

TANZANIA FOOD AND DRUGS AUTHORITY



APPLICATION FORM FOR MEDICAL DEVICES PREMISE PERMIT

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

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

	Information of Supervisor	
A3	Name of Supervisor(s):	
	Academic Qualifications:	

PART B: DECLARATION OF APPLICATION

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

PART C: ENCLOSURE

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

C1	<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.....
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Permit No.:

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

.....
Date

.....
Signature of Director General and stamp