TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

APPLICATION FORM FOR VARIATION OF A REGISTERED MEDICAL DEVICE INCLUDING IN VITRO DIAGNOSTIC DEVICE

1	Brand name	
1.1	Device classification:	
1.2	Intended use:	
2	Model/series/system (*if applicable*)	
3	Type of change(s) (*state which type of variation*)	
3.1	Scope (*Please specify scope of the change(s) in a concise way*)	
3.2	Background for change & Justification for change(s) (*if applicable*) *Please give brief background explanation for the proposed change(s) to your marketing authorization as well as a justification in case of consequential change(s)*	
3.3	Present (*Please specify precise current wording or specification*)	3.4 Proposed (*Please specify precise proposed wording or specification*)

Registrant should always enclose a working model clearly showing the differences between the proposed version and the current version.

4 Details of Registrant (*must be the holder of the marketing authorization/registration certificate)*

Name:
Business Address:
Postal Address:
Country
Phone: Fax: Email:

…….. …….. ……..

Name **Date** **Signature and stamp**