NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

Medical Devices, In vitro Diagnostics and Related Products Registration Regulations 2024

CLOSED FOR COMMENTS; UNDERGOING GAZETTING

Medical Devices, In vitro Diagnostics and Related Products Registration Regulations 2024

Arrangement of Regulations

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (CAP N1 LFN 2004)

Medical Devices, In vitro Diagnostics and Related Products Registration Regulations 2024

Commencement [ ]

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by Sections 5 and 30 of the NAFDAC Act Cap N1 LFN 2004 and Section 12 of the Food, Drugs and Related Products (Registration, Etc.) Act Cap F33 LFN 2004 and of all the powers enabling it in that behalf, THE GOVERNING COUNCIL OF THE NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL with the approval of the Minister of Health hereby makes the following Regulations: -

1. **Application**
   These Regulations shall apply to registration of medical devices, in vitro diagnostics (IVDs) and related products manufactured, imported, exported, advertised, sold, distributed, or used in Nigeria.

2. **Classification of Medical Devices and Related Products**
   The classification of Medical Devices, In vitro Diagnostics, and related Products Registrationshall be as stated below with details in the First Schedule to this Regulations:-
   (1) 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 and related products belongs to more than one class, the class representing the higher risk shall apply.

3. **Classification of In vitro diagnostics**
   The classification of IVDs shall be as stated below with details in the Second Schedule to this Regulations:-
   (1) Class A is low individual risk and low public health risk,
   (2) Class B is low to moderate individual risk and/or low public health risk,
   (3) Class C is high individual risk and/or moderate public health risk,
   (4) Class D is high individual risk and high public health risk.

4. **Application for Registration**
   An application for registration of Medical Devices, In vitro Diagnostics and related Products shall be: - required for each single medical device, IVD or related product, a medical device group, medical device family or medical device system.
   (1) made by submitting a completed online application accompanied by relevant documents as the Agency may from time to time prescribe and shall:-

(a) contain the particulars and description of the medical device in respect of which the application is made including the :-
   (i.) name of the Medical Devices, In vitro Diagnostics, and related Products
   (ii.) class of the Medical Devices, In vitro Diagnostics and related Products
   (iii.)identification of the Medical Devices, In vitro Diagnostics and related Products
   (iv.) identification of Medical Devices, In vitro Diagnostics and related Products that is part of a system, test kit, medical device group, medical device family or medical device group family.

(b) be accompanied by such fee as the Agency may from time to time prescribe.

(2) Medical device, IVD or related product for submitted for registration under this Regulations shall be designed and manufactured to be safe and to perform its intended use for the duration of use

(3) The medical device, IVD or related product particulars and description shall be detailed enough to consist of all administrative and technical information in sufficient details as may be required to allow the Agency to make informed decision about the product.

(4) The Agency, in considering an application -
   (a) may request the applicant to supply 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 registered in Nigeria; and
   (c) may register the medical device in accordance with the provisions of Food, Drug and Related Products (Registration etc.) Act cap F33 LFN 2004

(5) The registration of a medical devices, in vitro diagnostics and related products under these Regulations shall, unless cancelled, be valid for a period of five years and may be renewed.

(6) The Agency shall, from time to time, publish the list of registered medical devices, in vitro diagnostics and related products on the Agency's official website, notifying the registration of Medical Devices and Related Products.

(7) The Agency may refuse an application for registration where:-
   (a) it is found that the method, facility or control used in the manufacture, processing, and packaging of the medical device 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 Agency's extant Medical Devices, In Vitro Diagnostics And Related Products Labelling Regulations .

(8) Any other requirement as the Agency may from time to time prescribe.

5. **Registration of novel devices**

The registration of novel devices shall be subject to a satisfactory performance evaluation study.

6. **Post-registration changes**

(1) Except as prescribed in these Regulations, no change shall be carried out on medical devices, in vitro diagnostics, and related products without notification to the Agency.

(2) Changes that impact the quality of the product shall require prior approval from 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 to be effected, the Holder of Certificate of Registration shall not distribute the medical devices, in vitro diagnostics and related products unless the:-

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

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

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

A person shall not disclose an information supplied to the Agency in pursuance of regulation 5 of these Regulations except: -

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

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

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

8. **Suspension or cancellation of Certificate of Registration**

(1) The Agency may suspend or cancel the registration of a medical device, in vitro diagnostic, and related product where:-

(a) the grounds on which the medical device, in vitro diagnostic and related product was registered was later found to be false or incomplete or the circumstances under which the medical device or related product was registered no longer exist;

(b) any of the conditions under which the medical device or related products was registered has been contravened;

(c) the 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, in vitro diagnostic and related product thereof is manufactured, assembled, or stored on behalf of the Holder of Certificate of Registration are not in compliance with the requirements of Good Manufacturing Practice (GMP), 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, in vitro diagnostic and related product is suspended or cancelled, the Agency shall order the withdrawal from circulation of that 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 regulations (1) (a) of this regulation, a Holder of Certificate of Registration shall notify the Agency of his 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.

9. **Labelling**
The labelling of a medical device, in vitro diagnostic and related product shall be in accordance with the Agency's extant Medical Devices, In vitro Diagnostics and related Products Registration Labelling Regulations.

10. **Advertisement**
The advertisement of medical device, in vitro diagnostic and related product shall be in accordance with the Agency's extant Medical Device, In Vitro Diagnostic and Related Product Advertisement Regulations.

11. **Issuance of Certificate of Registration**
(1) Where the Agency considers the application to be satisfactory and having met all the requirements prescribed by the Agency for registration, the applicant shall be issued with a Certificate of Registration.
(2) Where the application for registration is unsatisfactory, the applicant shall be informed in writing, stating the reasons for non-registration.

12. **Validity of Registration**
The registration of a medical device and related product under these Regulations shall, except cancelled, be valid for a period of five years or as may be prescribed by the Agency and may be renewed.

13. **Storage, distribution, and display:**
Medical Device, In Vitro Diagnostic and Related Product shall be stored, distributed or displayed in accordance with conditions stated on the approved label and the Agency's extant Good Distribution Practice Regulations.

14. **Disposal**
The Holder of Certificate of Registration and the user of Medical Devices, In vitro Diagnostics and related Products shall ensure that the disposal of expired, degraded or obsolete medical device, in vitro diagnostic and related product shall be carried out in a manner prescribed by the competent authority and under the supervision of the Agency.

15. **Regulatory reliance**
(1) The Agency shall adopt regulatory reliance mechanisms in making regulatory decisions where the quality, safety and efficacy of medical device, in vitro diagnostic and related product have been confirmed or where any of the phases of a performance evaluation has been initiated or approved in a jurisdiction with a well-resourced regulatory Agent or where the National Regulatory Authority (NRA) is a WHO listed Authority or where the product has been assessed by experts within a competent body.

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

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

16. **Power to Seal**
The Agency shall have power to seal up any premises used or being used in connection with any 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.

17. **Prohibition**
(1) Medical devices, in vitro diagnostics 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 regulation 1 of this regulation, the Agency may grant a permit for the importation or manufacturing of sample of Medical Devices, In vitro Diagnostics 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 a medical devices, in vitro diagnostics and related products for the purpose listed in regulation 2 of this regulation shall be in accordance with the conditions specified on the permit.
(4) 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.

18. **Offences & Penalties.**
(1) Any person who contravenes any of the provisions of these Regulations commits an offence and liable on conviction. In the case of: -
(a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding N800,000:00 or both,
(b) a body corporate, to a fine not exceeding N5,000, 000:00.
(2) Where an offence under these Regulations is committed by a body corporate, firm, or any other association of individuals, every: -
(a) director, manager, secretary or other similar officer of the body corporate;
(b) partner or officer of the firm;
(c) trustee of the body concerned;
(d) person concerned in the management of the affairs of the association; or
(e) person who was purporting to act in a capacity referred to in paragraphs (a) to (d) of this regulation, commits an offence and liable to be proceeded against and punished in the same

manner as if he had himself committed the offence, unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

(5) **Forfeiture after conviction**

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

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

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

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

(6) **Enforcement of these Regulations.**

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

(7) **Interpretation.**

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.

"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 any person or institution or company that applies formally to the Agency to obtain Certificate of Registration for a medical device.

'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 (IVD)**' 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.

"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 (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

'Manufacturer' means any natural or legal person with responsibility for the design and/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 and/or manufactured by that person, or on that person's behalf, by another person(s).

"**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, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings or animals, for one or more of the specific medical purpose(s) 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,
e. disinfection of medical devices,
f. providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

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

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

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

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

'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.

'Reagent' any chemical, biological or immunological component, solution or preparation intended by the manufacturer to be used as IVD.

"Service Medical Device" means medical device including In vitro diagnostic (IVD) that are not registered by the Agency and is required for certain or critical medical and health purpose for human beings and animals but which cannot be found in-country.

"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;

(8) **Citation.**
These Regulations shall be cited as the Medical Devices, In vitro Diagnostics and related Products Registration Regulations 2024.

MADE at Abuja this ……. day of …….2024.

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

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	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
			unless they may be connected to an active medical device in Class B or a higher class, in which case they are Class B;	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: haemodializers; 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.
			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 extracorporial 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 electrodes, hospital beds.
2.	Invasive 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)
			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	Examples: tracheal tubes connected to a ventilator; suction catheters for stomach drainage; dental aspirator tips.

			intended to be connected to an active medical device in Class B	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. (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 cannulae; 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.

			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).
			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.	Active 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. 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; electrosurgical generators; external pacemakers and defibrillators; surgical lasers; lithotriptors; 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 equipment for ultrasonic diagnosis/imaging, capture of physiological 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.
			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
		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; heparincoated 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	Examples: leather components of orthopaedic appliances.

			that come in contact with intact skin only in which case, they are in Class A.	
		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.
			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	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;
			unless they are intended to clean medical devices by means of physical action only, in which case they are in Class A.	
		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.
		Rule 17	All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class C	Examples: condoms; contraceptive diaphragms.
			unless they are implantable or long-term invasive devices, in which case they are in Class D.	Example: intrauterine contraceptive device.

Second Schedule

Rules for Classification of In vitro Diagnostics

S/N	Class/Level of Risk	Rule	Rationale	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 IVD 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 IVDs 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 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	Blood gases, *H. pylori* and physiological markers such as hormones, vitamins, enzymes, metabolic markers, specific IgE assays and celiac disease markers.

			that present a low public health risk because they detect infectious agents that are not easily propagated in a population.	
		IVD 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	IVD 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. Examples: diagnostic assay for CMV, *Chlamydia pneumoniae,* Methycillin 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.	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.	

		NOTE: those IVD 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 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, IVD medical devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation belong to here.		
	Class D High Individual Risk and High Public Health Risk	IVD 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 blood grouping devices into two subsets, Class C or D, depending on the nature of the blood group antigen the IVD medical device is designed to detect, and its importance in	HLA, Duffy system (other Duffy systems except those listed in the rule as Class D are in Class C).

			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 transplantation, 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.