DEPARTMENT OF HEALTH

NO. 3817 **25 August 2023**

MEDICINES AND RELATED SUBSTANCES ACT, 1965

GENERAL REGULATIONS MADE IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965): AMENDMENT

The Minister of Health intends, in terms of section 35 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) (the Act), and on the recommendation of the South African Health Products Regulatory Authority, to make the regulations in the Schedule.

Interested persons are invited to submit any substantiated comments or representations on the proposed regulations to the Director-General of Health, Private Bag X828, Pretoria, 0001 (for attention of the Director: Public Entities Governance; mihloti.mushwana@health.gov.za and paul.tsebe@health.gov.za), within three months of the date of publication of this notice.

DR M.J. PHAAHLA, MP
MINISTER OF HEALTH
DATE: 01/08/2023

SCHEDULE

ARRANGEMENT OF REGULATIONS

DEFINITIONS

1. In these Regulations a word or expression defined in the Act bears the meaning so assigned and unless the context otherwise indicates:-

"accessory" means an article intended specifically by its manufacturer to be used together with a particular medical device to enable or assist that device to be used in accordance with its intended use;

"adverse event" means any untoward medical occurrence or undesirable incident, that may occur in association with the use of a medical device which—

(a) does not necessarily have a causal relationship with its use; or

(b) may occur due to its malfunction, its deterioration of safety, quality or performance or an error of its use;

"as determined by the Authority" means as determined by the South African Health Products Regulatory Authority (SAHPRA) in a guideline as published from time to time;

"authorised representative" means a natural person, resident in the Republic of South Africa, who—

(a) has the written mandate to represent a manufacturer, distributor or wholesaler in the Republic; and

(b) acts on behalf of a manufacturer, distributor or wholesaler, in whose name the licence in terms of section 22C(1)(*b*) of the Act or certificate of registration is issued;

"batch number" means a unique number or combination of numbers, cyphers or letters allocated to a batch or a lot;

"biological substance" means a substance derived from a human, animal or a micro-organism;

"bonded warehouse" means a customs and excise warehouse licensed in terms of section 19 of the Customs and Excise Act, 1964 (Act No. 91 of 1964);

"Chief Executive Officer" means the Chief Executive Officer of the Authority as appointed in terms of section 3 of the Act;

"clinical trial" means a study in or on human or animal subjects undertaken to assess the safety or clinical performance of the medical device;

"clinical performance assessment" means a study undertaken to establish or confirm the clinical performance of an IVD;

"conformity assessment" means relevant testing, calibration, inspection or certification of a medical device or a quality management system;

"conformity assessment body" means a local or international body corporate or other legal entity, recognised by the Authority as competent to carry out conformity assessment;

"control number" means a number or combination of numbers, cyphers or letters allocated to a unique accessory;

"custom-made medical device" means a medical device specifically made in accordance with—

(a) a written order given by a person authorised to do so by virtue of his or her professional qualification; and

(b) specific design characteristics,

which is intended for the sole use of a particular user, and excludes mass-produced medical devices that only require adaptation to meet the specific requirements of an individual user;

"declaration of conformity" means the attestation of the authorised representative of a manufacturer or distributor that the—

(a) relevant quality management systems fulfil requirements as determined by the Authority; and

(b) medical devices concerned fulfil the essential principles;

"distributor" means a person licensed in terms of section 22C(1)(b) of the Act to import or export a medical device in its final form, wrapping and packaging and sell such medical device to a person other than a manufacturer or distributor;

"essential principles" means the requirements relating to the safety and performance characteristics of medical devices as determined by the Authority;

"expiry date" means the date up to which a medical device retains the properties stated on the label, which properties can change after the lapse of time, and after which date the medical device may not be sold to the public or used;

"family" means medical devices or IVDs 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, and excludes a group;

"group" means a medical device comprising a collection of medical devices such as a procedure pack, procedure tray, system, procedure or IVD kit, that are packaged together for a specific intended purpose and sold under a single name;

"health care provider" means a health care provider as defined in section 1 of the National Health Act, 2003 (Act No. 61 of 2003);

"health establishment" means a health establishment as defined in section 1 of the National Health Act, 2003 (Act No. 61 of 2003);

"holder of a certificate of registration" means a manufacturer or distributor in whose name a certificate of registration for a medical device has been granted and who is responsible for all aspects of the medical device, including performance, quality, safety and compliance with conditions of registration;

"identification number" means the number drawn from a—

(a) birth certificate, passport, valid driver's licence;
South African identification document; or any other relevant document issued by the Department of Home Affairs;

"implantable device" means a medical device, which is intended to—

(a) be totally introduced into the body;

(b) be partially introduced into the body through surgical intervention and intended to remain in place after the procedure for at least 30 days;

(c) replace an epithelial surface; or

(d) replace the surface of the eye by surgical intervention, and includes a medical device that is partially or wholly absorbed by the body;

"Instructions for use" means general and technical information to inform the user of the medical device's intended purpose, proper use and of any contra-indications, warnings or precautions to be taken, as provided for in regulations 7 and 8, written in a manner which is easy for the end user to understand;

"intended purpose" means the objective, or use for which a medical device is intended according to the data supplied by the manufacturer or distributor and approved by the Authority;

"ISO 13485" means the International Standard "Medical devices — Quality management systems — Requirements for regulatory purposes"; reference number ISO 13485;

"maintain" means the—

(a) service, repair and re-establishment of the function; or

(b) update of software or hardware,

of a medical device without significantly changing the performance or safety characteristics of a medical device; and "maintenance" has corresponding meanings;

"manufacture" means operations that include the design, purchasing of material, specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, releasing, installation, maintaining, reprocessing or refurbishing of a medical device, and includes the assembly of a collection of medical devices;

"manufacturer" means a person licensed in terms of section 22C(1)(b) of the Act to manufacture, import or export a medical device and sell such medical device to a licenced wholesaler or end user;

"model" means a number or combination of numbers, cyphers or letters allocated to a medical device;

"modification" in relation to a medical device means—

(a) any change in the purpose and the intended use of a medical device;

(b) any significant change in the safety profile or specifications of a medical device as determined by the Authority;

(c) a change in the materials used in manufacture of a medical device, the design of a medical device, including its performance characteristics, principles of operation and specifications of materials, energy source, software or accessories;

(d) any new or extended use of a medical device;

(e) any addition or deletion of a contra-indication of a medical device; or

(f) any change to the period used to establish the expiry date of a medical device

(g) where significant change may relate to—

(i) the manufacturing process;

(ii) the facility or equipment; and

(iii) the quality control measures used to control the quality and sterility of a medical device;

"nomenclature system code" means the code linked to the common generic description as per the Global Medical Device Nomenclature (GMDN) for medical devices having similar features, characteristics and intended use;

"original manufacturer" means the manufacturer responsible for the design and specification development of a medical device;

"point of care testing" means testing performed outside a laboratory environment by a health care provider or veterinarian; and includes near patient testing;

"radiation" means—

(a) electromagnetic or particle radiation capable of producing ions, directly or indirectly, while passing through matter; or

(b) energy in the form of electromagnetic waves or acoustic waves;

"refurbish" means the substantial rebuilding, re-equipping, reworking or restoring of the whole or part of a medical device, including the substantial updating or modification of software or hardware, which does not significantly change the performance, safety specifications and intended purpose of the medical device;

"research use only" ("RUO") means an IVD which is intended only for research or investigational use and which may not be used for clinical diagnostic purposes;

"reprocess" means the activity carried out on a used medical device to allow its safe re-use including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoration of the technical and functional safety of the medical device;

"SANAS" means the South African National Accreditation System (SANAS) established by section 3 of the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act, 2006 (Act No.19 of 2006);

"SANS 10386" means the South African National Standard "The care and use of animals for scientific purpose", reference number SANS 10386;

"serial number" means a unique number or combination of numbers, cyphers or letters allocated to a unique medical device or unique accessory to a medical device;

"single use" means one use of—

(a) a medical device on or by an individual; or

(b) an IVD on a sample;

"the Act" means the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965);

"user" means a person or organisation that uses a medical device;

"version number" means a number or combination of numbers, cyphers or letters allocated to unique medical device software; and

"wholesaler" means a person licensed in terms of section 22C(1)(b) of the Act to purchase a medical device from a manufacturer or a distributor, licensed in terms of section 22C(1)(b) of the Act, and sells such medical device as per section 22H of the Act.

IMPORTATION OF MEDICAL DEVICES INTO REPUBLIC

2. (1) A person may not import a medical device into the Republic except through one of the following ports of entry:

(a) Cape Town International Airport or harbour;

(b) Chief Dawid Stuurman International or Port Elizabeth harbour;

(c) King Shaka International Airport or Durban harbour; or

(d) OR Tambo International Airport.

(2) A used medical device, other than a medical device designated by the original manufacturer or as determined by the Authority for single use only, may be imported by a manufacturer for purposes of refurbishing or maintenance through ports of entry, as determined by the Authority, other than those stipulated in sub-regulation (1).

(3) A person may only import a medical device if that person—

(a) is licensed in terms of section 22C(1)(*b*) of the Act to import a medical device; and

(b) in the case of an unregistered medical device, is authorised by the Authority to import such unregistered medical device.

TRANSMISSION OF MEDICAL DEVICES THROUGH REPUBLIC

3. (1) A medical device that is transmitted through the Republic must—

(a) while stored in the Republic, be stored in a bonded warehouse which is licensed in terms of section 22C(1)(*b*) by the Authority to import or export medical devices; and

(b) not be manipulated while in the bonded warehouse unless authorised by the Authority.

(2) A bonded warehouse referred to in sub-regulation (1) must comply with—

(a) good distribution practice; and

(b) licence conditions as determined by the Authority.

CLASSIFICATION OF MEDICAL DEVICES

4. (1) Medical devices are classified by the Authority into the following classes:

(a) Class A - Low Risk;

(b) Class B - Low-moderate Risk;

(c) Class C - Moderate-high Risk; and

(d) Class D - High Risk,

where the risk relates to the patient, user or to public health.

(2) The Authority must determine the classification rules in guidelines published from time to time.

(3) The manufacturer or importer must classify a medical device in accordance with the classification rules as determined by the Authority.

(4) Where the classification of a medical device is inconclusive and places it in more than one class, or between classes, the Authority must place the medical device in the higher of the risk classes.

LABELLING OF MEDICAL DEVICES

5. (1) The label of each medical device must be in at least English and must appear—

(a) on the medical device itself or on the packaging thereof; and

(b) on the packaging of multiple medical devices.

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(2) The label of each medical device must contain the following particulars:

(a) the proprietary name and, where applicable, the model of the medical device;

(b) product description and intended use;

(c) the registration number of the medical device allocated in terms of section 15(5) of the Act;

(d) the name and physical address of the holder of a licence as per regulation 12(1)(*a*)(i) or 12(1)(*a*)(ii), where applicable;

(e) the name and physical address of the holder of the certificate of registration;

(f) where appropriate, an indication that the medical device contains or incorporates a scheduled or biological substance;

(g) the batch number or serial number, where applicable;

(h) for accessories, the serial number may be substituted with a control number and for software it may be substituted with a version number;

(i) the expiry date, where applicable;

(j) where there is no indication of the expiry date, the manufacturing date;

(k) an indication of any applicable special storage or handling conditions;

(l) if the medical device is supplied sterile, an indication of its sterile state and, where appropriate, the sterilisation method;

(m) where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these or other terms which accurately reflect the contents of the package;

(p) warnings or precautions, where applicable; and

(q) where appropriate an indication that the medical device is intended for—

(i) single use;

(ii) clinical trial or premarket clinical performance assessment study;

(iii) non-clinical research, teaching or testing purposes;

(iv) exhibition or appraisal purposes;

(v) *in vitro* diagnostic (IVD) use or laboratory-developed tests; and

(vi) where relevant, "for professional use only" or “near patient testing” or “point of care testing” or “self-testing” or “custom-made”.

(3) If a medical device has been reprocessed, the label must—

(a) identify the medical device as having been reprocessed; and

(b) state the name of the manufacturer responsible for the reprocessing thereof.

(4) If an IVD kit includes individual reagents and articles that may be made available as separate IVDs, such reagents and articles must comply with the requirements set out in sub-regulation (1).

INSTRUCTIONS FOR USE OF A MEDICAL DEVICE WHICH IS NOT AN IVD

6. (1) Instructions for the use of a medical device must—

(a) appear on or be attached to or packed with each medical device,

(b) be in at least the English language;

(c) be in type having a minimum legibility, as determined by the Authority; and

(d) contain the particulars specified in sub-regulation (3).

(2) Instructions for use of a Class A medical device may be included, where applicable as determined by the Authority.

(3) The instructions for use must contain the following information:

(a) the name and proprietary name of the medical device;

(b) the registration number of the medical device allocated in terms of section 15(5) of the Act;

(c) the—

(i) name and physical address of the holder of the licence as per regulation 12(1)(*a*)(i) or 12(1) (*a*)(ii);

(ii) name and physical address of the original manufacturer; and

(iii) name and physical address of the holder of the certificate of registration;

(d) where practical, the approved intended purpose of the medical device and where appropriate, the intended user;

(e) residual risks, contraindications and any expected and foreseeable side effects, including information to be conveyed to the patient in this regard;

(f) any specifications that the user may require in order to use the medical device appropriately, including but not limited to the degree of accuracy claimed in the case of a device with a measuring function;

(g) if the medical device contains, or incorporates, a scheduled substance or a biological substance, identification of that substance, as appropriate;

(h) details of any preparatory treatment or handling of the medical device required before it is ready for use including but not limited to sterilisation, final assembly or calibration;

(i) any requirements for—

(i) special facilities; or

(ii) special training or qualifications of the intended user or other person;

(j) the information needed to verify whether the medical device is properly installed and is ready to perform as intended by the manufacturer, together with, where relevant—

(i) details of the nature, and frequency of preventive and regular maintenance, and of any preparatory cleaning or disinfection;

(ii) identification of any consumable components and how to replace them;

(iii) information on any necessary calibration to ensure that the medical device operates properly and safely during its intended life span; and

(iv) methods of eliminating the risks encountered by persons involved in installing, calibrating or servicing medical devices;

(k) an indication of any special transport, storage or handling requirements;

(l) if the medical device is supplied sterile, instructions in the event of the sterile packaging being damaged before use;

(m) if the medical device is supplied non-sterile with the intention that is sterilised before use, the appropriated instruction for sterilisation;

(n) if the medical device is reusable, information—

(i) on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilisation; and

(ii) to identify when the medical device should no longer be reused including signs of material degradation or the maximum number of allowable reuses;

(o) if a medical device is intended for use together with other medical devices or general-purpose equipment—

(i) information to identify such medical devices or equipment, in order to obtain a safe combination; and

(ii) information on any known restrictions to combinations of medical devices and equipment;

(p) if the medical device emits hazardous, or potentially hazardous levels of radiation for medical purposes—

(i) detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation; and

(ii) the means of protecting the patient, user, or other person from unintended radiation during use of the medical device;

(q) information that allows the user and patient to be informed of warnings, precautions, measures to be taken and limitations of use regarding the medical device which information must cover, where appropriate—

(i) warnings, precautions and measures to be taken in the event of malfunction of the medical device or changes in its performance that may affect safety;

(ii) warnings, precautions and measures to be taken in regard to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;

(iii) warnings, precautions and measures to be taken in regard to the risks of interference posed by the reasonably foreseeable presence of the medical device during specific diagnostic investigations, evaluations, therapeutic treatment or use (e.g., electromagnetic interference emitted by the medical device affecting other equipment);

(iv) if the medical device administers a scheduled substance or a biological substance, any limitations or incompatibility in the choice of substance to be delivered;

(v) warnings, precautions and limitations related to any scheduled substance or biological substance that is incorporated into the medical device as an integral part of the medical device; and

(vi) precautions related to materials incorporated into the medical device that are potentially carcinogenic, mutagenic or toxic, or could result in sensitisation or allergic reaction of the patient, user or any other person;

(r) warnings and precautions to be taken related to the disposal of the medical device, its accessories and the consumables used with it, if any: provided that this information includes, where appropriate—

(i) infection or microbial hazards associated with a medical device which may include an implant which has been removed;

(ii) environmental hazards such as batteries or materials that emit potentially hazardous levels of radiation; and

(iii) physical hazards;

(s) for medical devices intended for use by a person who is not a health care provider, the circumstances when the user must consult with a health care provider or veterinarian;

(t) the date of issue or latest revision of the instructions for use; and

(u) appropriate service and maintenance instructions for the medical device and associated technical equipment, where applicable.

INSTRUCTION FOR USE OF IVD

7. (1) Instructions for the use of an IVD must—

(a) appear on or be attached to or packed with each IVD;

(b) be in at least the English language;

(c) be in type having a minimum legibility, as determined by the Authority; and

(d) contain the particulars specified in sub-regulation (3).

(2) Instructions for ~~the~~ use of a Class A IVD may be included where applicable as determined by the Authority.

(3) The instructions for use must contain the following:

(a) The name and proprietary name of the IVD;

(b) the registration number of the medical device allocated in terms of section 15(5) of the Act;

(c) the—

(i) name and physical address of the holder of the certificate of registration;

(ii) name and physical address of the licensee as per regulation 12(1)(*a*)(i) or 12(1)(*a*)(ii); and

(iii) name and physical address of the original manufacturer;

(d) the intended purpose, including but not limited to—

(i) what is detected;

(ii) the function of the IVD;

(iii) the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;

(iv) whether it is automated or not;

(v) whether it is qualitative or quantitative;

(vi) the type of specimens required (e.g., serum, plasma, whole blood, tissue biopsy, urine); and

(vii) testing population;

(e) an indication that it is for *in vitro* diagnostic use and, where relevant, for "professional use only", for "near patient testing", for "point of care", for "self-testing" or for "research use only";

(f) the intended user, as appropriate;

(g) the test principle;

(h) whether provided as an individual reagent or in a group with other appropriate articles, a description of—

(i) the reagent, calibrators, controls and appropriate articles;

(ii) any limitation upon the use of the reagent or the IVD kit, such as suitability for a dedicated instrument;

(iii) the composition of the reagent by nature and concentration of the active ingredients; and

(iv) A statement, where appropriate, that the medical device contains other ingredients which might influence the measurement;

(i) a list of materials provided and a list of special materials required but not provided;

(j) if intended for use together with other IVDs, medical devices, or general-purpose equipment—

(i) information to identify such IVDs, medical devices or equipment, in order to obtain a safe combination; and

(ii) information on any known restrictions to combinations of IVDs, medical devices and equipment;

(k) an indication of any special transport, storage and handling requirements;

(l) in use stability which may include the storage conditions, and shelf life following the first opening of the immediate container or primary packaging, together with the storage conditions and stability of working solutions, where relevant;

(m) if the IVD is supplied sterile, instructions in the event of the sterile packaging being damaged before use;

(n) information that allows the user to be informed of warnings, precautions, measures to be taken and limitations of use regarding the IVD, which information must cover, where appropriate—

(i) warnings, precautions and measures to be taken in the event of malfunction of the IVD or its degradation as suggested by changes in its appearance that may affect performance;

(ii) warnings, precautions and measures to be taken with regard to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;

(iii) warnings, precautions and measures to be taken with regard to the risks of interference posed by the reasonably foreseeable presence of the medical device during specific diagnostic investigations, evaluations, therapeutic treatment including electromagnetic interference emitted by such medical device affecting other equipment, where applicable; and

(iv) precautions related to materials incorporated into the IVD that are carcinogenic, mutagenic or toxic, or could result in sensitisation or allergic reaction;

(o) warnings and precautions related to potentially infectious material that is included in the IVD;

(p) where relevant, requirements for special facilities including clean room environment, radiation safety or particular qualifications of the medical device user;

(q) conditions for collection, handling, and preparation of the specimen;

(r) details of any preparatory treatment or handling of the IVD before it is ready for use including reconstitution and calibration where applicable;

(s) the information needed to verify whether the IVD is properly installed and is ready to perform as intended by the manufacturer, together with, where relevant—

(i) details of the nature, and frequency, of preventive and regular maintenance including cleaning and disinfection;

(ii) identification of any consumable components and how to replace them;

(iii) information on any necessary calibration to ensure that the IVD operates properly and safely during its intended life span; and

(iv) methods of mitigating the risks encountered by persons involved in installing, calibrating or servicing an IVD;

(t) where relevant, recommendations for quality control procedures;

(u) the metrological traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials and reference measurement procedures of higher order;

(v) assay procedure including calculations and interpretation of results and where relevant if any confirmatory testing must be considered;

(w) analytical performance characteristics, as determined by the Authority such as sensitivity, specificity, and accuracy

(x) where relevant, clinical performance characteristics, as determined by the Authority such as diagnostic sensitivity and diagnostic specificity;

(y) where relevant, reference intervals;

(z) information on interfering substances or limitations such as visual evidence of hyperlipidaemia or haemolysis, age of specimen that may affect the performance of the assay;

(aa) warnings or precautions to be taken related to the disposal of the IVD, its accessories, and the consumables used with it, if any, which information must cover, where appropriate—

(i) infection or microbial hazards;

(ii) environmental hazards; and

(iii) physical hazards;

(bb) for an IVD intended for use by a person who is not a health care provider, the circumstances when the user must consult with a health care provider or veterinarian;

(cc) where relevant, a bibliography;

(dd) the date of issue or latest revision of the instructions for use and, where appropriate, an identification number; and

(ee) appropriate maintenance instructions for technical IVD machines, where applicable.

APPLICATION FOR REGISTRATION OF A MEDICAL DEVICE

8. (1) An application for the registration of each type of medical device, family or group or modification thereof as determined by the Authority and published as a notice in the Government *Gazette*, must be made providing details of the class and type of medical device, family or group as the case may be.

(2) A manufacturer or distributor residing in the Republic must submit an application for the registration of a medical device on an application form obtainable from the Authority.

(3) The application referred to sub-regulation (1) must, include the particulars of the authorised representative in South Africa who must be responsible for communication with the Authority.

(4) The application contemplated in sub-regulation (1) must be accompanied by—

(a) the appropriate form which is obtainable from the Authority which has been completed by the applicant;

(b) a proposed label for use on the medical device, if applicable;

(c) the instructions for use of the medical device;

(d) a copy of the licence referred to in regulation12(1)(*a*)(i) or 12(1)(*a*)(ii);

(e) a certified copy of the

(i) certificate(s) issued by a conformity assessment body;

(ii) test result(s); or

(iii) inspection certification,

for the medical device for which the application is made, as determined by the Authority

(f) any other information as may be required by the Authority; and

(g) the applicable application fee.

(5) The information referred to in sub-regulation (4) must be submitted in English.

(6) The application form referred to in sub-regulation (1) must contain at least the following information:

(a) Particulars of the prospective holder of the certificate of registration, including:

(i) name;

(ii) physical address;

(iii) postal address;

(iv) telephone number;

(v) fax number, if applicable;

(vi) e-mail address, if applicable; and

(vii) contact details of the authorised representative referred to in sub-regulation (3); and

(b) particulars of the medical device, including—

(i) proposed proprietary name and group or family name, and make and model, where applicable;

(ii) intended purpose;

(iii) classification as per regulation 4;

(iv) classification and registration status with other regulatory authorities recognised by the Authority;

(v) nomenclature system code;

(vi) in the case of a medical device which contains a medical or scheduled substance, the approved name and quantity of each active ingredient or biological substance; and

(vii) the name and physical address of the original manufacturer.

(7) Where a medical device is registered with a regulatory body outside the Republic, the following information in respect of the medical device must also accompany the application:

(a) A certified copy of the certificate of registration, market authorisation or premarket approval, where applicable;

(b) instructions for use, where applicable;

(c) conditions of registration, where applicable; and

(d) any other information as may be required by the Authority.

(8) A medical device, in respect of which an application for registration is made, must comply with the essential principles.

(9) A declaration of conformity to the essential principles, signed by the Authorised Representative must accompany an application for registration of a medical device as determined by the Authority.

INFORMATION THAT MUST APPEAR IN REGISTER FOR MEDICAL DEVICES

9. The medical device register must, in respect of any registered medical device, contain the following information:

(a) the—

(i) name, group or family name; and

(ii) make and model, where applicable;

(b) the registration number allocated to the medical device;
(c) in the case of a medical device which contains a scheduled substance, the name and quantity of each scheduled substance;
(d) the name of the holder of the certificate of registration;
(e) the name of the licence holder referred to in regulation12(1)(*a*)(i) or 12(1)(*a*)(ii);
(f) the name and physical address of the—
(i) original manufacturer(s); and
(ii) manufacturing facilities;
(g) the date of registration of the medical device;
(h) the conditions of registration of the medical device;
(i) the class of medical device; and
(j) the nomenclature system code allocated to the medical device.

APPLICATION FOR AMENDMENT TO REGISTER FOR MEDICAL DEVICES

10. (1) An application for an amendment of an entry in the register for medical devices in terms of section 15A of the Act must be accompanied by the relevant fee and must contain the following particulars:
(a) the registration number of the medical device;
(b) the name of the holder of the certificate of registration and the authorised representative;
(c) physical address of the holder of the certificate of registration;
(d) declaration by the holder of the certificate of registration that the information furnished is complete and accurate;
(e) the details of the amendment applied for; and
(f) any other information as may be required by the Authority.

(2) Where the provisions of section 11(1) are approved, an amended certificate will be issued in terms of section 15A (3) of the Act.

CERTIFICATE OF REGISTRATION

11. A certificate of registration for a medical device as contemplated in section 15(3) of the Act shall be in a form substantially similar to the form contained in **Annexure 1**.

LICENCE TO MANUFACTURE, DISTRIBUTE OR WHOLESALE MEDICAL DEVICES

12. (1) An application for a licence referred to in section 22C(1)*(b)* of the Act, must—

(a) be made on a form obtainable from the Authority for a licence—
  (i) to act as a manufacturer;
  (ii) to act as a distributor; and
  (iii) to act as a wholesaler.

(b) be submitted to the Authority;

(c) be accompanied by documentary proof of—
  (i) the particulars of the owner of the business;
  (ii) the particulars of the authorised representative;
  (iii) certification by a conformity assessment body to ISO 13485 in the case of an application in terms of sub-regulation (1)*(a)*(i) or 1(*a*)(ii);
  (iv) the payment of the prescribed application fee;
  (v) the physical address of the site; and
  (vi) any other information as may be requested by the Authority; and

(d) specify the—
  (i) name, group or family name; and
  (ii) make and model, where applicable,
  of medical devices to be manufactured, imported, exported and sold.

(2) The applicant contemplated in sub-regulation (1) shall appoint and designate an authorised representative who shall be responsible to the Authority for compliance with the Act.

(3) The Authority may, where applicable, inspect the business premises specified in the application.

(4) The Authority may issue a licence contemplated in sub-regulation (1) once the Authority is satisfied that the requirements of the Act and the regulations have been complied with and the authorised representative is able to provide certified evidence of certification to a quality management system in terms of sub-regulation (12)*(1)*(c)(iii), and as determined by the Authority.

(5) The Chief Executive Officer shall—

(a) keep a separate register for each of the categories of licensees contemplated in section 22C(1)*(b)* of the Act; and

(b) enter the licence number, the name of the licensee and his or her physical and postal addresses, in the register contemplated in paragraph (*a*).

(6) Notwithstanding the period of validity of the licence, the licensee must pay the annual fee in respect of the retention of the licence.

(7) A holder of a licence in terms of sub-regulation (1) must submit to the Authority an application, on a form obtainable from the Authority, accompanied by the prescribed fee, in order to amend any of the following details of the licence:

(a) name of the licence holder;

(b) authorised representative;

(c) physical address of the site;

(d) activities provided for by the licence; or

(e) the medical devices to be manufactured or sold,

as determined by the Authority.

(8) Following receipt of an application referred to in sub-regulation (7) the Authority may issue a revised licence: Provided that—

(a) the Authority is satisfied that the application complies with the provisions of sub-regulation (1) or any other conditions determined by the Authority; and

(b) the applicable licence fee is paid.

(9) An applicant must notify the Authority in writing of any change to any of the particulars furnished in the application contemplated in sub-regulation (1) within 30 days of such change.

(10) Any entry into the register in terms of sub-regulation (5) which is proved to the satisfaction of the Authority to have been made in error or through misrepresentation or in circumstances not authorised by the Act, may be removed from the register.

(11) A person in respect of whose entry a removal as contemplated in sub-regulation (10) has been made shall be notified of such removal and any licence issued in respect of this regulation shall be deemed to be cancelled as from the date on which notice has so been given.

(12) The Chief Executive Officer may make known to the public any information that pertains to the suspension or revocation of any licence referred to in this regulation in a manner which he or she thinks fit.

PERIOD OF VALIDITY AND RENEWAL OF LICENCE

13. (1) A licence issued in terms of section 22C(1)(*b*) and referred to in regulation 12 must, provided that the holder pays the applicable annual fee, be valid for a period of five years from the date of issue.

(2) A licence referred to in sub-regulation (1) may be renewed by application to the Authority.

(3) An application for the renewal of a licence must—

(a) contain at least the information or documentation referred to in regulation 12(1)(*c*) and 12(1)(*d*);

(b) be accompanied by a prescribed fee in terms of section 35(1)(xxxii) of the Act; and

(c) be made at least 90 days before the expiry of the existing licence.

CONFORMITY ASSESSMENT BODY

14. (1) The Authority must determine the criteria and standards required for recognition of a conformity assessment body.

(2) The criteria in sub-regulation (1) must include—

(a) certification of the conformity assessment body either by SANAS or an international accreditation body; and

(b) any other information as determined by the Authority.

(3) The Authority must publish the name and physical address of a conformity assessment body recognised by the Authority.

REPLACEMENT, MAINTENANCE, REFURBISHMENT AND SINGLE USE OF MEDICAL DEVICES

15. (1) A person who sells an article intended specifically to replace an identical or similar integral part or component of a medical device must ensure that the article complies with specifications applicable to that medical device as defined by the original manufacturer or as determined by the Authority.

(2) Where an article in sub-regulation (1) significantly changes the performance or safety characteristics of the medical device, the medical device shall be considered to be a different medical device.

(3) A person who maintains a medical device must keep records of such maintenance and on request, make the records available to the Authority.

(4) A person who refurbishes a medical device must—

(a) ensure that any article used to replace an integral part or component of the medical device is consistent with specifications applicable to that medical device as defined by the original manufacturer;

(b) follow procedures as defined by the original manufacturer relating to the refurbishment of the medical device; and

(c) keep records of such refurbishment and on request, make the records available to the Authority.

SINGLE USE MEDICAL DEVICE

16. (1) A medical device designated by the original manufacturer or as determined by the Authority for single use only —

(a) must be disposed of after use; and

(b) may not be reprocessed.

(2) If the sterility of a medical device designated by the original manufacturer or as determined by the Authority for single use only, is compromised it—

(a must be disposed of before use and

(b) may not be reprocessed.

DESTRUCTION OF MEDICAL DEVICES

17. (1) A medical device may only be disposed into a municipal sewerage system conditional to meeting the requirements of the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008), municipal by-laws regulating sewerage systems and disposal and according to the instructions provided by the original manufacturer.

(2) The destruction or disposal of a medical device must be conducted in such a manner to ensure that the medical device cannot be salvaged or reprocessed.

(3) A medical device which contains a scheduled substance must only be destroyed by a waste treatment facility authorised in terms of the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008).

(4) A medical device which contains a scheduled substance shall be destroyed in accordance with the provisions of regulation 44 of the General Regulations made in terms of the Act (*Government Gazette* 41064, Government Notice 859) 2017 as amended.

(5) The waste treatment facility must issue a certificate and maintain a record of the destruction contemplated in sub-regulation (3) which shall contain the following information:

(a) the name of the medical device which contains a scheduled substance, if known; or and the schedule of the scheduled substance concerned;
(b) the quantity of the medical devices destroyed;
(c) the date of destruction of the medical device
(d) the name and designation of the person in whose presence such destruction took place; and
(e) any other information as determined by the Authority.

CONDUCT OF CLINICAL TRIAL OR CLINICAL PERFORMANCE ASSESSMENT

18. (1) A person desiring to initiate or conduct a—

(a) clinical trial in respect of a medical device; or
(b) clinical performance assessment in respect of an IVD,

must apply on an application form obtainable from the office of the Chief Executive Officer to the Authority for authorisation to conduct such a clinical trial or clinical performance assessment.

(2) The application referred to in sub-regulation (1) must be accompanied by the prescribed fee and must contain at least the following information:

(a) A clinical trial or clinical performance assessment protocol;

(b) an investigator's brochure containing, where applicable, relevant pre-clinical, mechanical, electrical and radiation data and where applicable, human or animal safety and performance clinical data about the medical device concerned;

(c) the curriculum vitae of the investigator;

(d) a signed declaration by the applicant and the investigator that they are familiar with, and understand the protocol, and will, in the conduct of the clinical trial, comply with Good Clinical Practice as determined by the Authority;

(e) participant information form and informed consent documents in the case of human trials or owner consent document in the case of animal trials;

(f) approval of the clinical trial and clinical performance assessment by—

(i) any health research ethics committee registered with the National Health Research Ethics Council in terms of the National Health Act, 2003 (Act No, 61 of 2003); or

(ii) in the case of research on animals, an Animal Ethics Committee, which must conform to SANS 10386; and

(g) the name and physical address of the institution where the clinical trial or clinical performance assessment will be conducted.

(3) The clinical trial or clinical performance assessment protocol referred to in sub-regulation (2)(*a*) must contain at least the following information:

(a) The number of human or animal subjects, as applicable, to be involved in the clinical trial or clinical performance assessment;

(b) the names of all the investigators who must be—

(i) appropriately qualified and competent persons;

(ii) resident in the Republic; and

(iii) in charge of the sites where clinical trials or clinical performance assessments are conducted;

(c) the quantity of the medical devices under investigation to be used in the clinical trial or clinical performance assessment;

(d) information in respect of the design, manufacture and expected performance of the medical device;

(e) proof of current training in Good Clinical Practice of all investigators;

(f) in the case of trials involving human participants, proof of current, relevant and appropriate-

(i) study insurance for all participants undertaken by the applicant referred to in sub-regulation (1);

(ii) professional indemnity insurance for investigators; and

(g) any other information determined by the Authority.

(4) A clinical trial or a clinical performance assessment must be conducted in accordance with the guidelines for good clinical practice determined by the Authority.

(5) A person may not conduct a clinical trial or a clinical performance assessment referred to in sub-regulation (1), without the authorisation of the Authority.

(6) The person conducting the clinical trial or clinical performance assessment must submit to the Authority—

(a) progress reports after every six months from the date when the clinical trial or clinical performance assessment was started, and 30 days after the completion or termination of the clinical trial or clinical performance assessment; and

(b) adverse event reports immediately or as soon as practically possible.

(7) The Authority may—

(a) request additional information;

(b) inspect the site of a clinical trial or clinical performance assessment; or

(c) withdraw the authorisation to conduct a clinical trial or clinical performance assessment, if the Authority is of the opinion–

(i) that the safety of the subjects of the clinical trial or clinical performance assessment is compromised; or

(ii) that the scientific reasons for conducting the clinical trial or clinical performance assessment, have changed.

(8) The following information for a medical device referred to in sub-regulation (1) must be provided, where applicable:

(a) The intended purpose of the medical device under investigation in the proposed clinical trial or clinical performance assessment;

(b) the populations and indications for which the medical device under investigation is intended;

(c) the name or number of the model or type, including software version and accessories, if any, to permit full identification; and

(d) a description as to how traceability is to be achieved during and after the clinical trial or clinical performance assessment such as by assignment of batch numbers, or serial numbers.

(9) The medical device under investigation must—

(a) where practical, be labelled with the name and physical address of the premises where the clinical trial or clinical performance assessment is to be carried out; and

(b) be labelled "for investigational use only".

(10) The Authority may, subject to such conditions as may be determined by the Authority, authorise the conduct of a clinical trial or clinical performance assessment and may require approval in terms of section 21 of the Act.

VIGILANCE

19. (1) A holder of a licence in terms of section 22C(1)(*b*) or a holder of a certificate of registration in respect of a medical device, must inform the Authority, in the manner and within the time frame as determined by the Authority, of any—

(a) new or existing quality, safety or performance concerns related to any medical device, including but not limited to adverse events; and

(b) risk management activities associated with paragraph (a).

(2) An authorised representative of a holder of a licence in terms of section 22C(1)(*b*) or a holder of a certificate of registration referred to in sub-regulation (1) must maintain or have access to records of the reports and case reports referred to in sub-regulation (1) above.

(3) A health care provider, veterinarian or any other person should inform the Authority, in the manner as determined by the Authority, of any—

(a) suspected adverse events; or

(b) new or existing safety, quality or performance concerns,

occurring as a result of the use of any medical device.

(4) Any person referred to in sub-regulation (1) must-

(a) whenever requested by the Authority, conduct a concise critical analysis of the safety, quality or performance of the medical device submit the results thereof to the Authority within a specified time frame;

(b) in the case where, after receipt of the results referred to in paragraph (*a*), the Authority determines that the medical device may not be safe to use, submit to the Authority, if required to do so—

(i) case reports of all suspected or actual adverse events in respect of the medical device;

(ii) where applicable the usage figures of the medical device, as well as periodic safety update reports and performance studies; and

(iii) any other data as requested by the Authority; and

(c) keep and maintain or have access to records of the adverse event data in respect of the medical device.

(5) Sub-regulations (1), (2) and (3) apply in the case of registered and unregistered medical devices sold or used.

(6) A user who becomes aware of an adverse event caused or suspected of being caused by a medical device during the process of using or conducting post-marketing surveillance, must report the event to the holder of a licence in terms of section 22C(1)(*b*), holder of a certificate of registration in respect of a medical device, the authorised representative or the Authority.

(7) Nothing in this regulation must be interpreted as prohibiting any person from reporting any adverse event, safety, quality or performance concern caused or suspected of being caused by a medical device.

A MEDICAL DEVICE THAT IS CUSTOM-MADE

20. (1) A medical device that is custom made may only be manufactured, imported or exported and sold in compliance with the guidelines as determined by the Authority.

RECORD OF CLASS D MEDICAL DEVICE, IMPLANTABLE CUSTOM-MADE MEDICAL DEVICE OR ACTIVE CUSTOM-MADE MEDICAL DEVICE

21. (1) A permanent record in respect of a Class D medical device, implantable custom-made medical device or an active custom-made medical device must be kept by the health establishment where such medical device is sold to the patient, and must contain the following information:

(a) the name and model of the medical device used;
(b) the nomenclature system code, where applicable;
(c) the name of the manufacturer of the medical device used;
(d) the batch number or serial number of the medical device used, where applicable;
(e) the expected life of the medical device used;
(f) the name, identification number and physical address of the patient;
(g) where applicable, the name of the user and, in the case of an implantable medical device, the person responsible for the implantation of the medical device;
(h) the name and physical address of the health establishment;
(i) the name of the designated health care provider or veterinarian; and
(j) the date of use of the medical device.

(2) The permanent record in terms of sub-regulation (1) must be retained by the health establishment or health care provider or veterinarian for a period of at least five years beyond the expected life of the medical device.

(3) In the case of a Class D medical device, implantable custom-made medical device or an active custom-made medical device a record must be kept and shall contain the following particulars:

(a) the date of sale;

(b) the name, make and model of the medical device;

(c) the name and physical address of every purchaser;

(d) the quantity sold; and

(e) the nomenclature system code, batch number, or serial number, where applicable.

(4) A record referred to in sub-regulation (3) must be kept–

(a) in the case of a Class D medical device by the holder of a licence in terms of section 22C(1)(*b*); or

(b) in the case of an implantable or an active custom-made medical device, by the person authorised by virtue of his or her professional qualification to order the manufacture of such medical device, for a period of fifty years from the date of sale.

(5) For the purposes of this regulation "active custom-made medical device" means any custom-made medical device for which the operation depends on a source of electrical energy or any source of power, other than that directly generated by the human body or gravity which acts by converting this energy.

ADVERTISING OF MEDICAL DEVICES

22. (1) A medical device may be advertised to a health care provider or veterinarian.

(2) A Class A and Class B medical device may be advertised to the public.

(3) A Class C and a Class D medical device may only be advertised to the public as determined by the Authority.

(4) An advertisement for a medical device may not contain a statement or claim which deviates from, is in conflict with or goes beyond—

(a) in the case of a registered medical device, evidence submitted in the application for registration of the medical device with regard to its safety, quality, or performance where the evidence has been—

(i) accepted by the Authority in respect of the medical device; and

(ii) incorporated into the approved instructions for use of the medical device; or

(b) in the case of an unregistered medical device, evidence available to meet the essential principles.

(5) An advertisement for a medical device must contain—

(a) the name of the medical device;

(b) the intended purpose of the medical device;

(c) any contra-indication or warning;

(d) in the case of a written advertisement—

(i) the class of the medical device;

(ii) the name of the licence holder in terms of Section 22C(1)(*b*), where applicable; and

(iii) in the case of a registered medical device, the name and physical address of the holder of the certificate of registration and the registration number allocated to the medical device; and

(e) in the case of a Class C or Class D medical device, written information including at least the information referred to in regulation 6 or regulation 7, as the case may be, must be available to the health care provider or veterinarian.

EXHIBITION OR APPRAISAL OF MEDICAL DEVICES

23. (1) A Medical device made available for exhibition or demonstration may not be used for clinical purposes and must be clearly labelled "***For exhibition / demonstration purposes only – Not for clinical use***"—

(a) on the medical device itself or on the packaging of each unit; and

(b) on the packaging of multiple medical devices.

(2) A medical device may be made available for appraisal which may include training on the use of the medical device, provided that—

(a) the quantity supplied is limited to the quantity required for the purpose of such appraisal;

(b) such medical device is made available only to a health care provider or veterinarian that is appropriately qualified and informed in order to use or direct the use of the medical device;

(c) the full instruction for use of the medical device is available;

(d) a record of the:

(i) name and make of the medical device and model of the medical device, as applicable;

(ii) name of the original manufacturer of the medical device;

(iii) classification of the medical device as per regulation 4;

(iii) nomenclature system code of the medical device;

(iv) batch number or serial number of the medical device;

(v) control number or version number of the accessory or software as applicable;

(vi) name and qualification of the health care provider or veterinarian who conducts the appraisal;

(vii) name of the health establishment or place where the appraisal is conducted;

(viii) date of appraisal of the medical device; and

(ix) a written report of the appraisal, is available; and

(e) any adverse event experienced during the appraisal of the medical device is reported to the Authority.

APPEAL AGAINST THE DECISION OF THE AUTHORITY

24. (1) An entity or person who is aggrieved by the decision or lack of decision of the Authority may according to section 24A (1) and (2) of the Act, lodge an appeal to the Chief Executive Officer.

(2) Such appeal shall be submitted to the Chief Executive Officer within 30

days of becoming aware of the Authority's decision: -

(a) The appellant must submit a letter of appeal regarding the Authority's decision on the company's letterhead (where it is applicable), and the letter should be accompanied by supporting documents/information where possible;

(b) The Chief Executive Officer must within 30 days of receipt of the appeal meet and hear the applicant's grievance or complaint, in the absence of legal representatives, to try and resolve the matter;

(c) The Chief Executive Officer shall consider the applicant's submission and take a decision;

(d) The Chief Executive Officer shall inform the applicant of the outcome of the appeal in writing; and

(e) The Chief Executive Officer may uphold or reject an appeal, and in the event the appeal is rejected, the Chief Executive Officer must provide the applicant with written reasons thereof.

(3) Should the Chief Executive Officer and the appellant fail to resolve the matter, Section 24A (3) of the Act, provides that the appellant shall within 30 days of being notified by the Chief Executive Officer of the failure to resolve the matter and upon payment of a prescribed fee, request the Minister in writing to convene an appeal committee in terms of Section 24A (3) of the Act.

(4) The appeal committee shall: -

(a) be appointed within 30 days of receipt of the notice referred to above;

(b) determine the procedure for its hearings; and

(c) if it deems necessary, call for oral evidence or argument or summon any person who:-

(i) in its opinion may be able to give information concerning the subject of the appeal; or

(ii) it believes has in his or her possession or under control any document which has a bearing on the subject of the appeal, to appear before it at a time and place specified in the summons, to be asked questions or to produce any such document.

(d) if it calls for oral evidence or argument, -

(i) determine the date, time and place for the appeal and shall communicate these in writing to the appellant and the Minister; and

(ii) administer an oath to or accept an affirmation from any person called as a witness at the appeal.

(5) Persons appearing before an Appeal Committee may be represented by a legal practitioner.

(6) The Appeal Committee may –

(a) set aside or confirm the decision of the Authority;

(b) vary the decision of the Authority;

(c) direct the Authority to reconsider any matter; or

(d) make any finding that is just and equitable in the circumstances.

INVESTIGATIONS

25. The Authority may conduct an investigation with regard to a medical device if—

(a) the medical device is recalled in South Africa or any other country;

(b) an adverse event is reported in South Africa or any other country;

(c) the medical device is suspected or found not to comply with the requirements of the Act;

(d) there is an international alert with regard to the medical device; or

(e) for any other reason, the Authority considers it necessary to conduct an investigation on the medical device.

METHOD OF TAKING A SAMPLE DURING INVESTIGATION, CERTIFICATE TO BE ISSUED AND REPORTING OF RESULTS

26. (1) A sample taken in terms of section 28(1)(*b*) of the Act must—

(a) be taken in the presence of the authorised representative, or in the absence of that person, in the presence of any witness present;

(b) suitably labelled or marked;

(c) be taken and stored in such a manner as to ensure its integrity during the entire examination process of the sample;

(d) packed, sealed or transmitted, as applicable in such a manner as its nature may permit; or

(e) be transmitted by any suitable means to a person referred to in section 27 of the Act.

(2) An inspector may, in terms of these Regulations, identify and take the required sample during a routine inspection, from a holder of a licence issued in terms of section 22C(1)(*b*) or the holder of a certificate of registration of a medical device, for testing, examination or analysis.

(3) Any sample in sub-regulations (1) and (2) must be accompanied by the certificate in terms of section 28(2)(*a*)(iii) of the Act signed by the inspector, a copy of which shall be issued to the person in sub-regulation(1)(*a*) by the inspector.

(4) The certificate in sub-regulation (3) shall be supplied to the Chief Executive Officer within seven days from the date of issue.

(5) The person authorised in terms of section 27 of the Act must, as soon as possible after receipt of the sample, test, examine or analyse the sample and report the results of such test, examination or analysis to the Authority.

(6) The Authority may require a holder of a licence in terms of section 22C(1)(*b*), the holder of a certificate of registration of a medical device or a health establishment to supply the Authority with a sample of a particular medical device in order to test, examine or analyse the sample.

(7) In the case of a medical device where a sample cannot be taken, an onsite test, examination or analysis may be conducted by an inspector or a person authorised in terms of section 27 of the Act.

COMPLIANCE WITH REQUIREMENTS

27. (1) Every medical device must comply with—

(a) the essential principles as determined by the Authority; and

(b) any declaration of conformity furnished to the Authority, with regard to such medical device.

(2) Any proposed change or deviation related to the essential principles or declaration of conformity in sub-regulation (1) must be submitted and approved as determined by the Authority.

OFFENCES AND PENALTIES

28. (1) A person who fails to comply with, contravenes the provisions of, or wilfully furnishes incorrect information in respect of—

(a) regulation 2 or 3 with regard to the importation or transmission of medical devices;

(b) regulation 5 with regard to the labelling of medical devices;

(c) regulation 6 with regard to the instructions for the use of a medical device which is not an IVD;

(d) regulation 7 with regard to the instructions for use of an IVD;

(e) regulation 12 with regard to the licence to manufacture, distribute or wholesale medical devices;

(f) regulation 17 with regard to the destruction of medical devices;

(g) regulation 18 with regard to the conduct of clinical trials;

(h) regulation 19 with regard to reporting of adverse events and vigilance;

(i) regulation 22 with regard to the advertising of medical devices; or

(j) regulation 27 with regard to the compliance with requirements,

is guilty of an offence and upon conviction is liable to a fine, or to imprisonment for a period not exceeding 10 years or to both fine and imprisonment.

(2) A person who sells a medical device that has expired is guilty of an offence and upon conviction is liable to a fine, or to imprisonment for a period not exceeding 10 years or to both fine and imprisonment.

TRANSITIONAL ARRANGEMENTS REGARDING UNREGISTERED MEDICAL DEVICES

29. (1) An unregistered medical device sold in the Republic subject to regulation 8, is considered to be sold legally until such time as the call-up notice period referred to in sub-regulation (2), for the medical device, has expired.

(2) The Authority must from time to time, issue a notice in the Gazette calling for the registration of medical devices which notice must stipulate which class of medical device must be registered.

(3) Despite sub-regulation (1), the Authority may require a medical device to comply with the requirements that the Authority may determine in order to ensure that the medical device meets the essential principles.

REPEAL OF LAWS

30. Regulations Relating to Medical Devices and in vitro Diagnostic Medical Devices (IVD), Government Notice No. 1515 published in Government *Gazette* No. 40480 of 09 December 2016 are hereby repealed.

SHORT TITLE

31. These Regulations are called Regulations relating to Medical Devices, Amendment 2023.

SCHEDULES

Annexure 1

Certificate of registration for a medical device

MEDICINES AND RELATED SUBSTANCES ACT 1965, (ACT NO. 101 OF 1965)

MEDICAL DEVICE REGISTRATION CERTIFICATE

It is hereby certified that registration of the medical device described below has been approved by the Authority subject to the conditions indicated.

1. Product Name.....
2. Registration number .....
3. Class of medical device.....
4. In the case of a medical device which contains a scheduled substance the name and quantity of the active ingredient(s), or biological substance(s)
5. Nomenclature system code .....
6. Conditions under which the medical device is registered .....
7. Registered in the name of (holder of certificate of registration) .....
8. Name and physical address of the original manufacturer .....
9. Name and physical address of the licensed manufacturer or distributor .....
10. Date of registration.....

Chief Executive Officer

Issued

at.....on.....20.....