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NAFDAC MEDICAL DEVICES AND RELATED PRODUCTS (REGISTRATION, LABELLING AND ADVETISEMENT) REGULATIONS, 2024

ARRANGEMENT OF REGULATIONS

Regulation :

S. I. No. 42 of 2024

NAFDAC MEDICAL DEVICES AND RELATED PRODUCTS (REGISTRATION, LABELLING AND ADVETISEMENT) REGULATIONS, 2024

[16*th Day of October*, 2024] 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 all other powers enabling it in that behalf, the Governing Council, with the approval of the Minister, makes the following Regulations —

Part I — Objective and Application

Objective

1. The objective of these Regulations is to provide regulatory framework for the regulation of medical devices and related products manufactured, imported, advertised, sold, displayed for sale, distributed, or used in Nigeria.

Application

2. These Regulations shall apply to registration, labelling and advertisement of medical devices and related products manufactured, imported, exported, advertised, sold, distributed, displayed for sale, or used in Nigeria.

Part II — Registration of Medical Devices and Related Products

Classification of medical devices and related products

3.—(1) The classification of medical devices and related products shall be in accordance with the First Schedule to these Regulations and catagorised 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.

Application for Registration

4.—(1) Application for registration of medical device and related products shall be —

(*a*) required for each single medical device or related product, a medical device group, medical device family or medical device system;

(*b*) made by submitting an application accompanied by relevant documents prescribed by the Agency from time to time as follows —

(*i*) contain the particulars and description of the medical device and related products in respect of which the application is made,

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

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

(*iv*) identification of the medical devices and related products,

(*v*) identification of medical devices and related products that is part of a system, test kit, medical device group, medical device family or medical device group family, and

(*c*) accompanied by evidence of payment of such fee as the Agency may from time to time prescribe.

(2) The medical device and related product submitted for registration under these Regulations shall be designed and manufactured to be safe and perform its intended use for the duration of use.

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

(4) 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 or related products in accordance with the provisions of Food, Drug and Related Products (Registration etc.) Act, Cap. F33, LFN 2004.

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

(6) 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.

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

(8) Notwithstanding the provisions of subregulation (7) of this regulation, the Agency may suspend or cancel any Certificate of Registration issued in accordance with subregulation (5) of this regulation.

(9) The Agency shall, from time to time, publish on its official website, the list of registered medical devices and related products registered by the Agency.

(10) The Agency may refuse an application for registration where —

(*a*) 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;

(*b*) laboratory report for the product is unsatisfactory;

(*c*) good manufacturing practice inspection report is unsatisfactory; or

(*d*) product labeling contravenes the provisions of these Regulations.

(11) Medical devices and related products do not meet other requirements of the Agency.

Registration of novel devices

5. The registration of a novel device shall be subject to a satisfactory performance evaluation study conducted by the Agency.

Post-registration changes

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

(2) Any changes that may likely impact on the quality 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 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.

Disclosure of information supplied by applicant

7. A person shall not disclose information supplied to the Agency in pursuance of regulation 5 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.

Suspension or cancellation of Certificate of Registration

8.—(1) The Agency may suspend or cancel the registration of a medical device and related product, where —

(*a*) the grounds on which the medical device and related product was registered is false or incomplete;

(*b*) any of the conditions under which the medical device or 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 proved to be in-effective for the approved intended use;

(*e*) the premises in which the medical device and related product is manufactured, assembled, or stored on behalf of a holder of Certificate of Registration are not in compliance with the requirements of good manufacturing practice (GMP), good distribution practice and Good Warehouse Practice as may be determined by the Agency; or

(*f*) the holder of Certificate of Registration has given a notice to the Agency in writing of any intention to suspend product registration for a period not exceeding the validity of the Certificate of Registration.

(2) Where the registration of medical device and related product is suspended or cancelled, the Agency shall order the withdrawal from circulation of such medical device or 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 subregulation (1)(*a*) of this regulation, a holder of Certificate of Registration shall notify the Agency of the intention to resume marketing of a registered product and shall submit relevant document and pay the prescribed renewal fee for product registration, where the Certificate of Registration has expired.

Labelling

9. The labelling of a medical devices and related product shall be in accordance with these Regulations.

Advertisement

10. The advertisement of medical devices and related product shall be in accordance with the Agency's extant Medical Devices and Related Product Advertisement Regulations issued by the Agency.

Storage, distribution, and display

11. Medical devices and related product shall be stored, distributed or displayed in accordance with conditions stated on the approved label and the Good Distribution Practice Regulations issued by the Agency.

Marketing surveillance for medical devices and related products

12.—(1) Manufacturers of medical devices and related products shall —

(*a*) carry out pre-market evaluation of the products to establish the quality, safety and performance prior to entry into the market; and

(*b*) submit pre-market evaluation report of the pre-market evaluation referred to in subregulation (1)(*a*) of this regulation, which shall accompany the application for registration of such products.

(2) Manufacturers of medical devices and related products shall —

(*a*) put a system in place and carry out Post-Market Surveillance (PMS) of the products; and

(*b*) include in the PMS system, the minimum requirement to monitor, collect, evaluate and react to feedback.

(3) Manufacturers and importers of medical devices and related products shall comply with the Agency's Regulation on Pharmacovigilance in compliance with subregulation (2) of this regulation.

(4) Importers, distributors and such authorised representatives shall put a system in place to report feedback from users to manufacturers and the Agency in compliance with regulation (2) of this regulation.

Disposal

13. A holder of Certificate of Registration and the user of medical devices 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.

Regulatory reliance

14.—(1) The Agency shall adopt regulatory reliance mechanisms in making regulatory decisions, where —

(*a*) the quality, safety and efficacy of medical devices and related product have been confirmed;

(*b*) any of the phases of a performance evaluation has been initiated or approved in a jurisdiction with a well-resourced regulatory Agent; or

(*c*) the National Regulatory Authority (NRA) is a WHO listed Authority or a harmonised regional economic group with Maturity Level 3 (ML3) competent body.

(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.

Power to seal premises

15. 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 III — LABELLING OF MEDICAL DEVICES AND RELATED PRODUCT

Labelling information

16.—(1) Information required to be indicated on the label of medical device 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 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 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 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 location 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 and related product;

(*j*) storage conditions; and

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

(4) Notwithstanding the provisions of subregulation (8) of this regulation, a medical device and related product in a container having inadequate space shall indicate the —

(*a*) brand name, where applicable;

(*b*) product statement of identity;

(*c*) lot or batch number;

(*d*) net content and net weight;

(*e*) expiry date, where applicable;

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

(*g*) registration number assigned by the Agency in the manner prescribed.

(5) Where a medical device 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 and related product shall be affixed in a manner that is not removable from the medical device 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 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 and related product shall be substantiated.

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

(11) The Agency may require any other information as may be necessary.

Expiry Date

17.—(1) Medical devices and related product label shall indicate the expiry date of the product as prescribed in regulation 17(3) and (4) of this Regulations.

(2) Notwithstanding regulation 4(1) of these Regulation for Medical devices and related product for continuous use, the expiry date shall suffice.

Name and address of Manufacturer, Holder of Certificate of Registration, Packer on label

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

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

(5) Where a medical device and related product undergoes any processing which does not affect its contents in another country, 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 and related product shall be complete on the label of all packaging components, that is primary, secondary and tertiary, where applicable, unless the immediate container of the medical device and related product is inadequate, in which case the address needs not be shown on the primary label.

Product identification

19.—(1) A trademark and brand name —

(*a*) shall be displayed on the label without giving a wrong impression of the nature or quality of the medical devices and related product;

(*b*) shall not be in conflict with any Regulations or requirements of the Agency, but where it does, the latter shall supersede and prevail; and

(*c*) of a medical device and related product shall not be a sound or look alike to an already registered medical device or related product

(2) Statement of identity label of a medical device and related product, shall —

(*a*) shall bear the name of the medical device or related product and indicate the accurate nature of the medical device or related product;

(*b*) where a common name or statement of identity has been established for the medical device 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 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 and related product, the name shall not be misleading and be accompanied by an appropriate descriptive term.

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

(*c*) to be used as internationally recognized Symbols, Unique Device Identification (UDI), QR Code or barcode, electronic labelling as applicable.

Composition or components

20.—(1) A complete list of composition or components of the medical device 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 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 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 the Agency's extant Labelling Regulations.

(7) Where a composition or components of a medical device 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.

Date marking instructions

21.—(1) The date marking shall be stated for medical device and related product and indicated on the packaging components, where present.

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

Storage condition

22. The required storage condition shall be specified on the packaging components where applicable.

Registration number assigned by the Agency

23.—(1) The packaging component of a medical device 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 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 primary package is a Trade Item, NAFDAC REG. NO shall be assigned to the primary package.

Instruction for use

24. Instruction for use shall be included on the label to ensure correct utilisation of the medical device or related product.

Warnings and cautions

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

Displayed information, etc.

26.—(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.

Net content

27.—(1) The accurate average net content or net weight of medical device and related product shall be declared on the inner and outer label in the metric system.

(2) Medical device and related product that have only inner label shall meet the same requirements as those for the outer label of products having both an outer and inner label.

Part IV —Advertisement of Medical Device and Related Products

Application for the approval of advertisement

28.—(1) Advertisement materials including scripts, story-boards, 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 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 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 and related products to the Nigerian market, for new products;

(*g*) information about any previous advertisement of the medical devices 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 and related products;

(*k*) scripts and recordings; and

(*l*) such other materials as may be required by the Agency from time to time.

Labelling Information

29. Medical devices and related products for advertisement shall be labelled in accordance with these Regulations.

Nature of advertisement

30.—(1) Advertisements of medical devices 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.

Non-referential advertisement

31. Advertisement of medical devices and related products shall not —

(*a*) imitate the general layout, text, slogan or visual presentation of another medical device 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 and related products.

Validity of approval

32.—(1) An approval for advertisement of medical device 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 subregulation (1) of this regulation, consumer promotions shall have validity period of 15 weeks.

Alteration in approved Advertisement material

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

Withdrawal of approval within the validity period

34. 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.

Reference to professional bodies or associations, etc.

35. Advertisement of medical device 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.

Advertisement not to prejudice public confidence

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

Accurate interpretation of research findings

37.—(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.

Scientific articles and literature

38.—(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 as cientific article or series of articles, which emphasise only the positive features while ignoring negative findings, shall not be acceptable.

Contravention of ethical standards

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

Unfairly disparage competition

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

Claims

Restrictions

41.—(1) Advertisement for medical device and related product shall not state, imply in absolute terms or by quotations taken out of context, that any medical device or 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 and related product of choice", or any such statements, for a medical device 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 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 and related products.

(5) "Duration of action" claims in medical device 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 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.

Restrictions

42.—(1) Advertisement of a medical device 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 and related product;

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

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

(2) Medical device or 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 or 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 or related products.

Prohibition of misleading comparison

43.—(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.

Labelling advertisement for medical devices or related product

44. Medical devices 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.

Accurate interpretation of research findings for Medical Devices and related products advertisement

45.—(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 and related product shall be provided to the Agency for verification.

Product launch and press release for medical devices and related products

46.—(1) The material approved by the Agency for medical devices 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.

Prohibition

47.—(1) Medical devices and related products shall not be manufactured, imported, exported, distributed, advertised, sold, or used in Nigeria except it has been registered in accordance with the provisions of these Regulations.

(2) Notwithstanding the provisions of subregulation (1) of this regulation, the Agency may grant a permit for the importation or manufacturing of sample of medical devices and related products registration for the purpose of —

(*a*) registration;
(*b*) service medical devices
(*c*) performance evaluation studies;
(*d*) research;
(*e*) use in emergency situation; or
(*f*) donation for humanitarian interventions.

(3) The importation or manufacture of medical devices and related products for the purpose listed in subregulation (2) of this regulation, shall be in accordance with the conditions specified on the permit.

(4) A person shall not manufacture, import, export, distribute, sell, advertise, display for sale, or use a medical device and related product, except it is labelled in accordance with the provisions of these Regulations.

(5) A person shall not display, screen or present an advertisement of a medical device or related product except in accordance with the provisions of these Regulations.

(6) A person to whom a Certificate of Registration has been issued under these Regulations shall not lend, hire, sell, transfer, or otherwise dispose of the Certificate of Registration to any other person without the approval of the Agency.

Part V —Offences and Penalties

Offences and penalties

48.—(1) Any person who contravenes any of the provisions of these Regulations commits an offence and is 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 ₦800,000 or to both; and
(*b*) a body corporate, to a fine not exceeding ₦5,000, 000.

(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 is liable to be proceeded against and punished in the same manner as if the person committed the offence, unless the person proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

Forfeiture after conviction

49.—(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.

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

PART VI — MISCELLANEOUS

Enforcement of these Regulations

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

Interpretation

51. In these regulations —

"*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 sponsor, which is used to encourage, persuade or manipulate an audience (viewers, readers or listeners), to continue with or take some new action;

"*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, bill boards, 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;

"*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;

"*Agency*" means the National Agency for Food and Drug Administration and Control;

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

"*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;

"*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;

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

"*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;

"*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, stencilled, 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;

"*Manufacturer*" 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;

"*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 or contrivance (including components, parts and accessories thereof) manufactured, sold or advertised for internal or external use in the diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical state or the symptom thereof, in man or in animal;

"*Medical device*" also means any instrument, apparatus, implement, machine, appliance, implant, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings or animals, for one or more of the specific medical purpose of —

(*a*) diagnosis, prevention, monitoring, treatment or alleviation of disease,

(*b*) diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

(*c*) investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life,

(*d*) control of conception, and

(*e*) disinfection of medical devices ;

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 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;

"*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;

"*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.

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

"*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.

Citation

52. These Regulations shall be cited as the NAFDAC Medical Devices and Related Products (Registration, Labelling, Advertisement) Regulations, 2024.

FIRST SCHEDULE

Rules for Classification of Medical Devices

S/N	*Type of Device*	*Rule*	*Class*	*Illustration*
1.	Non-Invasive Devices	Rule 1	All non-invasive devices which come into contact with injured skin :	Devices covered by this rule are extremely claim sensitive
			- are in Class A if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates only, *i.e*., they heal by primary intent	Examples : bandages; cotton wool
			- are in Class B if they are intended to be used principally with wounds which have breached the dermis, including devices principally intended to manage the microenvironment of a wound.	Examples : non-medicated impregnated gauze, dressings.
			Unless they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent, in which case they are in Class C.	Devices used to treat wounds, where the subcutaneous tissue is as least partially exposed and the edges of the wound are not sufficiently close to be pulled together. To close the wound, new tissue must be formed within the wound prior to external closure. The device manufacturer claims that they promote healing through physical methods other than 'primary intent'. Example : dressings for chronic ulcerated wounds; dressings for severe burns.
		Rule 2	(*a*) All non-invasive devices intended for channeling or storing liquids, or gases for the purpose of eventual infusion, administration or Introduction into the body are in Class A unless they may be connected to an active medical device in Class B or a higher class, in which case they are Class B;	Such devices are 'indirectly invasive' in that they channel or store liquids that will eventually be delivered into the body. Examples : administration sets for gravity infusion; syringes without needles.

S/N	*Type of Device*	*Rule*	*Class*	*Illustration*
				Examples : syringes and administration sets for infusion pumps; anaesthesia breathing circuits. NOTE: "Connection" to an active device covers those circumstances where the safety and performance of the active device is influenced by the non-active device and vice versa.
			(*b*) All non-invasive devices intended to be used for - • channeling blood, or • storing or channeling other body liquids, or • storing organs, parts of organs or body tissues, for the purpose of eventual infusion, administration or introduction into the body are Class B	Examples: tubes used for blood transfusion, organ storage containers.
			Unless they are blood bags, in which case they are Class C.	Example: Blood bags that do not incorporate an anti-coagulant. NOTE: In some jurisdictions, blood bags have a special rule that places them within a different class.
		Rule 3	All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids, or other liquids, intended for infusion into the body are in Class C.	Such devices are 'indirectly invasive' in that they treat or modify substances that will eventually be delivered into the body. They are normally used in conjunction with an active device within the scope of either Rule 9 or 11. Examples : hemodialyzers - devices to remove white blood cells from whole blood.
				NOTE: For the purpose of this part of the rule, 'modification' does not include simple, mechanical filtration or centrifuging which are covered below.

S/N	*Type of Device*	*Rule*	*Class*	*Illustration*
			unless the treatment consists of filtration, centrifuging or exchanges of gas or of heat, in which case they are in Class B.	Examples: devices to remove carbon dioxide; particulate filters in an extracorporeal circulation system
		Rule 4	All other non-invasive devices are in Class A	These devices either do not touch the patient or contact intact skin only. Examples: urine collection bottles; compression hosiery; non-invasive lectrodes, hospital beds.
2.	Invassive Devices	Rule 5	All invasive devices with respect to body orifices (other than those which are surgically invasive) and which : • are not intended for connection to an active medical device, or • are intended for connection to a Class A medical device only.	Such devices are invasive in body orifices and are not surgically invasive. Devices tend to be diagnostic and therapeutic instruments used in ENT, ophthalmology, dentistry, proctology, urology and gynaecology. Classification depends on the duration of use and the sensitivity (or vulnerability) of the orifice to such invasion.
			are in Class A if they are intended for transient use;	Examples: - examination gloves; enema devices.
			are in Class B if they are intended for short-term use;	Examples: urinary catheters, tracheal tubes.
			unless they are intended for short-term use in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class A,	Examples: dressings for nose bleeds.
			are in Class C if they are intended for long-term use;	Example: urethral stent; contact lenses for long-term continuous use (for this device, removal of the lens for cleaning is considered as part of the continuous use)

S/N	*Type of Device*	*Rule*	*Class*	*Illustration*
			unless they are intended for long-term use in the oral cavity as far as the pharynx, in an ear canal up to the eardrum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class B.	Examples: or a higher class, are in Class B. orthodontic materials, removable dental prosthesis.
			All invasive devices with respect to body orifices (other than those which are surgically invasive) that are intended to be connected to an active medical device in Class B	Examples: tracheal tubes connected to a ventilator; suction catheters for stomach drainage; dental aspirator tips. NOTE: Independent of the time for which they are invasive.
		Rule 6	All surgically invasive devices intended for transient use are in Class B.	A majority of such devices fall into several major groups: those that create a conduit through the skin (e.g., syringe needles; lancets), surgical instruments (e.g. single- use scalpels; surgical staplers; single-use aortic punch); surgical gloves; and various types of catheter/ sucker etc.
			unless they are reusable surgical instruments, in which case they are in Class A; or	Examples: Manually operated surgical drill bits and saws NOTE: A surgical instrument connected to an active device is in a higher class than A.
			unless intended to supply energy in the form of ionizing radiation, in which case they are in Class C ; or	Example: catheter containing sealed radioisotopes.
			unless intended to have a biological effect or be wholly or mainly absorbed, in which case they are in Class C; or	NOTES: (*a*) The 'biological effect' referred to is an intended one rather than unintentional. The term 'absorption' refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body.

S/N	*Type of Device*	*Rule*	*Class*	*Illustration*
				(*b*) This part of the rule does not apply to those substances that are excreted without modification from the body. Example: Insufflation gases for the abdominal cavity.
			unless intended to administer medicinal products by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which they are in Class C; or	Example: insulin pen for self-administration. NOTE: The term 'administration of medicines' implies storage and/or influencing the rate/volume of medicine delivered not just channelling. The term 'potentially hazardous manner' refers to the characteristics of the device and not the competence of the user.
			unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D; or	Example: spinal needle
			unless intended specifically to diagnose, monitor, or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.	Examples: angioplasty balloon catheters and related guide wires; dedicated disposable cardiovascular surgical instruments.
		Rule 7	All surgically invasive devices intended for short-term use are in Class B,	Such devices are mostly used in the context of surgery or post-operative care, or are infusion devices, or are catheters of various types. Examples: infusion cannulas; temporary filling materials; non-absorbable skin closure devices; tissue stabilisers used in cardiac surgery. NOTE: Includes devices that are used during cardiac surgery but do not monitor or correct a defect.

S/N	*Type of Device*	*Rule*	*Class*	*Illustration*
			unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class C; or in which case they are in Class C; or	Example : surgical adhesive.
			unless they are intended to supply energy in the form of ionizing radiation, in which case they are in Class C; or	Example : brachytherapy device.
			unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; or	Example: NOTE: The 'biological effect' referred to is an intended one rather than unintentional. The term 'absorption' refers to the degradation of a material within the body and the metabolic elimination of the resulting degradation products from the body.
			unless they are intended specifically for use in direct contact with the central nervous system, in which case they are in Class D;	Example: neurological catheter.
			unless they are intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class D.	Examples: cardiovascular catheters; temporary pacemaker leads; carotid artery shunts.
		Rule 8	All implantable devices, and long-term surgically invasive devices, are in Class C,	Most of the devices covered by this rule are implants used in the orthopaedic, dental, ophthalmic, and cardiovascular fields. Example: maxilla-facial implants; bone plates and screws; bone cement; non-absorbable internal sutures; posts to secure teeth to the mandibula bone (without a bioactive coating).

S/N	*Type of Device*	*Rule*	*Class*	*Illustration*
			unless they are intended to be placed into the teeth or on prepared tooth structure, in which case they are in Class B; or	Examples materials for inlays, crowns, and bridges; dental filling materials.
			: unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D; or	Examples: prosthetic heart valves; cardiovascular stents; pacemaker leads and electrodes; deep brain stimulation electrodes; cerebrospinal catheter.
			unless they are intended to be life supporting or life sustaining, in which case they are in Class D; or	
			unless they are intended to be active implantable medical devices, in which case they are Class D; or	Example: pacemakers; implantable defibrillators.
			unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; or	Example: implants claimed to be bioactive. NOTE: Hydroxy apatite is considered as having biological effect only if so claimed and demonstrated by the manufacturer.
			unless they are intended to administer medicinal products, in which case they are in Class D; or	Example: subcutaneous infusion ports for long term use.
			unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class D; or	Example: surgical adhesives intended for long term use. NOTE: Bone cement is not within the scope of the term 'chemical change in the body' since any change takes place in the short rather than long term
			unless they are breast implants, in which case they are in Class D.	
3.	Invassive Devices	Rule 9	All active therapeutic devices intended to administer or exchange energy are in Class B	Such devices are mostly electrically powered equipment used in surgery; devices for specialised treatment and some stimulators.

S/N	*Type of Device*	*Rule*	*Class*	*Illustration*
				Examples: muscle stimulators; powered dental hand pieces; hearing aids; neonatal phototherapy equipment; ultrasound equipment for physiotherapy
			unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, including ionizing radiation, taking account of the nature, the density and site of application of the energy, in which case they are in Class C.	Examples: lung ventilators; baby incubators; electro-surgical generators; external pacemakers and defibrillators; surgical lasers; lithotripters; therapeutic X- ray and other sources of ionizing radiation NOTE: The term 'potentially hazardous' refers to the type of technology involved and the intended application.
			All active devices intended to control or monitor the performance of active therapeutic devices in Class C, or intended directly to influence the performance of such devices, are in Class C.	Examples: external feedback systems for active therapeutic devices.
		Rule 10	Active devices intended for diagnosis are in Class B:	Such devices include equip-ment for ultrasonic diagnosis/ imaging, capture of physiolo-gical signals.
			if they are intended to supply energy which will be absorbed by the human body (except for devices used solely to illuminate the patient's body, with light in the visible or near infra-red spectrum, in which case they are Class A), or	Examples: magnetic resonance equipment; diagnostic ultrasound in non-critical applications; evoked response stimulators.
			if they are intended to image in vivo distribution of radiopharmaceuticals, or	Example: gamma/nuclear cameras.
			if they are intended to allow direct diagnosis or monitoring of vital physiological processes,	Example: electronic thermometers, stethoscopes and blood pressure monitors; electrocardiographs.

S/N	*Type of Device*	*Rule*	*Class*	*Illustration*
			unless they are specifically intended for: monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of central nervous system, or	Example: monitors/alarms for intensive care; biological sensors; oxygen saturation monitors; apnoea monitors. Example: ultrasound equipment for use in interventional cardiac procedures.
			(*b*) diagnosing in clinical situations where the patient is in immediate danger, in which case they are in Class C.	
			Active devices intended to emit ionizing radiation and intended for diagnostic and/or interventional radiology, including devices which control or monitor such devices, or those which directly influence their performance, are in Class C.	Example: devices for the control, monitoring or influencing of the emission of ionizing radiation.
		Rule 11	All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are in Class B.	Such devices are mostly drug delivery systems or anaesthesia equipment. Examples: suction equipment; feeding pumps; jet injectors for vaccination; nebuliser to be used on conscious and spontaneously breathing patients where failure to deliver the appropriate dosage characteristics is not potentially hazardous.
			unless this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode and route of administration, in which case they are in Class C.	Examples: infusion pumps; anaesthesia equipment; dialysis equipment; hyperbaric chambers; nebuliser where the failure to deliver the appropriate dosage characteristics could be hazardous

S/N	*Type of Device*	*Rule*	*Class*	*Illustration*
		Rule 12	All other active devices are in Class A.	Examples: examination lamps; surgical microscopes; powered hospital beds & wheelchairs; powered equipment for the recording, processing, viewing of diagnostic images; dental curing lights.
4.	Additional Rules	Rule 13	All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, and which is liable to act on the human body with action ancillary to that of the devices, are in Class D.	These medical devices incorporate medicinal substances in an ancillary role. Examples NOTE: In some jurisdictions such products: antibiotic bone cements; heparin coated catheters; wound dressings incorporating antimicrobial agents to provide ancillary action on the wound; blood bags incorporating an anticoagulant. - are considered to be outside the scope of the medical device definition; - may be subject to different controls.
		Rule 14	All devices manufactured from or incorporating animal or human cells/tissues/derivatives thereof, whether viable or non-viable, are in Class D,	Example: porcine heart valves. NOTE: In some jurisdictions such products: - are considered to be outside the scope of the medical device definition; - may be subject to different controls
			unless such devices are manufactured from or incorporate non-viable animal tissues or their derivatives that come in contact with intact skin only in which case, they are in Class A.	Examples: leather components of orthopaedic appliances.
		Rule 15	All devices intended specifically to be used for sterilising or disinfecting medical devices are in Class B.	Example: desk-top sterilisers for use with dental instruments.

S/N	*Type of Device*	*Rule*	*Class*	*Illustration*
			unless they are disinfectant solutions or washer- disinfectors intended specifically for invasive medical devices, as the end point of processing, in which case they are in Class C; or unless they are intended to clean medical devices by means of physical action only, in which case they are in Class A.	Examples: washer-disinfector equipment specifically for disinfecting an endoscope or another invasive device. solutions intended to be used for the disinfection of medical devices without further processing (for example in a steriliser) including those where the infective agent is a prion;
		Rule 16	All devices that are intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in Class C.	NOTE: In some jurisdictions such products: - are considered to be outside the scope of the medical device definition; - may be subject to different controls.
				Examples: condoms; contra-ceptive diaphragms.
				Example: intrauterine contra-ceptive device.

SECOND SCHEDULE

Rules for Classification of Medical Devices

S/N	*Class/ Level of Risk*	*Rule*	*Class*	*Illustration*
1.	A Low Individual Risk and Low Public Health Risk	Reagents or other articles which possess specific characteristics, intended by the manufacturer to make them suitable for in vitro diagnostic procedures related to a specific examination. Instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures. Specimen receptacles	The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: these devices present a low individual risk and no or minimal public health risk.	Selective/ differential microbiological media (excluding the dehydrated powders which are considered not to be a finished medical device), identification kits for cultured microorganisms, wash solutions, instruments, and plain urine cup
2.	Class B Moderate Individual Risk and/or Low Public Health Risk	These are medical device) (IVD) not covered by other Rules	The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: These devices present a moderate individual risk as they are not likely to lead to an erroneous result that would cause death or severe disability, have a major negative impact on patient outcome or put the individual in immediate danger. The devices give results that are usually one of several determinants. If the test result is the sole determinant however other information is available, such as presenting signs and symptoms or other	Blood gases, H. pylori and physiological markers such as hormones, vitamins, enzymes, metabolic markers, specific IgE assays and celiac disease markers.

S/N	*Class/ Level of Risk*	*Rule*	*Class*	*Illustration*
			clinical information which may guide a physician, such that classification into Class B may be justified. Other appropriate controls may also be in place to validate the results. This Class also includes those devices that present a low public health risk because they detect infectious agents that are not easily propagated in a population.	
		Medical devices that are controls without a quantitative or qualitative assigned value.	For such controls, the qualitative or quantitative value is assigned by the user and not the manufacturer.	
3.	Class C High Individual Risk and/ or Moderate Public Health Risk	Medical devices that are intended for use: in detecting the presence of, or exposure to, a sexually transmitted agent. Examples: Sexually transmitted diseases, such as Chlamydia trachomatis, Neisseria gonorrhoeae. in detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation. Examples: Neisseria meningitidis or Cryptococcus neoformans. in detecting the presence of an infectious agent where there is a significant risk that an erroneous result would cause death or severe disability to the individual or fetus being tested.	The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: Devices in this. Class present a moderate public health risk, or a high individual risk, where an erroneous result would put the patient in an imminent life-threatening situation, or would have a major negative impact on outcome. The devices provide the critical, or sole, determinant for the correct diagnosis. They may also present a high individual risk because of the stress and anxiety resulting from the information and the nature of the possible follow-up measures.	

S/N	*Class/ Level of Risk*	*Rule*	*Class*	*Illustration*
		Examples: diagnostic assay for CMV, Chlamydia pneumoniae, Methicillin-Resistant Staphylococcus aureus. in pre-natal screening of women in order to determine their immune status towards transmissible agents. Examples: Immune status tests for Rubella or Toxoplasmosis. in determining infective disease status or immune status, and where there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life- threatening situation for the patient. Examples: Enteroviruses, CMV and HSV in transplant patients. in screening for selection of patients for selective therapy and management, or for or for disease staging, or in the diagnosis of cancer. Example: personalized medicine. NOTE: Those medical devices where the therapy decision would usually be made only after further investigation and those used for monitoring would fall into class B under rule 6. in human genetic testing. Examples: Huntington's Disease, Cystic Fibrosis. to monitor levels of medicines, substances or		

S/N	*Class/ Level of Risk*	*Rule*	*Class*	*Illustration*
		biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an immediate life- threatening situation for the patient. Examples: Cardiac markers, Cyclosporin, Prothrombin time testing. In the management of patients suffering from a life-threatening infectious disease. Examples: HCV viral load, HIV Viral Load and HIV and HCV geno- and subtyping. In screening for congenital disorders in the fetus. Examples: Spina Bifida or Down Syndrome. Also medical devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibi- lity of blood, blood components, cells, tissue or organs that are intended for transfusion or trans- plantation belong to here.		
	Class D High Individua l Risk and High Public Health Risk	Medical devices include those intended for ABO system [A (ABO1), B (ABO2), AB (ABO3)], rhesus system [RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e)], Kell system [Kel1 (K)], Kidd system [JK1 (Jka), JK2 (Jkb)] and Duffy system [FY1 (Fya), FY2 (Fyb)].	The application of this rule as defined above should be in accordance with the rationale for this rule which is as follows: A high individual risk, where an erroneous result would put the patient in an imminent life-threatening situation places the device into Class D. The rule divides	HLA, Duffy system (other Duffy systems except those listed in the rule as Class D are in Class C).

S/N	*Class/ Level of Risk*	*Rule*	*Class*	*Illustration*
			blood grouping devices into two subsets, Class C or D, depending on the nature of the blood group antigen the medical device is designed to detect, and its importance in a transfusion setting.	
	Class D	Devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, blood derivatives, cells, tissues, or organs in order to assess their suitability for transfusion or trans-plantation, or Devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening, often incurable, disease with a high risk of propagation	The application of this rule as defined above should be in accordance with the rationale that follows: Devices in this Class are intended to be used to ensure the safety of blood and blood components for transfusion and/or cells, tissues and organs for transplantation. In most cases, the result of the test is the major determinant as to whether the donation/ product will be used. Serious diseases are those that result in death or long-term disability, that are often incurable or require major therapeutic interventions and where an accurate diagnosis is vital to mitigate the public health impact of the condition.	Tests to detect infection by HIV, HCV, HBV, HTLV. This Rule applies to first-line assays, confirmatory assays, and supplemental assays.

MADE at Abuja this 16th day of October, 2024.

MUHAMMAD ALI PATE, CON
Coordinating Minister of Health and Social Welfare