FDA's framework demonstrates that adaptive AI algorithms can be effectively governed without requiring full re-review for every update, provided performance boundaries are clearly defined and monitored.

South Africa's South African Health Products Regulatory Authority has published specific SaMD guidance addressing AI and machine learning applications and establishing a regulatory classification pathway.[22]

[16] Section 3.

[17] See section 2.

[18] Vanguard, 'Comply with regulations or face sanctions, NAFDAC warns stakeholders.' https://www.vanguardngr.com/2025/12/comply-with-regulations-or-face-sanctions-nafdac-warns-stakeholders/#google_vignette retrieved on April 25, 2026.

[19] IntuitionLabs, 'FDA AI/ML SaMD Guidance: Complete 2026 Compliance Guide.' https://intuitionlabs.ai/articles/fda-ai-ml-samd-guidance-compliance retrieved on April 26, 2026.

[20] Including mandatory validation on diverse patient populations.

[21] US Food and Drug Administration, 'Artificial Intelligence in Software as a Medical Device.' https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-software-medical-device retrieved on April 26, 2026.

[22] SAHPRA, 'Regulatory Requirements of Artificial Intelligence and Machine Learning (AI/ML) Enabled Medical

Kenya's Digital Health Act 2023 provides the most directly applicable African legislative model.[23] It demonstrates that comprehensive digital health legislation, capable of serving as the foundation for AI-specific governance provisions, is achievable in the African regulatory context.

The IMDRF AI SaMD framework is developed collaboratively by all major regulatory jurisdictions and covering the full AI device lifecycle from pre-market development to post-market surveillance.[24] The IMDRF AI SaMD framework provides the most technically authoritative and immediately applicable international standard for NAFDAC's reform agenda, given NAFDAC's existing institutional engagement with the IMDRF.

The primary lesson from comparative analysis is unambiguous: effective governance of AI medical devices requires purpose-built regulatory instruments. No jurisdiction has successfully governed AI medical devices through the application of general medical device frameworks alone. Nigeria's regulatory gap is not unique — it reflects the global challenge of keeping regulation pace with technological change — but it is remediable through targeted legislative and regulatory action grounded in available international standards.

5. Critical Legal Gaps with NAFDAC's Regulatory Framework

5.1 Absence of AI-Specific Classification Criteria

NAFDAC's four-class risk classification system was designed for hardware medical devices. It does not incorporate the dimensions relevant to AI risk assessment - specifically, the nature and extent of the AI's contribution to clinical decision-making, the adaptivity of the algorithm, the opacity of its reasoning, and the potential for systematic bias in its outputs. An AI tool that makes autonomous diagnostic recommendations with no physician review poses fundamentally different regulatory risks from an AI tool providing supplementary probability scores to a specialist radiologist, yet both may be classified identically under current NAFDAC criteria. This classification inadequacy produces systematic misregulation: high-risk autonomous AI diagnostic tools are subject to no greater regulatory scrutiny than low-risk decision-support tools, and manufacturers face no incentive to seek higher-risk classifications that would trigger more burdensome requirements

5.2 No Mandatory Pre-Market AI Performance Validation

NAFDAC's SaMD registration pathway requires technical documentation and, for foreign products, evidence of approval in a reference jurisdiction.[25] It does not require mandatory pre-market performance validation demonstrating that an AI tool achieves its claimed clinical purpose

Devices.' https://www.sahpra.org.za/wp-content/uploads/2025/09/MD08-20252026_-SAHPRA-Communication-to-Industry-AI-Medical-devices_Acknowledgements.pdf retrieved on April 26, 2026.

[23] Policy Vault Africa, 'Digital Health Act, 2023.' https://www.policyvault.africa/policy/digital-health-act-2023/ retrieved on April 26, 2026.

[24] IMDRF, 'Consultation decision pending
Technical Framework for Artificial Intelligence Life Cycle Management.' https://www.imdrf.org/consultations/technical-framework-artificial-intelligence-life-cycle-management retrieved on April 26, 2026.

[25] Pharma Regulatory.in, 'Medical Device Regulation and Classification by NAFDAC – medical affairs pharma.' https://www.pharmaregulatory.in/medical-device-regulation-and-classification-by-nafdac-medical-affairs-pharma/#google_vignette retrieved on April 26, 2026.

in the Nigerian patient population. There is no provision for this in the extant NAFDAC Medical Devices Regulations. This gap has immediate patient safety consequences. AI diagnostic tools trained on predominantly non-African patient data — the source of the overwhelming majority of AI medical tools available in the Nigerian market — may perform substantially less accurately on Nigerian patients without any mechanism for detecting this performance gap before deployment. An AI tuberculosis detection tool with 95% sensitivity in a Western validation population might perform significantly less accurately in Nigerian clinical settings where disease presentation patterns differ, without NAFDAC's current framework requiring any Nigeria-specific validation before the tool reaches patients.

5.3 The Adaptive Algorithm Problem

Many AI medical devices incorporate machine learning algorithms that continue to learn and adapt after deployment, updating their parameters based on new clinical data.[26] This adaptivity – clinically attractive for enabling continuous performance improvement — creates regulatory challenges that conventional device frameworks were not designed to address. NAFDAC's change management framework requires regulatory notification for modifications to registered medical devices, but applying this framework to adaptive AI algorithms that may update continuously based on each patient encounter is both impractical and regulatory inadequate. Neither the 2024 Regulations nor the 2025 draft includes a predetermined change control framework — analogous to the FDA's model — that would allow AI developers to obtain advance regulatory approval for planned algorithm modifications within specified performance boundaries. The result is a regulatory lacuna in which the most clinically dynamic category of medical device operates without any structured oversight of its ongoing evolution.

5.4 Algorithmic Transparency and Post-Market Surveillance

NAFDAC's framework imposes no requirements for algorithmic transparency. It does no obligate manufacturers to explain, in clinically meaningful terms, how an AI medical device reaches its outputs. This is usually required for the use of AI in healthcare.[27]This opacity undermines physician clinical oversight, patient informed consent rights, and NAFDAC's own capacity to evaluate AI devices effectively. Equally, the post-market surveillance framework established by the 2024 Regulations — relying primarily on manufacturer-initiated adverse event reporting — is inadequate for detecting the gradual, systematic performance degradation that characterises AI model drift. AI performance can degrade as clinical practice patterns shift, as new disease variants emerge, or as patient population characteristics evolve, and this degradation may be invisible to conventional adverse event reporting until it has caused significant patient harm. A proactive AI-specific surveillance framework — including mandatory periodic performance monitoring reports and algorithmic performance thresholds requiring regulatory notification — is conspicuously absent from NAFDAC's current instruments.

[26] Y A Fahim, *et al,* 'Artificialintelligence in healthcare and medicine: clinical applications, therapeutic advances, and future perspectives.' (2025) European Journal of Medical Research, 1-4.

[27] Blatti and STramacere, 'The Transparency and Liability Issues Associated with AI-Based Medical Systems,' in F Casarosa, F Gennari and A Rossi (Eds.) 'Enabling and Safeguarding Personalized Medicine.' (Springer, Cham, 2025) pp. 292-296.

5.5 Algorithmic Bias and Health Equity

Nigeria faces a distinctive algorithmic bias risk.[28] The overwhelming majority of AI medical devices available for deployment in Nigeria were developed using patient data from high-income countries — populations that differ from Nigerian patients in disease prevalence patterns, genetic characteristics, environmental exposures, and clinical presentation. NAFDAC's current framework imposes no requirement that AI device manufacturers demonstrate equitable performance across Nigerian demographic subgroups, and no obligation to test performance on Nigerian patient populations as a condition of market authorisation. This silence is not defensible in a regulatory authority whose mandate is to protect the health of all Nigerian citizens — including those whose characteristics are underrepresented in the training datasets of imported AI tools. The absence of bias assessment requirements constitutes both a patient safety failure and a health equity concern directly implicating Nigeria's obligations under the right to health.

5.6 Data Protection Interface and Liability Framework

The deployment of AI medical devices involves processing patient health data designated as sensitive personal data under the Nigeria Data Protection Act 2023. Presently, there is no coordination framework between NAFDAC and the Nigeria Data Protection Commission (NDPC) ensuring that AI medical device manufacturers comply with both device safety and data privacy obligations as integrated components of coherent regulatory governance. Distinctively, the Nigerian legal landsscape lacks specific liability framework for AI diagnostic errors, leaving out the pertinent questions of whether a physician, hospital, or technology developer bears liability when AI causes patient harm entirely unresolved. This is a gap that simultaneously denies patients clear legal recourse and deprives providers and developers of the legal certainty needed to make responsible deployment decisions.

6. Conclusion and Recommendations

This paper has reviewed, briefly, NAFDAC's regulatory framework for AI-powered medical devices. Despite the genuine progress represented by the 2024 Regulations and the 2025 draft, there are critical gaps that leave Nigerian patients exposed to unmitigated risks of algorithmic harm. The absence of AI-specific classification criteria, mandatory pre-market performance validation, adaptive algorithm governance, algorithmic transparency requirements, bias assessment obligations, and proactive post-market surveillance collectively constitute a regulatory failure commensurate with the scale of AI deployment in Nigerian healthcare.

The reform agenda proposed in this paper is targeted, technically grounded, and normatively justified by both NAFDAC's statutory mandate and Nigeria's human rights obligations. The window for proactive action is narrowing as AI deployment accelerates, but the tools for reform are available: NAFDAC's existing IMDRF engagement provides a ready-made international standards framework. Also, the growing legislative momentum around AI governance in Nigeria — reflected in the National AI Commission (Establishment) Bill 2025[29] creates a favourable policy environment for regulatory reform. NAFDAC must diagnose its own regulatory inadequacies with the same analytical rigour it expects of the AI devices it governs — and act on that diagnosis with the urgency that patient safety demands.

In view of the foregoing, the following are recommended:

[28] N Sani *et al*, 'Harnessing the power of Artificial Intelligence for better health data management.' (2024) Intl J Health Recs & Info Mgt. *op. cit.*

[29] IAPP, 'Nigeria moves toward comprehensive AI regulation.' https://iapp.org/news/a/nigeria-moves-toward-comprehensive-ai-regulation retrieved on April 26, 2026.

6.1 Enactment of AI-Specific SaMD Regulations

NAFDAC should develop and enact specific regulations for AI-powered SaMD as subsidiary legislation under the existing NAFDAC Act, aligned with the IMDRF AI SaMD framework and incorporating Nigeria-specific provisions. These regulations should establish a dedicated AI SaMD classification pathway within the existing four-class risk system, with regulatory requirements calibrated to the nature of the AI's contribution to clinical decision-making and the severity of the healthcare context. The public comment period for the 2025 draft regulations provides an immediate opportunity to advocate for the incorporation of AI-specific provisions before finalisation — either through amendment of the 2025 draft or through a parallel AI SaMD instrument developed concurrently.

6.2 Mandatory Pre-Market AI Performance Validation

NAFDAC's AI SaMD regulations should require mandatory pre-market performance validation for all AI medical devices above the lowest risk threshold, including clinical validation demonstrating the AI's intended clinical purpose is achieved in the relevant patient population; analytical validation of accuracy and reproducibility; and — critically — performance testing on Nigerian or representative African patient populations, or documented evidence that training and validation data is sufficiently representative of Nigerian patients to support clinical validity claims. NAFDAC should develop Nigeria-specific performance standards for AI tools addressing priority disease areas including tuberculosis, cardiovascular disease, cervical cancer, and malaria.

6.3 Establish an AI Medical Device Expert Advisory Committee

NAFDAC should establish an AI Medical Device Expert Advisory Committee comprising clinical specialists, AI and data scientists, health lawyers, bioethicists, and patient advocates. The committee should advise on the classification of complex AI devices, evaluate pre-market submissions for high-risk tools, develop AI performance standards, and review AI-related adverse events. This institutional mechanism would address NAFDAC's most significant practical challenge — the limited in-house technical expertise for evaluating AI performance, transparency, and bias questions — and would strengthen the quality and credibility of its AI governance decisions.

6.4 Post-Market Surveillance and Algorithmic Transparency

NAFDAC should develop proactive AI-specific post-market surveillance requirements including mandatory periodic performance monitoring reports; algorithmic performance thresholds requiring regulatory notification; and a national AI medical device adverse event registry enabling systematic analysis across the healthcare system. Simultaneously, AI SaMD regulations should mandate minimum algorithmic transparency standards — requiring manufacturers to provide NAFDAC, healthcare providers, and patients with accessible information about AI performance characteristics, training data limitations, and the basis for AI recommendations — addressing both the patient rights dimensions of AI opacity and the regulatory oversight requirements of effective post-market governance.

6.5 Mandatory Algorithmic Bias Assessment and NAFDAC-NDPC Coordination

All AI medical devices above the lowest risk threshold should be required to demonstrate equitable performance across relevant Nigerian demographic subgroups as a condition of market

authorisation, with NAFDAC empowered to require additional validation on underrepresented groups where significant disparities are identified. Concurrently, NAFDAC and the NDPC should develop a formal regulatory coordination framework — initially through a Memorandum of Understanding — establishing clear division of responsibility, information sharing protocols, and joint enforcement mechanisms for AI medical device compliance failures involving both safety and data protection dimensions. These reforms, combined with alignment with IMDRF international standards and sustained investment in NAFDAC's technical regulatory capacity, would collectively constitute a comprehensive and credible governance architecture for AI-powered medical devices in Nigeria.