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IMPORTANT

Information

from Government Printing Works

Dear Valued Customers,

Government Printing Works has implemented rules for completing and submitting the electronic Adobe Forms when you, the customer, submits your notice request.

Please take note of these guidelines when completing your form.

GPW Business Rules

1. No hand written notices will be accepted for processing, this includes Adobe forms which have been completed by hand.
2. Notices can only be submitted in Adobe electronic form format to the email submission address submit.egazette@gpw.gov.za. This means that any notice submissions not on an Adobe electronic form that are submitted to this mailbox will be **rejected**. National or Provincial gazette notices, where the Z95 or Z95Prov must be an Adobe form but the notice content (body) will be an attachment.
3. Notices brought into GPW by "walk-in" customers on electronic media can only be submitted in Adobe electronic form format. This means that any notice submissions not on an Adobe electronic form that are submitted by the customer on electronic media will be **rejected**. National or Provincial gazette notices, where the Z95 or Z95Prov must be an Adobe form but the notice content (body) will be an attachment.
4. All customers who walk in to GPW that wish to submit a notice that is not on an electronic Adobe form will be routed to the Contact Centre where the customer will be taken through the completion of the form by a GPW representative. Where a customer walks into GPW with a stack of hard copy notices delivered by a messenger on behalf of a newspaper the messenger must be referred back to the sender as the submission does not adhere to the submission rules.
5. All notice submissions that do not comply with point 2 will be charged full price for the notice submission.
6. The current cut-off of all Gazette's remains unchanged for all channels. (Refer to the GPW website for submission deadlines – www.gpwonline.co.za)
7. Incorrectly completed forms and notices submitted in the wrong format will be rejected to the customer to be corrected and resubmitted. Assistance will be available through the Contact Centre should help be required when completing the forms. (012-748 6200 or email info.egazette@gpw.gov.za)
8. All re-submissions by customers will be subject to the above cut-off times.
9. All submissions and re-submissions that miss the cut-off will be rejected to the customer to be submitted with a new publication date.
10. Information on forms will be taken as the primary source of the notice to be published. Any instructions that are on the email body or covering letter that contradicts the notice form content will be ignored.

You are therefore advised that effective from **Monday, 18 May 2015** should you not comply with our new rules of engagement, all notice requests will be rejected by our new system.

Furthermore, the fax number **012- 748 6030** will also be **discontinued** from this date and customers will only be able to submit notice requests through the email address submit.egazette@gpw.gov.za.

government printing
Department:
Government Printing Works
REPUBLIC OF SOUTH AFRICA

eGazette

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CORRECTION NOTICE

Government Notice 602, published on **14 July 2015**, within *Government Gazette* **38990,** was erroneously published with a blank page. The **Notice 602** is hereby withdrawn and replaced with the following:

GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF HEALTH

NO. R. 665 **31 JULY 2015**

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

GENERAL REGULATIONS RELATING TO MEDICAL DEVICES AND *IN VITRO* DIAGNOSTIC MEDICAL DEVICES (IVDs)

The Minister of Health, in consultation with the Medicines Control Council, in terms of section 35 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), intends to make the regulations in the Schedule.

Interested persons are invited to submit, within **one** (1) month of publication of this notice, comments on the proposed regulations to the Department of Health, for the attention of the Registrar: Medicines Control Council, Private Bag X828, Pretoria, 0001.

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DEFINITIONS

1. In these Regulations any word or expression defined in the Act and not defined herein bears the same meaning as in the Act and unless the context otherwise indicates-

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

"adverse event" in relation to a medical device or IVD means possible faults or failures of the medical device or IVD, difficulties in the use of or an undesirable outcome associated with the use of the medical device or IVD that can or does result in permanent impairment, injury or death to the professional user or patient user;

"as determined by Council" means as determined by Council in the guidelines as published in the Gazette from time to time;

"authorised representative" means any natural person, resident in the Republic of South Africa, who has the written mandate to represent a manufacturer, importer, distributor, wholesaler, retailer or service provider in the Republic and to act on his or her behalf for specified tasks with regard to the latter's obligations and in whose name the manufacturer licence, distributor licence, wholesaler licence and or certificate of registration is issued. The authorised representative is responsible for all aspects of the medical device or IVD, including performance, quality, safety and compliance with conditions of registration;

"batch number" or **"lot number"** or **"serial number"** means a unique number or combination of numbers or cyphers allocated to a lot or a batch or a unique medical device by the manufacturer;

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

"clinical investigation" means a study in respect of a medical device or IVD for use in humans and animals that involves human or animal subjects and that is intended to discover or verify the safety or clinical performance of the medical device or IVD;

"combination device" means a medical device incorporating as an integral part, a substance which if used separately, can be considered to be a medicine and which is liable to act on the human body with action ancillary to that of the medical device;

"conformity assessment" means the systematic examination of evidence generated and procedures undertaken by the manufacturer, to determine that a medical device is safe and performs as intended and conforms to the Essential Principles of Safety and Performance for Medical Devices as determined by the Council;

"Conformity Assessment Body" means a body corporate or other legal entity, locally or internationally, accredited by SANAS or an international body recognized by Council, according to a standard as determined by the Council, as competent to carry out the assessment, verification and certification of medical devices or IVDs before they are placed on the market by manufacturers;

"conformity assessment certificate" means the certificate used to demonstrate that a manufacturer has been assessed and has the appropriate systems in place to manufacture the device;

"continuous use" in terms of medical devices or IVDs means -

(a) the entire duration of use of the medical device or IVD without regard to temporary interruption of use during a procedure, or temporary removal for purposes such as cleaning or disinfection of the medical device or IVD;
(b) the accumulated use of a medical device or IVD that is intended by the manufacturer to be replaced immediately with another of the same type;

"custom made medical device" means any medical device specifically made in accordance with a written prescription or order given by a person authorised for the same by virtue of professional qualifications and in accordance with specific design characteristics and is intended for the sole use of a particular user and excludes mass produced medical devices which only need adaptation to meet the specific requirements of the health professional user;

"declaration of conformity" means the procedure whereby the manufacturer ensures and declares that the application of the quality system approved for the design, manufacture and final inspection of the products concerned as required by Council, which are subject to audit and surveillance, are fulfilled;

"distributor" means the natural or legal person who imports or exports a medical device or IVD which is on the register for medical devices or on the register for IVDs in its final form, wrapping and packaging, with a view to their being placed on the market under the natural or legal person's own name and sells them to a healthcare professional, healthcare institution, wholesaler or the user;

"essential principles" set out the requirements relating to the safety and performance characteristics of medical devices and IVDs as determined by Council;

"expiry date" means the date up to which a medical device or IVD will retain the properties which are mentioned on the label which properties can change after the lapse of time and after which date the medical device or IVD shall not be sold to the public or used;

"family" means a medical device comprising of the same type of device available in different models and sizes;

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

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

"implantable device" means any device, including those that are partially or wholly absorbed, which is intended to be totally introduced into the human body or, to replace an epithelial surface or the surface of the eye by surgical intervention which is intended to remain in place after the procedure, for at least 30 days;

"intended purpose" means the objective intended use or purpose as the case may be, for which the medical device or IVD is intended according to the data supplied by the manufacturer or authorised representative on the labelling, in the instructions and in the promotional materials;

"lay person" means an individual that does not have formal training in a relevant field or discipline;

"manufacture" means all operations including the design, purchasing of material, specification development, production, fabrication, assembly, processing, reprocessing, releasing, packaging, repackaging, and labelling of a medical device or IVD as the case may be, including putting a collection of medical devices or IVDs, and possibly other products, together for a medical purpose in accordance with quality assurance and related controls;

"manufacturer" means –

(a) the natural or legal person with the responsibility for the design, manufacture, packaging and labelling of a medical device or IVD before it is placed on the market under the natural or legal person's own name, or in the name of a firm or company, regardless of whether these operations are carried out by that person by himself or on his behalf by a third party; or

(b) any other person who assembles, packages, reprocesses, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a medical device or IVD with a view to their being placed on the market under the natural or legal person's own name, apart from a person who assembles or adapts medical devices or IVDs already on the market to their intended purpose for patients;

"manufacturer's evidence" is the substantive evidence of the manufacturer's quality system, that demonstrates that the manufacturer has appropriate manufacturing processes in place to manufacture the device(s);

"minimum legibility" means a printing in 6-point Helvetica, typeface in black ink on white cartridge paper or the equivalent thereof;

"misbranded" means the medical device labelling is false, misleading, inaccurate or fails to provide information as required;

"modification" in terms of a medical device or IVD means any significant change in the medical device or IVD or any change in the purpose thereof where significant change may include the manufacturing process, facility or equipment, the quality control measures used to control the quality and sterility of the medical device or IVD or of the materials used in manufacture, the design of the medical device or IVD, including its performance characteristics, principles of operation and specifications of materials, energy source, software or accessories and the intended use of the medical device or IVD including any new or extended use, any addition or deletion of a contra-indication of the medical device or IVD and any change to the period used to establish its expiry date;

"near patient testing" means testing performed outside a laboratory environment by a healthcare professional not necessarily a laboratory professional, generally near to, or at the side of, the patient;

"nomenclature" means the common generic description as per the Global Medical Device Nomenclature for medical devices having similar features, characteristics and intended use;

"person" means both a natural and a legal person;

"radiation" means energy in the form of electromagnetic waves or acoustical waves;

"radiation-emitting device" means any device that is capable of producing and emitting radiation and any component of, or accessory to, such a device;

"refurbished medical device" means a medical device the whole or any part of which has been substantially rebuilt, re-equipped or restored, whether or not using parts from one or more used medical devices of that same kind, so as to create a medical device that can be used for the purpose originally intended by the original manufacturer of the original medical device, and without prejudice to the generality of the foregoing, a refurbishment of a medical device may involve any or all of the following actions including , but are not limited to, repair, rework, update of software /

hardware and replacement of worn parts with parts approved for use by the original manufacturer, performed in a manner consistent with product specifications and service procedures defined by the original manufacturer for that type of equipment without significantly changing the finished equipment's performance, safety specifications and/or intended use as defined in its original registration;

"self-testing" means testing performed by lay persons;

"single use device" means medical device or IVD that is intended to be used on an individual user during a single procedure and then disposed of and which is not intended to be reprocessed and used again;

"trademark" means a trademark as defined under section 2 of the Trade Marks Act, 1993 (Act No. 194 of 1993);

"unique device identification" means the combination of words, numbers, symbols, or letters assigned by the manufacturer to uniquely identify the device and any of its variants;

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

"wholesaler" means a dealer who purchases medical devices or IVDs from a manufacturer or distributor and sells them to a retailer.

THE MANNER AND CONDITIONS FOR ALLOWING INTERNATIONAL TENDERING

2. (1) The State may tender for a medical device or IVD internationally if such a medical device or IVD can be obtained at a lower price outside of the Republic or is, in the opinion of the Minister, essential for national health.

(2) A medical device or IVD cannot be procured by international tender unless such medical device or IVD is registered in terms of the Act.

PARTICULARS TO BE PUBLISHED IN THE GAZETTE

3. The following particulars with regard to applications for registration referred to in section 15(11) shall be published in the Gazette:

a. The name and or group or family of the medical device or IVD; where applicable;
b. the name of the holder of the certificate of registration who is responsible for the product;
c. the number allocated to it in terms of section 15 of the Act;
d. the name and address of the manufacturer;
e. the class of medical device or IVD; and
f. the nomenclature system or code of the medical device or IVD.

IMPORTATION OF MEDICAL DEVICES AND IVDs INTO THE REPUBLIC

4. (1) No person shall import any medical device or IVD, into the Republic except through one of the following ports of entry:

a. Cape Town Airport or harbour;
b. Port Elizabeth Airport or harbour;
c. King Shaka International Airport or Durban harbour; or
d. OR Tambo International Airport.

(2) A person may only import a medical device or IVD if such person:

a. is licensed in terms of the Act to import medical devices or IVDs; and
b. in the case of unregistered medical devices or IVDs, is authorised by the Council to import such unregistered medical devices or IVDs.

TRANSMISSION OF MEDICAL DEVICES OR IVDs THROUGH THE REPUBLIC

5. (1) Medical devices and IVDs that are transmitted through the Republic shall-

a. while in the Republic be stored in a bonded warehouse which is registered with the Council; and
b. not be manipulated while in the bonded warehouse unless authorised by the Council.

(2) A bonded warehouse referred to in subregulation (1) must comply with specified storage conditions as determined by the Council.

LICENCE TO MANUFACTURE, IMPORT, EXPORT OR ACT AS A DISTRIBUTOR OR WHOLESALER OF MEDICAL DEVICES OR IVDs

6. (1) A person referred to in section 22C(1)(b) of the Act-

a. must prior to commencing business as such-

i apply to the Council for:

aa. a manufacturer licence to manufacture, import or export medical devices or IVDs; or

bb. a distributor licence to import, export and distribute medical devices or IVDs; or

cc. a wholesale licence to act as wholesaler of medical devices or IVDs;

ii appoint, and designate a natural person who resides in the Republic, as such an authorised representative who shall in South Africa:

aa. be responsible to the Council for compliance with the Act and

bb. control the manufacturing, distribution, wholesaling and the sale of medical devices or IVDs.

b. must submit to the Registrar an application, on a form approved and provided by the Council, for a licence as contemplated in sub-regulation (1) (a) (i);

c. must as part of the application in sub-regulation (1)(b) provide acceptable documentary proof of:

i. the particulars of the owner of the business;

ii. the particulars of the authorised representative; and

iii. evidence of accreditation to a Quality Management System for medical devices and IVDs as determined by the Council,

d. must specify, as determined by the Council, the medical devices or IVDs or group or family of medical devices or IVDs to be manufactured, imported, exported or distributed and sold; and

e. must pay the application fee.

(2) The Registrar may give the person referred to in sub-regulation (1) written notice to furnish the Council with such additional documentation or information as the Council may require, within a reasonable time, specified in the notice.

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

(4) If the Council is satisfied that:

a. the person referred to in subregulation (1) complies with the prescribed requirements;
b. the application for a licence
i) to manufacture, import, export or
ii) to act as a distributor, or
iii) to act as a wholesaler of medical devices or IVDs
complies with the prescribed requirements; and
c. the authorised representative is able to provide certified evidence of accreditation to a Quality Management System as determined by Council, then the Council must approve, with or without conditions, the application and issue such person with a licence.

(5) The Registrar must:

a. keep a separate register for each of the categories of licensees referred to in sub-regulation (1)(a)(i); and
b. enter the licence number, the name of the licensee and his or her physical and postal addresses, in such register.

(6) Notwithstanding the period of validity of the licence the licensee shall pay the annual fee for continued registration as determined by the Council.

(7) A licensee must notify the Registrar in writing of any change to any of the particulars furnished in the application or entered in the register, which occurs after the issue of the licence.

(8) Any entry into the register which is proved to the satisfaction of the Council to have been made in error or through misrepresentation or in circumstances not authorised by the Act, may be removed from the register.

(9) A person in respect of whose entry or removal as contemplated in sub-regulation (8) has been made, must be notified of such removal and any certificate issued

in respect of the registration in question shall be deemed to be cancelled as from the date on which notice has so been given.

(10) The Council may direct the Registrar to remove from the register the name of the licensee-

a. who does not comply with the Act or the conditions of a licence;
b. if the authorised representative fails to control the manufacturing or distribution, wholesaling or sale of medical devices or IVDs as applicable and the licensee has failed to furnish written reasons within 21 days after the date upon which a notice is given of the Council's intention to remove the name of the licensee from the relevant register and to close such business why the licensee's name should not be removed or the business should not be closed: Provided that if the Council is of the opinion that it is in the interest of the public, it may dispense with the required notice.

PERIOD OF VALIDITY OF A LICENSE ISSUED IN TERMS OF REGULATION 6 AND RENEWAL OF LICENCES

7. (1) A licence issued in terms of regulation 8 shall be valid for a period of 5 years from the date of issue.

(2) A licence referred to in subregulation (1) which has expired may be renewed by application to the Council.

(3) An application referred to in subregulation (2) shall –

a. contain at least the information or documentation referred to in regulation 6(1)(c), as the case may be;
b. be accompanied by a prescribed fee; and
c. be made at least 90 days before the expiry of the existing licence.

APPEAL AGAINST THE DECISION OF THE COUNCIL

8. (1) An appeal to be lodged or representations to be made in terms of Section 24 of the Act against a decision of the Council, shall be lodged or made within 30 days from the date on which the decision appealed against or in respect of which

representations are made was communicated to the appellant or person making representations.

(2) In lodging the appeal or making representations, the appellant or person making representations shall send a notice in writing to the Chairperson of the Council, for attention the Registrar, Medicines Control Council, Private Bag X828, Pretoria, 0001

(3) The notice referred to in sub-regulation (2) shall set out clearly and succinctly the basis for the appeal or representations.

(4) The Registrar shall within 30 days of receipt of notice of appeal in the absence of legal representatives, meet with the appellant to try and resolve the matter.

(5) Should the matter not be resolved as contemplated in subsection 9(4), the appellant, within shall within 30 days of being notified by the Registrar of the failure to resolve the matter, and upon payment of a prescribed fee, request the Minister in writing to convene an appeal committee.

(6) The appeal committee –

a. shall determine the procedure for its hearings;
b. may, 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 document; and

c. shall, 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 Council;
    ii. administer an oath to or accept an affirmation from any person called as a witness at the appeal.

(7) Persons appearing before the Appeal Committee may be represented by a legal practitioner.

(8) The appeal committee shall consider the appeal and make a decision in regard thereto within a period of 30 days from the date on which it first meets to hear the appeal.

(9) A party that is not satisfied with the decision of the appeal committee may approach the High Court for a judicial review.

APPLICATION FOR THE REGISTRATION OF A MEDICAL DEVICE OR IVD

9. (1) Any person residing and doing business in the Republic may make an application for the registration of a medical device or IVD.

(2) The application referred to subregulation (1) shall include the particulars of the authorised representative in South Africa with appropriate knowledge of all aspects of the medical device or IVD who shall be responsible for communication with the Council.

(3) An application referred to in subregulation (1) shall be made on the appropriate form obtainable from the Registrar and shall be accompanied by:

a. a properly completed application form obtainable from the Registrar;
b. a proposed label for use on the medical device or IVD, if applicable;
c. where applicable,
    i. a copy of the manufacturer licence or distributor licence together with certified evidence of a Quality Management System for the local medical device establishment, as determined by Council;
    ii. a certified copy of the conformity assessment certificate which confirms conformity to a quality standard, as determined by Council, for the medical device or IVD to be registered, and which is issued by a conformity assessment body that the Council approves of;
f. any other information as the Council may determine; and
g. the application fee.

(4) All information referred to in subregulation (3) shall be at least in English.

(5) The application form referred to in subregulation (3) shall contain at least the following information:

a. Particulars of the prospective holder of the certificate of registration:
   i. Name;
   ii. Business Address;
   iii. Postal Address;
   iv. Telephone Number;
   v. Fax Number;
   vi. e-mail address; and
   vii. contact details of the authorised person referred to in sub regulation (2)

b. particulars of the medical device or IVD:
   i the name and group or family name, make and model where applicable;
   ii. intended purpose or use;
   iii. classification and registration status in recognised authorities outside the Republic, as determined by Council, and proposed classification in the Republic;
   v. nomenclature system code;
   vi. in the case of a combination medical device the name and quantity of the scheduled substance(s);
   vii. name and physical address of the original manufacturer(s); and
   viii. name and physical address of the clinical investigation site(s), where applicable.

(6) A medical device or IVD in respect of which an application for registration is made must comply with the Essential Principles for Safety and Performance of Medical Devices which include requirements for quality, safety and performance, as determined by the Council.

(7) An application for registration of a medical device or IVD must be accompanied by a Declaration of Conformity by the Authorised Representative as determined by Council.

(8) An application must be made in respect of each individual medical device or IVD, or medical device or IVD group or family.

(9) In an instance where a medical device or IVD in respect of which an application is made or was registered with any regulatory body outside the Republic, the following information in respect of such medical device or IVD must accompany the application:

a. a copy of certificate of registration where applicable;
b. instructions for use where applicable ;
c. conditions of registration; and
d. any other information as determined by the Council.

INFORMATION THAT MUST APPEAR IN THE REGISTER FOR MEDICAL DEVICES OR IVDs

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

a. the name and / or group or family; make and model, where applicable of the medical device or IVD;
b. the registration number allocated to the medical device or IVD;
c. in the case of a combination medical device the name and quantity of the scheduled substance(s) in the medical device;
d. the intended purpose or use of the medical device or IVD;
e. the name of the holder of the certificate of registration;
f. the name and address of the original manufacturer;
g. the date of registration of the medical device or IVD;
h. the conditions of registration of the medical device or IVD determined in terms of section 15(6) of the Act;
i. the class of medical device or IVD; and
j. the nomenclature system code allocated to the medical device or IVD.

AMENDMENT TO THE MEDICAL DEVICE AND IVD REGISTER

11. (1) A holder of a certificate of registration may submit to the Registrar an application on a form as determined by the Council to amend an entry made into the

medical devices or IVDs register with regard to a particular medical device or IVD.

(2) The application referred to in subregulation (1) shall be accompanied by a prescribed fee and must contain the following information:

a. the registration number of the medical device or IVD;
b. the name and business address of the holder of a certificate of registration and the authorised representative;
c. declaration by the authorised representative that the information furnished is complete and accurate;
d. the details of the amendment applied for;
e. the manufacturer licence number of the manufacturer or the distributor licence number of the distributor; and
f. any other information as determined by the Council.

CLASSIFICATIONS OF MEDICAL DEVICES AND IVDs

12. (1) The following are the classes of medical devices and IVDs –

(a) Class A - Low Risk
(b) Class B - Low-moderate Risk
(c) Class C - Moderate-high Risk
(d) Class D - High Risk

where risk relates to the patient or to public health.

(2) All medical devices, except custom made devices, and all IVDs shall be registered with the Council in terms of such call up notices before they may be sold or used in the Republic.

(3) The classification of medical devices and IVDs shall be as determined by Council in accordance with the classification rules.

(4) Where the classification of a medical device or IVD is inconclusive and places it in more than one class or between classes after following the classification rules the Council will place it in the higher of the risk classes.

(5) The Council shall consider the classification of a medical device or IVD individually taking into account its design and intended use.

REGISTRATION CERTIFICATE

13. A registration certificate substantially in the form shown below shall be issued by the Registrar in terms of section 15(4) after a medical device or IVD has been registered:

MEDICINES AND RELATED SUBSTANCES ACT 1965, (ACT 101 OF 1965)
MEDICAL DEVICE OR IVD REGISTRATION CERTIFICATE

It is hereby certified that registration of the medical device or IVD described below has been approved by the Council in terms of Section 15(4) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), subject to the conditions indicated.

1. Name .....
2. Registration number .....
3. Class of medical device or IVD .....
4. In the case of combination medical devices the name and quantity of the scheduled substance(s)
5. Nomenclature system or code .....
6. Conditions under which the medical device or IVD is registered .....
7. Registered in the name of (holder of certificate of registration) .....
8. Name and physical address of the original manufacturer .....
9. Date of registration .....

.....
Registrar

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

DESTRUCTION OF MEDICAL DEVICES OR IVDs

14. (1) No medical devices or IVDs may be disposed of into municipal sewerage systems.

(2) The destruction or disposal of medical devices or IVDs must be conducted in such a manner as determined by the Council.

METHOD OF TAKING SAMPLES DURING AN INVESTIGATION, THE CERTIFICATE TO BE ISSUED AND THE REPORTING OF ANALYSIS RESULTS

15. (1) An inspector may, in terms of the Act, take a sample, or any quantity of samples, of a medical device or IVD for purposes of testing, examination or analysis by a person

suitably qualified within their professional scope of practice, such as a clinical engineer, technician, or pathologist.

(2) The sample or samples contemplated in subregulation (1) must –

a. be taken in the presence of the person who is in charge of such medical device or IVD, or in the absence of such person, in the presence of any witness present;
b. be taken and stored in such a manner as to ensure its integrity during the entire examination process of the sample;
c. be packed and sealed and suitably labelled or marked in such a manner as its nature may permit and must be transmitted by any suitable means to aperson suitably qualified within their professional scope of practice such as an analyst, clinical engineer, technician or pathologist together with the certificate signed by the inspector, a copy of which must be issued to the person contemplated in paragraph (a) by the inspector at the earliest possible time.

(3) The suitably qualified person referred to in subregulation (1) must as soon as possible after receipt of the sample, test, examine or analyse the sample and report the results thereof.

(4) An inspector referred to in subregulation (1) may take a sample during a routine inspection from a manufacturer, a wholesaler or retailer for testing, examination or analysis in terms of these regulations.

(5) Notwithstanding subregulation (1), the Council may require any holder of a certification of registration to supply the Council with a sample of a particular medical device or IVD in order to test, examine or analyse such sample.

(6) Certificates or reports issued in terms of this regulation must be submitted to the Registrar within 7 days from the date of issue.

SEIZURE OF MEDICAL DEVICES OR IVDs

16 (1) A medical device or IVD may be seized if it-

a. is unregistered and sold in contravention of the Act;
b. is suspected counterfeit;

c. is misbranded;
d. has expired;
e. is suspected stolen;
f. is possessed by an unauthorised person or by an authorised person in unauthorised quantities;
g. has been declared undesirable in terms of the Act;
h. belongs to the State and is found possessed by an unauthorised person; or
i. is used in unauthorised clinical trial or investigation.

(2) An inspector seizing any item in terms of section 28 (1) (c) of the Act shall as soon as possible and at the scene of seizure make a written inventory of all items seized and the inventory shall include:

a. the date, place and time of seizure;
b. the name and personal details of the person from whom the items were seized;
c. the name and quantity of every item seized; and
d. the name of the inspector conducting the seizure.

(3) An item contemplated in section 28 (1) (c) of the Act may be used as evidence in any criminal proceedings in terms of this Act.

(4) An inspector taking any sample in terms of section 28 (1) (d) shall make a written inventory of all samples taken which shall include:

a. the date on which, the place where and time when the sample was taken;
b. a description of nature and size of each sample taken;
c. the personal details of the person in whose presence the samples were taken; and
d. the name of the inspector taking the sample.

(5) An inspector may:

a. seal or disable, as the case may be, any medical device or IVD to prevent its further use;
b. remove seized medical devices or IVDs to a secure place designated by the Council pending the outcome of any investigation; and

c. condemn seized medical devices or IVDs for permanent destruction, decommissioning and disposal after a due investigation has been conducted by the Council.

(6) No person may, without the permission of the Council, continue to use, destroy, decommission, remove, cause or permit to be removed, any medical device or IVD that has been seized and placed under an embargo.

(7) The Council shall safely decommission and dispose of any condemned seized medical devices or IVDs in accordance with regulation 16.

(8) The Council shall recover the cost of decommission, removal, storage or disposal of any medical device or IVD that was seized from the licence holder or holder of certificate of registration.

CONDUCT OF CLINICAL TRIALS AND CLINICAL INVESTIGATIONS

17 (1) A person desiring to initiate or conduct a clinical trial or clinical investigation in respect of an unregistered medical device or performance assessment for an IVD, or a new intended purpose of a registered medical device or IVD, shall apply to the Council on a form determined by the Council for authorization to conduct such a clinical trial or clinical investigation.

(2) The application referred to in subregulation (1) shall be accompanied by a prescribed fee and must contain at least the following information:

a. clinical investigation plan or clinical trial protocol;
b. investigator's brochure containing, where applicable, relevant pre-clinical, mechanical, electrical and radiation data and where applicable, human or animal clinical data with the medical device or IVD concerned;
c. Curriculum Vitae of all investigators;
d. signed declaration by the applicant and all investigators that they are familiar with and understand the protocol and will comply with Good Clinical Practice as determined by the Council in the conduct of the clinical investigation or clinical trial;
e. informed consent document(s) and endorsement by any ethics committee recognised by the Council; and

f. name and address of the institution where the clinical trial or clinical investigation will be conducted.

(3) The clinical investigation plan or clinical trial protocol referred to in paragraph (a) of subregulation (2) shall contain at least the following information:

a. number of human or animal subjects as applicable to be involved in the clinical investigation or clinical trial;
b. the name of an investigator who shall be an appropriately qualified and competent person approved by the Council, resident in the Republic, and must be in charge of the site where clinical trials are conducted;
c. quantity of the investigational medical device or IVD units to be used in the clinical trial or clinical investigation;
d. information in respect of the design, manufacture and expected performance of the medical device or IVD; and
e. any other information as determined by the Council.

(4) Clinical investigations and clinical trials must be conducted in accordance with guidelines for good clinical practice determined by the Council.

(5) No person shall conduct clinical investigations or clinical trials referred to in subregulation (1) without the authorisation of the Council.

(6) The person conducting the clinical investigation or clinical trial must:
a. submit progress reports to the Council after every six months from the date when the clinical investigation or clinical trial was started and 30 days after the completion or termination of the clinical investigation or clinical trial;
b. submit adverse event reports immediately or as soon as practically possible to the Council.

(7) The Council may request additional information, inspect a clinical investigation or clinical trial or withdraw the authorisation to conduct a clinical investigation or clinical trial if the Council is of the opinion that the safety of the subjects of the clinical investigation or clinical trial is compromised, or that the scientific reasons for conducting the clinical investigation or clinical trial have changed.

(8) The following information for a medical device or IVD referred to in sub regulation (1) shall be provided, where applicable;

a) Intended purpose or use of the investigational device in the proposed clinical investigation or clinical trial.

b) The populations and indications for which the investigational device is intended.

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

d) Description as to how traceability shall be achieved during and after the clinical investigation, (e.g. by assignment of lot numbers, batch numbers or serial numbers).

e) The medical device or IVD shall, where practical, be labelled with the name(s) and address(es) of the premises where the clinical investigation or clinical trial is to be carried out and

f) be labelled "for investigational use".

(9) Any authorisation for the conduct of a clinical investigation or clinical trial by the Council may be made subject to such conditions as determined by the Council.

ADVERSE EVENT REPORTING AND VIGILANCE

18 (1) The authorised representative or holder of a certificate of registration in respect of a medical device or IVD shall inform the Council, in the manner and within the time frame as determined by the Council, of suspected device adverse events reported to him or her occurring as a result of the use of such a medical device or IVD.

(2) Subregulation (1) also applies in the case of unregistered medical devices or IVDs used in terms of sections 14(4), and 21 of the Act.

(3) The authorised representative or the holder of the certificate referred to in subregulation (1) with regard to medical devices or IVDs referred to in subregulation (2) as the case may be, shall-

a. within the time frame determined by the Council after receipt of the report referred to in subregulation (1) inform the Council of the steps to be taken to address the adverse events;

b. whenever requested by the Council, conduct a concise critical analysis of the safety and performance of the medical device or IVD and submit the results thereof to the Council within a specified time frame; and

c. in the case where, after receipt of the results referred to in paragraph (b), the Council determines that the medical device or IVD may not be safe to use, submit, if required to do so to the Council–

i case reports of all suspected device adverse events in respect of the medical device or IVD;

ii where applicable medical device or IVD usage figures, periodic safety update reports, performance studies; and

iii any other data as requested by Council.

d. Keep and maintain or have access to records of all device adverse event data in respect of his, her or its medical devices or IVDs.

(4) Nothing in this regulation shall be interpreted as prohibiting any person from reporting any adverse event to the Council.

(5) Notwithstanding the provisions of subregulation (1) or (4) any user who becomes aware of any adverse event caused or suspected of being caused by a medical device or IVD during the process of using or conducting post-marketing surveillance shall report such events either to the holder of the certificate of registration, the manufacturer, the authorised representative or the Council.

INVESTIGATIONS

19. The Council may conduct an investigation with regard to a medical device or IVD, its manufacturer, distributor or wholesaler if-

a. such a medical device or IVD is recalled in South Africa or any other country;

b. a device adverse event is reported in South Africa or any other country;

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

d. there is an international alert with regard to such a medical device, IVD or the manufacturer of a medical device or IVD; or

e. for any other reason, the Council deems it fit to conduct an investigation on the medical device or IVD.

OFFENCES AND PENALTIES

20. Any person who fails to comply with, contravenes the provisions of or wilfully furnishes incorrect information in respect of –

a. Regulations 4 or 5 with regard to the importation or transmission of medical devices or IVDs;
b. Regulation 6 with regard to the licence to manufacture, act as a distributor or act as a wholesaler of medical devices or IVDs;
c. Regulation 14 with regard to the destruction of medical devices or IVDs;
d. Regulation 17 with regard to the conduct of clinical trials;
e. Regulation 22 with regard to the advertising of medical devices or IVDs;
f. Regulation 23 with regard to the labelling of medical devices or IVDs;
g. Regulation 24 with regard to the instructions for use for a medical device;
h. Regulation 25 with regard to the instructions for use for an IVD;
i. Sells a medical device or IVD that has expired;
j. Regulation 21 with regard to the compliance to the Essential Principles as confirmed in the Declaration of Conformity; or
k. Regulation 18 with regard to reporting of Adverse Events and vigilance shall be guilty of an offence and upon conviction be liable to a fine, or to imprisonment for a period not exceeding 10 years.

COMPLIANCE WITH REQUIREMENTS

21 (1) Every medical device or IVD shall conform with the standards and specifications which were furnished to the Council on the form prescribed by regulation 9 and which has been accepted by Council with respect to such medical device or IVD.

(2) Every medical device or IVD shall conform with the essential principles furnished to the Council with a Declaration of Conformity prescribed by regulation 9

(3) Any proposed deviation from accepted standards and specifications as intended in subregulation (1) and (2) shall be submitted to the Council for prior approval.

ADVERTISING OF MEDICAL DEVICES OR IVDs

22. (1) The under mentioned requirements shall apply to any advertisement of a medical device or IVD.

(2) Only Class A and Class B medical devices and IVDs may be advertised to the public or a lay person.

(3) No advertisement for a medical device or IVD may contain a statement which deviates from, is in conflict with or goes beyond the evidence submitted in the application for registration of such medical device or IVD with regard to its safety, quality, or performance where such evidence has been accepted by the Council in respect of such medical device or IVD and incorporated into the approved instructions for use of a medical device or IVD.

(4) A written advertisement for a medical device or IVD shall contain-

a. the name of such medical device or IVD;
b. in the case of a registered medical device or IVD, the registration number allocated to it in terms of section 15 (6);

(5) When a Class C or Class D medical device or IVD is advertised for the first time to any prospective user, written information, which shall include at least the information referred to in regulation 24 or regulation 25 as the case may be, shall simultaneously be given to the person(s) to whom the oral, electronic or printed advertisement is directed, and when the medical device or IVD is advertised on subsequent occasions such information shall be available on request.

LABELLING OF MEDICAL DEVICES OR IVDs

23 (1) The label of each medical device or IVD should contain the following particulars in at least English which must appear on the medical device or IVD itself, or on the packaging of each unit, or on the packaging of multiple devices or IVDs

(a) name or trade name of the medical device or IVD;
(b) product description and intended use;
(c) product catalogue code where applicable;
(d) name and business address of the manufacturer;
(e) name and business address of the holder of certificate of registration;

(f) where appropriate, an indication that the device contains or incorporates a scheduled or biological substance(s);
(g) the lot number where applicable;
(h) the serial number where applicable;
(i) for accessories the serial number may be substituted with a control number and for software it may be substituted with a version number;
(j) the expiry date where applicable;
(k) where there is no indication of the expiry date, the manufacturing date;
(l) an indication of any special storage and/or handling conditions applicable;
(m) if the device is supplied sterile, an indication of its sterile state and, where appropriate, the sterilization method;
(n) 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;
(o) warnings or precautions where applicable; and
(p) where appropriate an indication that the device is intended for:
(i) single use;
(ii) clinical investigation or premarket clinical performance study;
(iii) non-clinical research, teaching or testing purposes;
(iv) presentation or demonstration purposes;
(v) *in vitro* diagnostic use or Laboratory Developed Tests; and
(vi) where relevant "for professional use only".

(2) If the medical device is a reprocessed medical device the label must state the name of the re-processor and identify the medical device as a reprocessed medical device.

(3) If the IVD kit includes individual reagents and articles that may be made available as separate IVD medical devices, they must comply with the content in subregulation (1) of this regulation.

INSTRUCTIONS FOR USE OF MEDICAL DEVICES

24 (1) The instructions for use shall contain the following in at least English:

(a) name or trade name of the medical device;
(b) name and business address of the manufacturer;

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

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

(e) specifications that the user requires to use the device appropriately (e.g. if the device has a measuring function, the degree of accuracy claimed for it);

(f) if the device contains, or incorporates, a medicinal substance and/or material of biological origin, identification of that substance or material, as appropriate;

(g) details of any preparatory treatment or handling of the device before it is ready for use (e.g. sterilization, final assembly, calibration, etc.);

(h) any requirements for special facilities, or special training, or particular qualifications of the device user and/or third parties;

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

  (i) details of the nature, and frequency, of preventative 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 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;

(j) an indication of any special transport, storage and/or handling condition that applies;

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

(l) if the device is supplied non-sterile with the intention that it is sterilized before use, the appropriate instructions for sterilization;

(m) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilization including information to identify when the device should no longer be reused (e.g. signs of material degradation or the maximum number of allowable reuses);

(n) for devices intended for use together with other medical devices and/or general purpose equipment:

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

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

(o) if the 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 third party from unintended radiation during use of the device;

(p) information that allows the user and/or patient to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device which information should cover, where appropriate:

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

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

(iv) if the device administers medicinal or biological products, any limitations or incompatibility in the choice of substances to be delivered;

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

(vi) precautions related to materials incorporated into the device that are carcinogenic, mutagenic or toxic, or could result in sensitisation or allergic reaction of the patient or user.

(q) warnings or precautions to be taken related to the disposal of the device, its accessories and the consumables used with it, if any. This information should cover, where appropriate:

(i) infection or microbial hazards (e.g. explants, needles or surgical equipment contaminated with potentially infectious substances of human origin);

(ii) environmental hazards (e.g. batteries or materials that emit potentially hazardous levels of radiation); and

(iii) physical hazards (e.g. from sharps);

(r) for devices intended for use by lay-persons, the circumstances when the user should consult with a healthcare professional;

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

(t) appropriate service and maintenance instructions for technical equipment and devices , where applicable.

(2) Instructions for use for Class A medical devices to be included where applicable

INSTRUCTIONS FOR USE OF IVDs

25 (1) The instructions for use shall contain the following in at least English,

(a) the name or trade name;

(b) name and address of the manufacturer;

(c) the intended purpose/use, including but not limited to:

(i) what is detected;

(ii) its function;

(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 specimen(s) required (e.g. serum, plasma, whole blood, tissue biopsy, urine); and

(vii) testing population;

(d) an indication that it is for in vitro diagnostic use and where relevant for "professional use only";

(e) the intended user as appropriate;

(f) test principle;

(g) a description of the reagent, calibrators and controls and any limitation upon their use (e.g suitable for a dedicated instrument only);

Note: IVD kits include individual reagents and articles that may be made available as separate IVDs. In this situation, where appropriate, these IVDs should comply with the instructions for use content in this section.

(h) composition of the reagent product by nature and concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the 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) for IVDs intended for use together with other IVDs or medical devices, or general purpose equipment:

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

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

(k) an indication of any special storage and handling conditions that apply;

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

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

(n) information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the IVD which information should 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 in regards 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 regards to the risks of interference posed by the reasonably foreseeable presence

of the device during specific diagnostic investigations, evaluations, therapeutic treatment including electromagnetic interference emitted by the device affecting other equipment where applicable;

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

(o) any 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 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 safely and as intended by the manufacturer, together with, where relevant:

(i) details of the nature, and frequency, of preventative 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;

(iv) methods of mitigating the risks encountered by persons involved in installing, calibrating or servicing 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 should be considered;

(w) analytical performance characteristics, such as sensitivity, specificity, and accuracy;

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

(y) where relevant, reference intervals; and

(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 device, its accessories, and the consumables used with it, if any, which information should cover, where appropriate:

(i) infection or microbial hazards;

(ii) environmental hazards; and

(iii) physical hazards;

(bb) for IVDs intended for use by lay persons, the circumstances when the user should consult with a healthcare professional;

(cc) where relevant, a bibliography;

(dd) 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.

CUSTOM MADE MEDICAL DEVICES

26 (1) All custom made medical devices must be manufactured and sold complying with the guidelines applicable to medical devices.

RECORD OF IMPLANTABLE MEDICAL DEVICES AND CUSTOM MADE MEDICAL DEVICES

27 (1) A permanent record in respect of all Class D implantable medical devices and high-risk custom made medical devices shall be kept on all premises where such devices are sold and shall contain the following information:

a. the name and the product code of the medical device;

b. the date on which the order for the implantable or custom made medical device was raised;

c. the model number, batch number, and serial number (if applicable);

d. the name, address and identity number of the patient;

e. where applicable the name of the user and who will, in the case of an implantable medical device, be responsible for the implantation of the medical device;

f. the name and address of the health establishment;

g. the name of the manufacturer of the implantable or custom made medical device; and

h. information relating to the design, manufacturing and performance of the medical device including expected performance.

(2) The order record shall be retained at the business address of the seller for a period of at least five years beyond the expected life of the medical device.

(3) The manufacturer, distributor or wholesaler of Class D or implantable custom made medical devices shall keep a record of Class D or implantable custom made medical devices in the form of invoices that will reflect:

a. the date and transaction of every sale;

b. the proprietary name of the medical device;

c. the name and address of every purchaser;

d. the quantities sold; and

e. the batch number or serial number.

(4) A record referred to in subregulation (3) shall be kept for a period of fifty years from the date of sale.

TRANSITIONAL ARRANGEMENTS UNLICENCED MANUFACTURERS, DISTRIBUTORS AND WHOLESALERS

28 (1) Manufacturers, distributors or wholesalers selling medical devices or IVDs in the Republic at the time of the commencement of these regulations shall, subject to regulation 6, be deemed to be trading legally.

(2) The Council shall issue notices in the Gazette calling for the licensing of manufacturers, distributors and wholesalers which notices will stipulate the conditions and time periods for licensing.

TRANSITIONAL ARRANGEMENTS - UNREGISTERED MEDICAL DEVICES AND IVDs

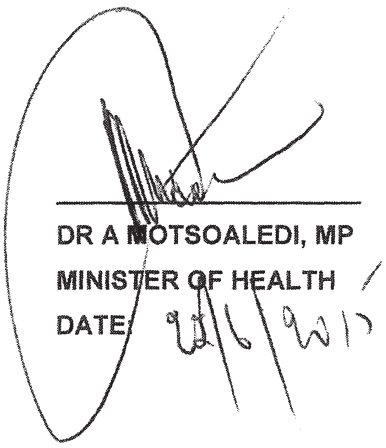
29 (1) Unregistered medical devices or IVDs sold in the Republic at the time of the commencement of these regulations shall, subject to regulation 9, be deemed to be sold legally until such time as the call-up notice period for the medical device or IVDs has expired.

(2) The Council shall issue notices from time to time in the Gazette calling for the registration of medical devices and IVDs which notices will stipulate which classes of medical devices and IVDs must be registered and providing the conditions and time periods for the application for registration.

(3) Notwithstanding subregulation1 the Council may require any medical device or IVD to comply with any requirements that the Council may determine in order to ensure that the medical device or IVD meets the Essential Principles of safety and performance, as determined by the Council.

COMMENCEMENT

30. These Regulations are called Regulations relating to Medical Devices and *In vitro* Diagnostic Medical Devices (IVDs) made in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) and will commence upon the date signed by the Minister.



DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 26/6/2015

IMPORTANT

Information

from Government Printing Works

Dear Valued Customers,

Government Printing Works has implemented rules for completing and submitting the electronic Adobe Forms when you, the customer, submits your notice request.

Please take note of these guidelines when completing your form.

GPW Business Rules

1. No hand written notices will be accepted for processing, this includes Adobe forms which have been completed by hand.
2. Notices can only be submitted in Adobe electronic form format to the email submission address submit.egazette@gpw.gov.za. This means that any notice submissions not on an Adobe electronic form that are submitted to this mailbox will be **rejected**. National or Provincial gazette notices, where the Z95 or Z95Prov must be an Adobe form but the notice content (body) will be an attachment.
3. Notices brought into GPW by "walk-in" customers on electronic media can only be submitted in Adobe electronic form format. This means that any notice submissions not on an Adobe electronic form that are submitted by the customer on electronic media will be **rejected**. National or Provincial gazette notices, where the Z95 or Z95Prov must be an Adobe form but the notice content (body) will be an attachment.
4. All customers who walk in to GPW that wish to submit a notice that is not on an electronic Adobe form will be routed to the Contact Centre where the customer will be taken through the completion of the form by a GPW representative. Where a customer walks into GPW with a stack of hard copy notices delivered by a messenger on behalf of a newspaper the messenger must be referred back to the sender as the submission does not adhere to the submission rules.
5. All notice submissions that do not comply with point 2 will be charged full price for the notice submission.
6. The current cut-off of all Gazette's remains unchanged for all channels. (Refer to the GPW website for submission deadlines – www.gpwonline.co.za)
7. Incorrectly completed forms and notices submitted in the wrong format will be rejected to the customer to be corrected and resubmitted. Assistance will be available through the Contact Centre should help be required when completing the forms. (012-748 6200 or email info.egazette@gpw.gov.za)
8. All re-submissions by customers will be subject to the above cut-off times.
9. All submissions and re-submissions that miss the cut-off will be rejected to the customer to be submitted with a new publication date.
10. Information on forms will be taken as the primary source of the notice to be published. Any instructions that are on the email body or covering letter that contradicts the notice form content will be ignored.

You are therefore advised that effective from **Monday, 18 May 2015** should you not comply with our new rules of engagement, all notice requests will be rejected by our new system.

Furthermore, the fax number **012- 748 6030** will also be **discontinued** from this date and customers will only be able to submit notice requests through the email address submit.egazette@gpw.gov.za.

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Department:
Government Printing Works
REPUBLIC OF SOUTH AFRICA

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