

APPLICATION FOR FULL REGISTRATION OF MEDICAL DEVICE

M/shereby apply for registration of the medical device specified below for sale/distribution in Bhutan.

Generic Name	Brand Name	Permissible variants (in case of FAMILY)	Pack Size	Material of construction/composition	Manufacturer

Medical Device Classification :

Medical Device group:

Intended Indication:

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 and information submitted 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: