AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

World Health Organization

Draft

African Medical Devices Forum

Guidelines for registration of medical devices establishments

CONTENTS

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ABBREVIATIONS

ISO	International Organization for Standardization
IVD	in-vitro diagnostics
NRA	national regulatory authority

DEFINITIONS

Act: a statute or law made by a legislative body.

Authority: the regulatory authority <Name of Authority>. A government body or other entity that exercises a legal right to control the use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements.

Authorized representative: a natural or legal person established within a country or jurisdiction that has received a written mandate from the manufacturer, distributor or wholesaler to act on its behalf for specified tasks related to the latter's obligations under that country or jurisdiction's legislation (3).

Classification name: the term used by the Authority and its classification panels to describe a device or class of devices for purposes of classifying devices under specific sections of an Act/regulation.

Classification system: the classification system for medical devices, including in-vitro diagnostics (IVDs), that guides the regulatory controls to be implemented for each device class. It is widely accepted that medical devices are separable into groups or classes (typically four: A, B, C and D) by applying a set of classification rules and specifying separately the various conformity assessment procedures that should apply to each group of devices.

Commercial distribution: any distribution of a medical device intended for human use which is held or offered for sale.

Distributor: a natural or legal person in the supply chain who, on his/her own behalf, furthers the availability of a medical device to the end user. Source: (1).

Distributor (Canada): a person, other than a manufacturer, importer or retailer, who sells a medical device in Canada for the purpose of resale or use, other than for personal use. A person outside of Canada selling medical devices into Canada is also considered to be a distributor. Source: (2).
Establishment registration: registration of the medical devices establishment that manufactures, imports and/or distributes medical devices as required under the Act and, if required by laws, and any applicable governmental Authority.

Importer: a natural or legal person in the supply chain that is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed. Source: (3).

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In-vitro diagnostic (IVD): a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. Source: Source: (4).

Manufacturer: any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his/her name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s). Source: (3).

Note: This "natural or legal person" has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical device in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the regulatory authority within that jurisdiction.

Material change: includes any change or modification in the labelling of or advertisements for that affects the identity or safety and effectiveness of the device. These changes may include, but are not limited to, changes in the common, usual or proprietary name, declared ingredients or components, intended use, contraindications, warnings or instructions for use. Changes that are not material may include graphic layout, grammar, correction of typographical errors which do not change the content of the labelling, changes in lot number and, for devices where the biological activity or known composition differs with each lot produced, the labelling containing the actual values for each lot.

Medical device: any instrument, apparatus, implement, machine, appliance, implant, reagent for in-vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment and alleviation of or compensation for an injury;
- investigation, replacement, modification or support of the anatomy or of a physiological process;
- supporting or sustaining of life;
- control of conception;
- disinfection of medical devices;
- providing information by means of in-vitro examination of specimens derived from the human body; and which does not achieve its primary intended action by pharmacological, immunological or met abolic means, in or on the human body, but which may be assisted in its intended function by such means. Source: (4).

Official correspondent: the person designated as in charge of the establishment and responsible for the following:

- annual registration of the establishment;
- market authorization and regulatory matters
- contact with the Authority
- safety and performance of the products.

Owner or operator: the corporation, subsidiary, affiliated company, partnership or proprietor directly responsible for the activities of the registering establishment.

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Product code: the code used by the Authority to identify the generic category of a device.

Quality management system: set of interrelated or interacting elements of an organization to establish quality policies and quality objectives and to establish the processes that are needed to ensure that those policies are followed, and those objectives are achieved. Source: (5).

1. INTRODUCTION

Medical devices play a critical role in the diagnosis, management and prevention of disease. It is therefore critical that medical devices should be available which are safe and high-quality and perform as intended by the originating manufacturer throughout their life cycle. The International Organization for Standardization (ISO) standard ISO 13485:2016 (Medical devices – quality management systems – requirements for regulatory purposes) is widely accepted by regulators as the basis of the appropriate quality management systems requirements for medical devices establishments that need to demonstrate their ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services throughout the product lifecycle.

The medical devices establishment is expected to have an established quality management system to ensure continued safety, quality and performance of all medical devices throughout the product's life cycle and within the supply chain. The registration of the establishment is one of the processes which ensures that the manufacturer, importer and/or distributor fulfils the regulatory requirements, as determined through the legislative framework informing the control of medical devices.

This guidance is intended to provide medical device, manufacturers, importers, wholesalers, distributors and retailers in <Name of Country> with the requirements for registration of medical devices establishments, based on implementation of quality management systems, to ensure their conformity with the requirements of ISO 13485:2016 through established processes.

The manufacture, importation, exportation and distribution of medical devices is subject to control in terms of the provisions of the legislative framework in <Name of Country>. The intent of the medical devices establishment registration is to ensure that <Name of Authority> is made aware of:

a) manufacturers of medical devices in <Name of Country> and the classification of the medical devices manufactured in <Name of Country>;
b) persons importing and distributing medical devices in <Name of Country> and the risk classification of those medical devices; and
c) to establish criteria for importation of medi cal devices into <Name of Country>.

Manufacturers, importers and distributors shall ensure that the quality, safety and performance of medical devices are maintained throughout their life cycle, as specified in national regulations, by registering medical devices establishments and ensuring compliance with regulations. Other law enforcers shall collaborate with national regulatory authorities (NRAs) when executing their legal mandate to ensure optimum enforcement of the Act and other relevant national laws.

Manufacturing, use and handling of medical devices is guided by risk classification rules established by the guidelines issued by the Global Harmonization Task Force and the International Medical Device Regulators Forum. It is the role of the manufacturer to determine and establish the risk class of the medical device. A medical devices establishment registration certificate shall be required for all medical devices establishments.

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2. REGISTRATION OF MEDICAL DEVICES ESTABLISHMENTS

Any establishment that manufactures, imports or distributes a medical device in <Name of Country> shall be registered by the NRA.

In terms of section <X> of the Act, the NRA may, on application in the prescribed manner and on payment of the prescribed fee, issue to a manufacturer, wholesaler or distributor of a medical device a registration certificate to:

a) manufacture; or
b) import; or
c) export; or
d) act as a wholesaler of

as the case may be, such medical device, in such conditions and with the application of such acceptable quality assurance principles as the NRA may determine. No company or individual shall manufacture, import or export or distribute any medical device unless he or she is the holder of a registration certificate, as provided for in section <X> of the Act. Medical devices intended to be manufactured, imported or distributed by the Applicant must be listed in the application for the registration of a medical devices establishment. Individuals importing medical devices for personal use shall not be required to make an application to the NRA for the registration of a medical devices establishment; however, authorization to import medical devices for personal use must be obtained from the Authority.

3. APPLICATION FOR REGISTRATION OF MEDICAL DEVICES ESTABLISHMENTS

Applications for registration of medical devices establishments shall be submitted to the Authority and must be accompanied by the following documents:

a) application form, duly filled in, signed and dated (see Annex 1 for the form to be used for the initial application and Annex 2 for the form to be used for registration renew al);
b) copy of the quality manual;
c) attestation by an Official Correspondent of the establishment that the establishment has documented procedures in place with respect to: complaints handling, including field safety corrective action; handling of substandard and falsified products; dispos al; and any other procedure as required by quality management systems;
d) an attestation by an Authorized Represen tative or responsible establishment offi cial that the establishment has document ed procedures in place, where applicable, for handling, storage, delivery, installation, corrective action and servicing in respect of the devices.
e) electronic copy of the establishment quality management system manual and establishment procedures and processes;
f) copy of practice/certificate of registration of the Official Correspondent;
g) copy of items required for national registra tion of companies, such as a business li cence;
h) evidence of payment of prescribed fees.

3.1 Processing of the application

The Authority shall review the application and perform a desk review of the quality manual and the establishment procedures and processes.

The minimum requirements (evaluation criteria) for a medical devices establishment registration certificate shall be confirmed by the Authority upon receipt, review and verification of the application and supporting documents.

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In order to be eligible for a registration certificate, the applicant should have available and have implemented at least the following:

a) quality management system addressing all aspects of quality assurance and covering: contracts (agreements); purchasing; manufacturing; final product handling; storage; facility installation; servicing; cleanliness; documentation controls and records; international regulatory control; internal and external audits; training; complaints handling; emergency plan and recalls; quality assurance; management review; distribution (transport, delivery, temperature control); and export documentation (proof of export);

b) written formal agreement in the case that any of the activities are delegated to a competent third party.

The applicant must submit the following information to the Authority in the application:

a) list of all medical devices imported into <Name of Country>, product codes, product description, brand name and group/family name, as applicable;

b) for a medium-to-high-risk (Class C) or high-risk (Class D) medical device, proof of pre-market approval or registration of the device from at least one of the member regulatory authorities of the International Medical Device Regulators Forum or confirmation of WHO prequalification; such pre-market approval(s) or registration(s) submitted with an application will be referred to as the “originating approval(s)”;

c) for a low-to-medium-risk (Class B), medium-to-high-risk (Class C) or high-risk (Class D) medical device, certificate of free sale from country of manufacture or final assembly; the certificate of free sale is evidence that the medical devices are legally sold or distributed in the open market, freely and without restriction, and are approved by the regulatory authorities in the country of origin;

d) for a medium-to-high-risk (Class C) or high-risk (Class D) medical device, the holder of the medical devices establishment registration certificate must be able to provide full technical documentation on the request of the Authority;

e) where relevant, certificate of conformance/analysis.

The Authority will conduct onsite inspection to assess implementation of the quality management system requirements.

3.2 Issuance of a registration certificate

Upon confirmation of fulfilment of the requirements specified in section 3.1 above, the Authority shall issue a registration certificate for the medical devices establishment (Annex 2).

A medical devices establishment registration certificate shall expire on <Date> each year, unless it is renewed upon application by the Applicant in accordance with the conditions set forth in the application form. In addition, the registration certificate for manufacturers will be valid for five years following a successful reinspection.

3.3 Refusal to issue a medical devices establishment registration certificate

The Authority may refuse to issue a medical devices establishment registration certificate if:

a) the applicant has made false or misleading statement(s) in the application; or

b) the Authority has reasonable grounds to believe that issuing the medical devices establishment registration certificate will constitute a risk to the health or safety of patients, users or other persons; or

c) the applicant has failed to meet the conditions for medical devices establishment registration as specified in section 3.1 above.

In any case where the Authority does not recommend the issuing of a medical devices establishment registration certificate, the Authority shall:

a) notify the applicant in writing of the reasons for not recommending/refusing the registration of

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the establishment; and

b) give the applicant an opportunity to respond to the Authority and provide relevant documentation/evidence in support of the application.

3.4 Notification of change

After the issuance of a medical devices establishment registration certificate, if there is a change to any of the information submitted at the time of application, the holder of the registration certificate shall submit the new information to the Authority within <XXX> days of the change.

The Authority shall be notified of any changes to the application for registration of a medical devices establishment. The applicant shall obtain written authorization from the Authority prior to the implementation of any change(s) that are likely to impact the quality, safety or performance of medical devices.

3.5 Revocation or cancellation of a registration certificate

Subject to the requirement stated under section 3.4 above, the Authority may suspend or cancel a medical devices establishment registration certificate if the Authority has reasonable grounds to believe that:

a) the holder of a registration certificate has contravened these Regulations or any provision of the Act relating to medical devices; or

b) the holder of a medical devices establishment registration certificate has made false or misleading statement(s) in the application or notification of change; or

c) failure to suspend the medical devices establishment registration certificate would compromise the safety, performance and/or quality of the medical device, or constitute a risk to the health or safety of patients, users or other persons.

The Authority shall not cancel or suspend a medical devices establishment registration certificate unless:

a) it has sent written notice of <XXX> days to the holder of a establishment registration certificate, setting out the reason for the proposed suspension;

b) the period of time set out in the notice for corrective action, if required, has passed without the action having been taken; and

c) the establishment registration certificate holder has been given an opportunity to respond to the Authority in respect of the suspension.

3.6 Restoration of a registration certificate

The Authority may, within <XXX> days of the date of receiving the response from the holder of a registration certificate and considering the supporting documentation/information provided by the holder, reinstate the medical devices establishment registration certificate.

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4. OTHER GENERAL REGULATORY REQUIREMENTS FOR HOLDERS OF ESTABLISHMENT REGISTRATION CERTIFICATES FOR MEDICAL DEVICES ESTABLISMENTS

a) Holders of registration certificates are required to follow the WHO Guide on post-marketing surveillance and market surveillance of medical devices including in vitro diagnostics (6), including adverse event reporting and recalls, in the event of an incident or need to withdraw a medical device from the market.

b) Holders of registration certificates that are responsible for the manufacture, import, export, distribution and/or wholesale of medical devices are required to be certified under ISO 13485 within <Number of years> from date of issuance of registration certificate.

c) In terms of the exportation of medical de vices, it is the responsibility of the holder of the registration certificate to comply with the legal registration information approved by the relevant Ministry of Health of the im porting country.

REFERENCES

1. Definitions of the terms manufacturer, authorised representative, distributor and importer (document GHTF/SG1/N055:2009). Global Harmonization Task Force (GHTF) Study Group 1; 2009 (*www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n055-definition-terms-090326.pdf*, accessed 7 June 2021).

2. Guidance on medical devices establishment licensing (GUI-0016). In: Government of Canada [website]. Ottawa: Government of Canada; 2021 (*https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/directives-guidance-documents-policies/guidance-medical-device-establishment-licensing-0016/document.html#appa2*), accessed 7 June 2021).

3. ISO 13485:2016. Medical devices — quality management systems — requirements for regulatory purposes. Geneva: International Organization for Standardization; 2016 (*https://www.iso.org/obp/ui#iso:std:iso:13485:ed-3:v1:en*, accessed 7 June 2021).

4. Definition of the terms ‘medical device’ and ‘in vitro diagnostic (IVD) medical device’ (document GHTF/SG1/N071:2012). Global Harmonization Task Force Study Group 1; 2012 *(http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-of-terms-120516.pdf*, accessed 7 June 2021).

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6. WHO. Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics.(*https://www.who.int/publications/i/item/guidance-for-post-market-surveillance-and-market-surveillance-of-medical-devices-including-in-vitro-diagnostics*, accessed 7 June 2021.)

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ANNEX 1. APPLICATION FOR CERTIFICATE OF REGISTRATION FOR A MEDICAL DEVICES ESTABLISHMENT

APPLICATION FOR CERTIFICATE OF REGISTRATION OF MEDICAL DEVICES ESTABLISHMENT

<Reference National Act>

<NRA Address>

I/We hereby apply for registration of my/our existing/new establishment registration certificate in accordance with the <<Reference National Act>

Name of applicant.....

Physical postal address.....Tel. No..... Email.....

Full name(s) of partner(s)/director(s).....

Full name(s) of official correspondent/registered practitioner.....,

Certificate number .....

Establishment type.....

The business will be under the direct supervision of (full name(s) of Official Correspondent and Registered Practitioner)....., Certificate no. .....

My/our financial resources committed to this business amount to..... and my/our annual projected turnover is <Currency>.....

If my/our establishment is registered, I/we shall keep it in hygienic condition and in a good state of repair as required under the above-mentioned <Reference National Act> and Regulations.

I/we have not been convicted of any offence relating to any provision of <Reference National Act> and Regulations or any other written law related to the business being applied for in the <XXX> months immediately preceding this Application and have not been disqualified from holding a certificate, and my/our certificate has been/has not been suspended.

NB False declaration constitutes an offence.

Date ..... Signed .....

Fees <Currency> .....Receipt No. ..... dated .....

FOR OFFICIAL USE ONLY

Registration granted/not granted

because.....

....

Registration No.....Approved by management meeting No.....

dated.....

Date ..... Signature of Applicant .....

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ANNEX 2. APPLICATION FOR RENEWAL OF REGISTRATION CERTIFICATE OF MEDICAL DEVICES ESTABLISHMENTS

<NRA>

APPLICATION FOR RENEWAL OF REGISTRATION CERTIFICATE OF MEDICAL DEVICES ESTABLISHMENTS

<As per National Act>

<NRA Address>

PART I:

I/We hereby apply for renewal of certificate/for a new certificate to manufacture, sell, pack, store or distribute the following:

....

Name of Applicant ....

Postal address ....Tel. No ....Fax .... Email ....

Full name(s) of

partner(s)/director(s)...

Establishment situated at...................... Street/village/plot No........................

District/municipality ....

Region...

Establishment registered for the business of..

Establishment Registration No..................................... Dated..

Existing certificate No................................ Dated............................ Expiry

date ....

My/our financial resources committed for this business amount to <Currency>.................................

and my/our annual projected turnover is <Currency>..

XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

PART II: APPLICABLE TO MANUFACTURERS ONLY

PRODUCT REGISTRATION STATUS

I wish to manufacture the following item, whose registration status is shown below:

Serial No.	Common Trade Name Registration

For official use only/generic No.

Name ....

PART III: APPLICANT DECLARATIONS

If my/our business is registered, I/we shall keep the establishment in hygienic condition and in a good state of repair as required under the above-mentioned <Reference National Act> and Regulations.

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I/we have not been convicted of any offence relating to any provision of the <As per National Act> and Regulations made there under or any other written law related to the business being applied for within <XXX> months immediately preceding this application and have not been disqualified from holding a certificate and my/our certificate is/is not suspended.

NB False declaration constitutes an offence.

Date..... .....
Signature of Applicant and stamp

Fees <National currency>.....Receipt No.....
dated.....

FOR OFFICIAL USE ONLY
Certificate granted/not granted because.....
Certificate No.....Approved by management meeting No. ..... dated .....

....
Date Signature

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ANNEX 3. REGISTRATION CERTIFICATE OF MEDICAL DEVICES ESTABLISHMENT

<NRA>

REGISTRATION CERTIFICATE OF MEDICAL DEVICES ESTABLISHMENT

<As per National Act>

This is to certify that the establishment owned by (Name) ..... of (Postal address)..... which is located at..... Street, in.....Village/township/municipality/city, have been registered to be used as..... for preparation/selling/packing/carrying/advertising/storing/manufacturing of..... with establishment Registration No.....

Subject to the following conditions.

1. The establishment and the manner in which the business is to be conducted must conform to requirements of the <National Act> or any other written law related to the establishment registration at all times failing of which this certificate shall be suspended or revoked.
2. Any change in the ownership, name and location of the registered establishment shall be approved by the Authority**.**
3. This certificate is not transferable to any other establishment or person.
4. This certificate shall be displayed conspicuously in the registered establishment.

.....	.....
Date	Stamp
Signature of	Date
.....	.....

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