

# DRUG NATIONAL AUTHORITY



## **DRAFT GUIDELINE FOR REGISTRATION OF MEDICAL DEVICES FOR HUMAN USE IN UGANDA, SEPTEMBER 2009**

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## 1. Introduction

This guideline is intended to provide guidance for submission of registration applications for medical devices to the National Drug Authority, NDA, of Uganda.

All medical devices manufactured, imported and distributed in Uganda, except those listed in annex I, must be registered with NDA.

## 2. Definition of medical device<sup>7</sup>

The term 'medical device' means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article:

- a) Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
  - diagnosis, prevention, monitoring, treatment or alleviation of disease,
  - diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
  - investigation, replacement, modification, or support of the anatomy or of a physiological process,
  - supporting or sustaining life,
  - control of conception,
  - disinfection of medical devices,
  - providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body; and
- b) Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

## 3. Scope of the guideline

This guideline generally applies to all products that fall within the definition of a 'medical device' in section (2) above. Exceptions to the applicability of this guideline include devices for which specific guidelines exist, for the time being only malaria rapid diagnostic tests.

## 4. Policy

NDA derives the mandate to regulate and control medical devices from the National Drug Policy and Authority Act Cap. 206 of the laws of Uganda, Sections: 1(k); 2 (2); 5 (d) and (k); 30 (a); 64 (1) d, f and g.

## 5. Submission of Application

- (a) All applications for registration are to be submitted type written or computer printed in ENGLISH. Where originals are in another language, they should be presented together with certified English translations. SI Units should be used throughout, except where convention requires other units to be used.
- (b) The application shall consist of one tightly bound hard copy and an electronic copy containing a complete index and each section of the application dossier must be numbered according to the numbering system used in this guideline.
- (c) Each complete application should be accompanied by a non-refundable fee of US\$ 100.

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<sup>7</sup> The above definition is adopted from the Global Harmonisation Task Force (GHTF) whose membership is drawn from the medical device regulatory agencies and the regulated industry of Australia, Canada, European Union, Japan and United States of America.

(d) Registration procedures shall commence only if a complete application dossier, fees and samples, where practicable, have been submitted.

(e) All applications should be addressed to: The Executive Secretary / Registrar, National Drug Authority, Plot 46 –48 Lumumba Avenue, P.O. Box 23096, Kampala, UGANDA, Phone: (+256) 41-255665 / 347391/ 347392, Fax: (+256) 414-255758, E-mail: [ndaug@nda.or.ug](mailto:ndaug@nda.or.ug)

(f) Payment of fees may be made by Bank Transfer to: National Drug Authority, Stanbic Bank Uganda Limited, Kampala, Account no: 0240060034201 **OR** by bank draft in favour of National Drug Authority.

## 6. Applicant

An application for registration of a medical device may be submitted by:

(a) The license holder

(b) The manufacturer

(c) An authorized local agent of the license holder or manufacturer, also known as Local Technical Representative (LTR), who may be a body corporate licensed to deal in medicines and/or medical devices, a diagnostic laboratory, hospital, health centre or clinic.

## 7. Information in the application form (Annex II)

**7.1 Product details** shall comprise of the following information:

(a) Proprietary/brand name

(b) Brief description of the device

(c) Category of the device

(d) Intended use and method of use

(e) Medical specialty in which the device is used

(f) Contraindications, warnings, precautions, potential adverse events

(g) List of accessories and other devices or equipment to be used in combination with the device.

(h) Variations in shape, style or size of the device, if applicable

(i) Labeling details

(j) Packaging description including pack sizes

(k) Recommended storage conditions

**7.2 Manufacturer details** shall comprise of the following information:

(a) The name, physical address, telephone number, fax number and e-mail

(b) Where different activities of manufacture of a given product are carried out at different manufacturing sites, the above particulars shall be provided for each site and the activity carried out at the particular site as in the example below:

	<b>Name</b>	<b>Address</b>	<b>Activity</b>
1.	Taurus International	GLN, 13LT, London, UK Tel: 235 898	Manufacture and assembly of components
2.	Steritech Limited	Plot 73, Government Avenue, Nairobi PO Box 3459, Nairobi, Kenya Tel: 222218	Sterilization
3.	Starpac Industries	491 Plot 4, City Rd, Kampala PO Box 5445, Kampala, Uganda Tel: 222207	Packing

(c) A copy of a valid manufacturing licence for each site

(d) The name, physical address, telephone number, faxes number, and e-mail of the manufacturer's LTR

## 8. Registration tracks

### Track 1-Applications for devices licensed in one of the GHTF Member

**Countries** should contain:

- (a) A covering letter containing the applicant's attestation that all information in the application is true and correct
- (b) Product details as listed in 7.1 above
- (c) Manufacturer details as listed in 7.2 above
- (d) Notarized copy of a license in the GHTF founding member country (table 1 below)
- (e) Certificate of Analysis confirming compliance to a Quality System Standard in table 2 below
- (f) Evidence of repeat sales in country of manufacture
- (g) Appropriate number product samples, where practicable
- (h) A filled application submission checklist (section 11 below)

Table 1-Licensing requirements in the five GHTF founding member countries

	<b>Australia</b>	<b>Canada</b>	<b>European Union</b>	<b>Japan</b>	<b>United States</b>
Marketing permit/condition	GMPALS License or CE Mark	Device license	CE mark	Device license	510K device letter

Table 2-Acceptable quality system standards in the five GHTF founding member countries

<b>Country</b>	<b>Quality system standards for medical devices</b>	<b>Certification body</b>
Australia	ISO 13485 or ISO 13488	Government or third party accredited by the government
Canada	ISO 13485 or ISO 13488	Third party accredited by the government
European Union	ISO 13485 or ISO 13488	Third party accredited by the EU
Japan	GMP (QS Standard for medical devices #1128)	Government
United States	QS (21 CFR part 820)	Government

### Track 2-Applications for devices NOT licensed in one of the GHTF

**Member Countries** should contain:

- (a) A covering letter containing the applicant's attestation that all information in the application is true and correct
- (b) Product details as described in 7.1 above
- (c) Manufacturer details as listed in 7.2 above
- (d) Documented evidence of conformity to a Quality System Standard in table 2 above from a certification body accredited by a regulatory authority in one of the GHTF founding member countries **or** WHO Prequalification **or** any other international organizations recognized by NDA
- (e) Certificate of Analysis confirming compliance to a Quality System Standard in table 2 above
- (f) Evidence of repeat sales in country of manufacture
- (g) Appropriate number of product samples, where practicable
- (h) A filled application submission checklist (section 11 below)

**Track 3-Applications for devices that do NOT** have certification for any of the Quality System Standards listed in table 2 above should contain:

- (a) A covering letter containing the applicant's attestation that all information in the application is true and correct

- (b) Manufacturer's Declaration of Conformity (DOC) to GHTF Essential Principles of Safety and Performance
- (c) Summary information on pre-clinical design verification and validation
- (d) Product details as described in 7.1 above
- (e) Manufacturer details as listed in 7.2 above
- (f) Evidence of repeat sales in country of manufacture
- (g) Appropriate number of product samples, where practicable
- (h) A filled application submission checklist (section 11 below)

**9. Variations to the application**

Subsequent changes to any part of the application (e.g. manufacturing site, device specifications, local technical representative) should be brought to the attention of NDA.

**10. Maintenance of registration**

Maintenance of registration status is subject to consistent quality and satisfactory performance of the device on the market and a five-yearly registration review process. A fee of US\$ 100 shall be charged for maintenance of registration every five years.

**11. List of annexes**

Annex I: List of Medical Devices Exempted from Registration

Annex II: Application Form

**12. Application Submission Checklist**

HAVE YOU INCLUDED THE FOLLOWING ITEMS IN YOUR APPLICATION? (INDICATE WITH A TICK)		YES	NO
ALL APPLICATIONS	1. Both hard and soft copies of application		
	2. Cover letter		
	3. Correct application fees		
	4. Product details:		
	(a) Proprietary/brand name		
	(b) Brief description of the device		
	(c) Category of the device		
	(d) Intended use and method of use		
	(e) Medical specialty in which device is used		
	(f) Contraindications, warnings, precautions, potential adverse effects		
	(g) List of accessories and other devices or equipment to be used in combination with the device		
	(h) Variations in shape, style or size of the device, if applicable		
	(i) Labelling details		
	(j) Packaging description including pack sizes		
	(k) Recommended storage condition		
	(l) Two samples where practicable		
	(m) Certificate of analysis		
	5. Manufacturer details		
	(a) Site name, physical address, telephone, fax and e-mail		
	(b) Particulars of other sites, if applicable		
	(c) Copy of manufacturing license(s)		
(d) LTR name, physical address, telephone, fax and e-mail			
6. Evidence of repeat sales in country of manufacture			
TRACK 1	7. <i>If the device is licensed in one of the GHTF founding member countries</i>		
	• Notarized copy of a license in a GHTF member country		
TRACK 2	8. <i>If the device is NOT licensed in one of the GHTF founding member countries</i>		
	• Evidence of conformity to standards from a certification body accredited by a regulatory authority in one of the GHTF founding member countries or a recognized international organization		
TRACK 3	9. <i>If the device does NOT have certification for any of the international quality system standards</i>		
	(a) Manufacturer's Declaration of Conformity (DOC) to GHTF Essential Principles of Safety and Performance		
	(b) Summary information on pre-clinical design verification and validation		
<p><b>Confirmation:</b> I confirm that all the relevant information for my application has been submitted as filled out in this checklist</p> <p><b>Name and designation of signatory:</b> .....</p> <p><b>Signature and date:</b> .....</p> <p><b>Tel:</b> .....<b>Email:</b> .....</p> <p><b>Name and designation of full-time contact person (if different from signatory):</b> .....</p> <p><b>Tel:</b> .....<b>Email:</b> .....</p> <p><b>Note:</b> <i>In case there is a change in the contact person, NDA should be notified immediately.</i></p>			