APPLICATION FORM FOR REGISTRATION OF MEDICAL DEVICES

Under Section No.53 (1) of the Zanzibar Food, Drug and Cosmetic Act, 2/2006

Please read this section carefully before completing the form

1. Please check the corresponding boxes in the "Encl." column if any document is enclosed and indicate the respective indexes in the submission folder
2. Please check the boxes as appropriate

Note	Part A: Particulars of Applicant		Encl.
A1	Applicant's name		
	Address of Head Office		
	Post Code:	Country:	
	Contact Person:	Telephone:	
	Fax:	E-mail:	
	Website:		
	Part B: Particulars of Manufacturer		
B1	Manufacturer's name		
	Address of Head Office		
	Physical address of the site		
	Post Code:	Country:	
	Contact Person:	Telephone:	
	Fax:	E-mail:	
	Website		
B2	Quality Management System Established by the Manufacturer Mention current Standards with which the system complies : ☐ _____		☐

<table>
<tr><td></td><td>☐ _____
☐ _____
☐ System certified by _____
and a certified copy of the certificate is enclosed.
Indicate areas covered by Quality Management System
☐ Device design,
☐ Production
☐ Post-production processes
☐ Others (please specify)
_____</td><td></td></tr>
<tr><td rowspan="5">C1</td><td colspan="2">Part C: Particulars of Local Responsible Person (LRP)</td><td></td></tr>
<tr><td>LRP's name</td><td></td><td rowspan="4">☐</td></tr>
<tr><td>Address of the registered business premise</td><td></td></tr>
<tr><td>Contact person:</td><td>Telephone:</td></tr>
<tr><td>Fax:</td><td>E-mail:</td></tr>
<tr><td colspan="3">Contact telephone for public enquiries (if different from the number given above):</td></tr>
<tr><td>C2</td><td>☐ Certified copy of business registration certificate with business registration number: _____ is enclosed</td><td></td></tr>
<tr><td>C3</td><td>☐ Certified copy of Power of attorney or formal agreement or any other official authorization of the LRP is enclosed</td><td></td></tr>
<tr><td>C4</td><td>☐ The LRP is also an importer of the device named in Part D</td><td></td></tr>
</table>

	Part D: Particulars of the Device		
D1	Generic name of the Device		
D2	Brand name of the Device		
D3	Model /Series/System (***if applicable***)		
D4	Family (***if applicable***)		
D5	Country of origin		
D6	Select GMDN (Global Medical Device Nomenclature) Categories: 01 - Active implantable device 02 - Anaesthetic and respiratory devices 03 - Dental devices 04 - Electro mechanical devices 05 - Hospital hardware 06 - In vitro diagnostic devices 07 - Non-active implantable devices 08 - Ophthalmic and optical devices 09 - Reusable instruments 10 - Single use devices 11 - Technical aids for disabled persons 12 - Diagnostic and therapeutic radiation devices 13 - Complimentary therapy devices 14 - Biologically -derived devices 15 - Healthcare facility products and adaptations 16 - Laboratory equipment 17 - Others _____		
D7	Description of the device ***(Please enter appropriate GMDN description. If none of the descriptions in GMDN appear appropriate, enter a short description of the device)*** _____		

	_____	
D8	GMDN Code: _____ ***(Please enter if known)***	
D9	Other common descriptions of the device: _____ _____ _____	
D10	Intended use of device	
D11	Class of the medical device: ☐ Class A ☐ Class B ☐ Class C ☐ Class D Reasons for classifying the device as Class A, B, C or D device: _____ _____	
D12	<u>History</u> ☐ No previous recalls, reportable adverse incidents, banning in other countries or post-market surveillance studies ☐ Yes ***(Please tick the appropriate boxes and provide details):*** ☐ Recalls completed or in progress ☐ Any reportable adverse incidents bearing implications to the device ☐ The device banned previously in other countries ☐	☐

	Pro-active post-market surveillance studies	
D13	Performance and Safety International or national standards with which the device complies _____ _____ (Please enclose copy of the standard)	☐
	Part E: Marketing Approvals in Foreign countries	
E1	Mention the countries where the device has obtained marketing approvals _____ _____ (Please enclose certified copy of valid marketing authorization)	☐
E2	Mention the countries where the device approval is still pending _____ _____	☐
	Part F: Declaration of conformity (DoC)	
F1	Submit a written declaration of conformity. The DoC should contain the following:- a) An attestation that a device complies with the applicable EPSP, has been classified accordingly and has met applicable conformity assessment elements. b) Information sufficient to identify the device including its nomenclature. c) The risk class allocated to the device. d) Which of the conformity assessment elements have been applied. e) The date from which the DoC is valid. f) The name and address of the device manufacturer.	☐

	g) The name, position and signature of the responsible person who has been authorized to complete the DoC.	

Declaration by applicant

I, the undersigned certify that all the information in this form and accompanying documentation is correct and true to the best of my knowledge.

Name:_____

Position: _____

Signature: _____

Date: _____