APPLICATION FOR POST APPROVAL VARIATION OF MEDICAL DEVICE

M/s…….... hereby applies for Post approval variation of the medical device specified below for sale/distribution in Bhutan.
Product Registration no:
Generic Name:
Brand Name:
Product Code (If applicable):
Date of Expiry of the Registration:

Sl. No	Current Specification or details	Proposed Change	Reason for Change
1			
2			

Note: Attach all the required documents stated in the guidelines for registration of medical devices.

Declaration (please tick the boxes):

☐I hereby declare that the documents submitted above/all information provided in the document above is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.

☐I declare that I have read the regulation and I am fully aware that my application may be rejected if I do not fulfill the conditions or contravene the provision(s) of the act and regulations made there under.

☐If my application is granted, I shall abide by the Medicines Act and Regulations and any other standards set by the Authority.

Signature of applicant
with name and contact No
Date: