

**TANZANIA FOOD AND DRUGS AUTHORITY**



**GUIDELINE FOR APPLICATION OF PERMITS TO DEAL WITH  
BUSINESS OF MEDICAL DEVICES**

*(Made under section 20(1) of Tanzania Food Drugs and Cosmetics, 2003)*

**DRAFT**

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## **Abbreviations**

<b>CFDC</b>	-	Council food and Drugs Committee
<b>DMO</b>	-	District Medical Officer
<b>GDPMD</b>	-	Good Distribution Practice for Medical Devices
<b>GHTF</b>	-	Global Harmonization Task Force
<b>GMDN</b>	-	Global Medical Devices Nomenclature
<b>GMP</b>	-	Good Manufacturing Practices
<b>HSA</b>	-	Health Science Authority
<b>ISO</b>	-	International Organization for Standardization
<b>MoHSW</b>	-	Ministry of Health and Social Welfare
<b>MSD</b>	-	Medical Store Department
<b>RMO</b>	-	Regional Medical Officer
<b>TFDA</b>	-	Tanzania Food and Drugs Authority
<b>TFDCA</b>	-	Tanzania Food, Drugs and Cosmetic Act of 2003

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## **Disclaimer**

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In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

## **Foreword**

The Tanzania Food and Drugs Authority (TFDA) were established under the Tanzania Food, Drugs and Cosmetics Act, 2003 to regulate among other things importation, manufacture and distribution of medical devices.

The regulation of medical devices involves amongst other things issuance of permit (licensing) for premises dealing with medical devices.

Issuance of permit enables the Authority to be aware of persons or entities which manufacturer, imports and supply medical devices in Tanzania and provides assurance to the Authority that permit holders have met regulatory requirements and have documented procedures in place, where applicable, related to distribution records, complaint handling, product recall and mandatory problem reporting.

The guideline is first of its kind and together with other requirements; it requires permit seekers to provide information in a specified format of devices which are exempted from registration but marketed in Tanzania

Applicants are encouraged to familiarize with the guidelines and follow them when preparing and submitting applications for permits to deal with business of medical devices.

Adherence to this guideline will ensure that all relevant information and supporting documents are submitted for processing. This will facilitate approval process and also help to avoid unnecessary delays in giving approvals.

**H.B. Sillo**  
**Acting Director General**  
**Tanzania Food and Drugs Authority**

## **Introduction**

This guideline has been developed to provide general guidance for submission of application for permits to deal with business of medical devices pursuant to legal requirements prescribed under section 20(1) of the Tanzania Food, Drugs and Cosmetics Act, 2003 (TFDCA).

The document applies to any person who performs any of the following activities in Tanzania:-

- (a) manufacture medical device(s)
- (b) import medical device(s)
- (c) supply by wholesale medical device(s)
- (d) supply by retail medical device(s)

In developing the guideline, reference was made from the following documents:-

- (a) GN-02: Guidance on Licensing for Manufacturers, Importers and Wholesalers of Medical Devices, Revision 1, October 2008 of Health Science Authority of Singapore;
- (b) Canadian Medical Devices Regulations.

The guideline provides information in regard to:-

- (a) application process
- (b) suspension and revocation of permits
- (c) annual renewal of permits
- (d) notification of change
- (e) key regulatory responsibilities of permit holder
- (f) quality management system and good distribution practice and
- (g) surveillance inspection

It has to be noted that approval process will be based on fulfillment of requirements prescribed in this guideline.

Applicants are also requested to read the guideline together with Guidelines on Good Distribution Practice for Medical Devices in Tanzania (GDPMD), the Tanzania Food, Drugs and Cosmetics Act, 2003 and Regulations made there under.

## **Definition of terms**

In the context of this guideline, the following terms shall be defined as follows:

### **Applicant**

Means a person applying for the permit.

### **Authority**

Means Tanzania Food and Drugs Authority.

### **Export**

With its grammatical variations and cognate expression, means to take or cause to be taken out of Tanzania by land, sea or air.

### **Import**

With its grammatical variations and cognate expressions, means to bring or cause to be brought into Tanzania by land, sea or air.

### **Label**

Written, printed or graphic information provided upon the medical device itself. Where physical constraints prevent this happening, this term includes information provided on the packaging of each unit or on the packaging of multiple devices.

### **Labeling / information supplied by the manufacturer**

Written, printed or graphic matter affixed to a medical device or any of its containers or wrappers, or, accompanying a medical device, related to identification, technical description, and use of the medical device, but excluding shipping documents.

### **Manufacture**

Includes all operations involved in the production, fabricating, processing, refining, transformation, packing, packaging, re-packaging and labeling of medical devices.

### **Manufacturer**

Means any natural or legal person<sup>1</sup> with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his 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).

### **Medical Device or Devices**

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<sup>1</sup> The term “person” includes legal entities such as a corporation, a partnership or an association.

Refer to an instrument, apparatus, implement, medical equipment, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is -

- (a) recognized in the Official National Formulary, or Pharmacopoeia or any supplement to them;
- (b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals or;
- (c) intended to affect the structure or any function of the body of man or other animals and which does not achieve any of its principal intended purposes through chemical action within the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principle intended purposes.

**Permit holder**

Means holder of a permit issued by the Authority.

**Premise**

Means a location that is used for activities dealing with medical devices, including storage and manufacture.

## 1. APPLICATION PROCESS

Application for a permit to deal with medical device(s) business or renewal of permit shall be made in prescribed application forms to the Director General of TFDA through the relevant Districts and Regional organs handling TFDA matters.

The application form shall be obtained from the Secretary to CFDC, DMOs or RMOs Offices of the respective Districts or Regions, TFDA Head quarter and Zonal Offices or through TFDA website ([www.tfda.or.tz](http://www.tfda.or.tz)).

Issuance of permits shall be based on the activity to be performed by a person in relation to medical devices. Four types of permits will be issued; Manufacturer's permit, Importer's permit, Wholesaler's permit and Retailer's permit.

### 1.1 Contact person for premise

- (a) The contact person listed in the application form is the key contact person for the premise. The contact person will be the person who will liaise with the Authority on all issues regarding applications submitted by the premise, including input request on applications.
- (b) All renewal notice for permit will be notified to the contact person. Information of the contact person of the premise provided in the application form should be up to date.

### 1.2 Application requirements

Application for a permit to deal with medical devices business shall be made by submitting:-

- (a) A dully filled in application form (**annex I**) accompanied with the following supporting documents:-

Document	Manufacturer's Permit	Importer's Permit	Wholesaler's Permit	Retailer's Permit
Business/Company registration certificate	√	√	√	√
List of class A exempted medical devices manufactured or imported	√	√	-	-
Sketchy design of the premise	√	√	√	√
Academic Certificates of Supervisor		√	√	√

(b) Application fees as prescribed in the Fees and Charges Regulations, 2005

To minimize delay in the processing of the application, the form must be completed in full with all required supporting documents. One permit shall only apply to one premise whose address shall be specified in the permit.

Every applicant shall be required to ensure that the list of class A exempted medical devices manufactured or imported is up-to-date at the point of application and shall be updated on annual basis during renewal of permit. The list shall be submitted as per format provided in **annex II** of this guideline.

#### **Note**

- All Applicants are obliged to comply with requirements for GDPMD in order to obtain a permit.
- A person who is engaged both in importation and wholesaling of medical device(s) or is seeking to engage in both is required to obtain both import and wholesale permits.
- A person who is engaged both in pharmaceutical and medical device(s) or is seeking to engage in both is also required to obtain both permits.

#### **1.3 Payment of fees**

Every application shall be accompanied by appropriate fees as specified in the Fees and Charges Regulations and its guidelines in force at the time of application. Any application that will not be accompanied by appropriate fees will not be processed.

The fees may be paid directly to TFDA or by bank transfer to:-

**Tanzania Food and Drugs Authority, Account No. 6503900110 National Microfinance Bank, Kariakoo Branch OR by bankers draft in favour of the Tanzania Food and Drugs Authority.**

When payment is made by bank transfer all bank charges shall be borne by the applicant who shall also make sure that advice note is submitted to TFDA giving details of the payment in particular the name of the applicant and amount of fees paid.

#### **Note:**

- All bank charges shall be borne by the applicant.
- For details of fee schedule refer to the Fees and Charges Regulations, 2005.

#### **1.4 Processing of applications**

- (a) Once an application has been accepted the processing of application will take 8 weeks. This will involve initial assessment of application and its supporting documents and inspection of the premise for import, wholesale and retail premises to ascertain compliance with requirements for Good Distribution Practice of Medical Devices in Tanzania.
- (b) Depending on the outcome of initial assessment and inspection carried out, applicant may be required to make certain amendments or rectification to address the shortcomings within a given time frame prior to final verification.
- (c) All Applicants are obliged to comply with requirements of Good Distribution Practice of Medical Devices in Tanzania and directives issued by the Authority in order to obtain a permit.

#### **1.5 Decision by the Authority**

- (a) The authority may approve, withhold or reject any application by providing reasons for its decision thereof.
- (b) The Authority shall within 14 days from the date the decision was made inform all applicants, whose applications have been approved, withhold or rejected as the case may be the status of their application.

#### **1.6 Issuance of permit**

- (a) The Authority shall issue to approved applicants, premise registration certificate and the respective retail, wholesale, import and manufacturer permit to allow the applicant to start carrying out the business of medical devices.
- (b) The permit shall be valid for one year and shall be subject to renewal annually.

### **2. SUSPENSIONS AND REVOCATION OF PERMIT**

- (a) A permit may be suspended or revoked if there are reasonable grounds to believe that:-
  - (i) The permit has been obtained by fraud or misrepresentation;
  - (ii) The permit holder has contravened or is contravening any provision of the Act and Regulations relating to medical devices, any condition attached to the permit or any other prescribed requirement;
  - (iii) The permit holder no longer satisfies any of the prescribed requirements based on which the permit was issued;
  - (iv) It is in the public interest to do so.

- (b) The compliance history of the permit holder and the risk to the health and safety of patients, users or other persons of allowing the permit to remain valid will also be considered.
- (c) When a decision to suspend or revoke a permit has been taken, the permit holder shall be given written notice of the intention and the reason(s). The permit holder shall also be given an opportunity to be heard prior to the suspension or revocation.
- (d) As soon as a permit is suspended or revoked, the permit holder shall be required to immediately suspend all activities related to the manufacturing, importation, or supply of medical devices until such time as the permit is reinstated.
- (e) Suspended permit may be reinstated if the situation that gave rise to the suspension is corrected or the reason for the suspension was unfounded.
- (f) If revoked permit is not reinstated. The permit holder may submit a fresh application for a new permit provided that the situation that gave rise to the revocation is corrected.

### **3. ANNUAL RENEWAL OF PERMITS**

- (a) All permits shall expire on 30<sup>th</sup> June of each year. Renewal notice will be issued by the authority through media. However it is the responsibility of the permit holder to renew the permit before its expiry regardless whether a notice has been issued or not by the authority.
- (b) Dealers who shall delay to renew their permits beyond 30<sup>th</sup> September every year shall be required to pay the Authority the prescribed annual permit fee together with 25% penalty of the fee. Contrary to that the registration certificate may be revoked and premises closed down.

### **4. NOTIFICATION OF CHANGE**

Every permit holder is required to notify the Authority whenever there is a change to any particulars declared by him to the Authority at the point of application. For changes that may significantly affect the operations of the permit holder, the permit holder shall not effect, or operate according to, the change until and unless the Authority has given its approval for the change.

### **5. KEY REGULATORY RESPONSIBILITIES OF PERMIT HOLDERS**

A permit holder has other key obligations defined in the law as described below. It is important that a permit holder has access to and is familiar with the current version of the Act and Regulations in order to meet the regulatory requirements.

## **5.1 Labelling**

Section 92(1) of the Act states that no person shall, in the course of a business operated by him, sell or supply or have in his possession for purposes of selling or supplying any product regulated under this Act in a container or package which is not labelled in accordance with the regulations made under section 122. All medical devices, must comply with the labelling requirements as set out in the regulations.

## **5.2 Registered Device**

Permit holders shall only import or supply registered and/or exempted medical devices upon approval by TFDA. Permit holders are not allowed to import or supply unregistered devices unless authorisation has been obtained from the Authority.

## **5.3 Device Advertisement**

All permit holders shall be required to obtain a permit from the Authority with regards to the promotion and advertising of medical devices. It is an offense for a person to publish an advertisement that contravenes the Act and Regulations, such as a false or misleading advertisement.

## **5.4 Furnishing of information**

Permit holders shall be required to furnish information or documentation regarding the medical devices within specified period when requested by the Authority.

## **5.5 Verification of quality, safety, and efficacy of medical devices**

Permit holders shall be required to take measures to verify quality, safety, or efficacy of medical devices. Measures may include product evaluation and testing.

## **5.6 Maintenance of Records**

### **5.6.1 Distribution Records**

Permit holders are required maintain records of distribution for each device sold to facilitate accountability and traceability of medical devices. The distribution records shall contain sufficient information to permit a complete and rapid withdrawal of the device from the market where necessary. Information may include:-

- (a) name and address of initial consignee;
- (b) identification and quantity of medical devices supplied;
- (c) date supplied and;
- (d) any control numbers used including lot/batch/serial number of the medical device.

The minimum retention period for distribution records shall be the projected useful life of the product or two years after the product is shipped or sold, whichever is longer.

The distribution record maintained shall also contain a record of the information of the implant when supplied by a healthcare facility.

#### **5.6.2 Complaint Handling**

Permit holders are required to maintain records of reported problems regarding medical devices they are dealing with. These records must include all actions taken in response to these problems.

#### **5.7 Recalls**

The permit holder is required to notify the Authority upon undertaking a recall or intending to activate one and the reason(s) for doing so. As soon as possible after completion of a recall, the permit holder and registrant are required to report to the Authority the results of the recall and the action taken to prevent a recurrence of the problem.

#### **5.8 Reporting of adverse events**

Permit holders are required to report incidents involving devices they deal with.

### **6. QUALITY MANAGEMENT SYSTEMS AND GOOD DISTRIBUTION PRACTICE**

Manufacturers of medical devices are obliged to operate at a high level of quality assurance. This is achieved through establishing and maintaining quality management systems such as those conforming to standards like ISO 13485. This ensures that medical devices releases for distribution are of appropriate quality.

This quality management system should be established and maintained throughout the supply chain to ensure that the quality of medical devices is not adversely affected during their distribution and to ensure that appropriate records are kept.

Importers, wholesalers and retailers of medical devices should ensure that the device products that they handle are stored at the correct conditions, including during transportation, and that contamination is avoided.

### **7. SURVEILLANCE INSPECTION**

The Authority shall conduct surveillance inspection from time to time and wherever necessary to determine if permit holders comply with requirements of the Act and Regulations.

## TANZANIA FOOD AND DRUGS AUTHORITY



## APPLICATION FORM FOR MEDICAL DEVICES PREMISE PERMIT

## PART A: PARTICULARS OF OWNER(S), PREMISE AND SUPERVISOR

	<b>Particulars owner(s)</b>	
<b>A1</b>	Name of owner(s)	
	Postal address:	
	Telephone:	
	Fax:	
	E-mail:	
	<b>Information of the premise</b>	
<b>A2</b>	Name of the premise:	
	Postal Address:	
	Physical Address:	
	Telephone:	
	E-mail:	
	Fax:	
	Name of Contact Person:	
	E-mail of Contact Person:	
	Telephone:	

<b>Information of Supervisor</b>	
<b>A3</b>	Name of Supervisor(s):
	Academic Qualifications:

**PART B: DECLARATION OF APPLICATION**

<b>B1</b>	<i>(Please tick as appropriate)</i>
	I/We hereby apply for a new permit / renewal to:-
	<input type="checkbox"/> Manufacture
	<input type="checkbox"/> Import
	<input type="checkbox"/> Wholesale
	<input type="checkbox"/> Retail
<b>B2</b>	Existing Permit No: ..... Dated .....
	Expiring on .....
	My/our financial resources committed for this business amount to.....and my/our annual projected turnover is Tshs.....

**PART C: ENCLOSURE**

<b>C1</b>	<i>(Please tick as appropriate)</i>
	Find enclosed the following supporting documents:-
	<input type="checkbox"/> Business/company registration certificate
	<input type="checkbox"/> Sketchy Design of the Premise
	<input type="checkbox"/> Certified Copies of Academic Certificates of Supervisor
	<input type="checkbox"/> List of class A Exempted Medical Devices Imported
	<input type="checkbox"/> List of class A Exempted Medical Devices Manufactured

**PART D: ATTESTATION**

<b>C1</b>	<p><i>(Please tick as appropriate)</i></p> <p>The establishment has documented procedures in place for:-</p> <p><input type="checkbox"/> Distribution records</p> <p><input type="checkbox"/> Complaint handling</p> <p><input type="checkbox"/> Recalls</p> <p><input type="checkbox"/> Adverse event reporting</p>
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*“As owner(s) of the premise name in this application,*

- a) I/ We hereby attest that the information provided in this application is correct and complete.*
- b) I/ We hereby attest that I have direct knowledge of the documented post- market procedures in place in respect to distribution records, complaint handling, recalls and adverse event reporting.*
- c) I/ We hereby attest that the establishment has documented procedures in place, where applicable, for handling, storage, delivery, installation, corrective action and servicing in respect to medical devices handled by the premise.*
- d) I/ We acknowledge that it is a serious offence to knowingly make false attestations on this application.*
- e) I/ We acknowledge that knowingly making false attestations is grounds for refusal to issue a permit.*
- f) I/ We acknowledge that the discovery, at some future time, that false attestations were knowingly made in this application is grounds for suspension or revocation of my premise permit.*

\_\_\_\_\_  
**Name of Owner(s)**

\_\_\_\_\_  
**Official Stamp of the Company**

\_\_\_\_\_  
**Signature**

\_\_\_\_\_  
**Date**

**FOR OFFICIAL USE ONLY**

Fees Tshs..... Receipt No..... of .....

Permit granted/not granted because.....  
.....

Permit No.: .....

Approved by meeting No.....of.....

.....  
Date

.....  
Signature of Director General and stamp

**TANZANIA FOOD AND DRUGS AUTHORITY**



**INFORMATION ON MEDICAL DEVICES**

**Name of importer :** \_\_\_\_\_  
**Address:** \_\_\_\_\_  
**Telephone:** \_\_\_\_\_  
**Fax:** \_\_\_\_\_  
**E-mail:** \_\_\_\_\_

S/N	Brand name of the Device	Common name or preferred name	Description of the device as per GMDN or as applicable	Category of the device as per GMDN	Intended use of the device	Name and complete address of the manufacturer	Device Class**	Marketing approval status in GHTF Member Countries and/or other countries
1								
2								
3								
4								

**Name of authorized person:** \_\_\_\_\_  
**Signature:** \_\_\_\_\_  
**Date:** \_\_\_\_\_  
**Stamp:** \_\_\_\_\_

\*\* Classification as per GHTF Rules

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