

APPLICATION FOR RENEWAL OF MEDICAL DEVICE REGISTRATION

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

Product Registration no:

Name of the product:

Date of Expiry of the Registration:

Generic Name	Brand Name	Permissible variant (in case of FAMILY)	Pack Size	Material of construction/com position	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 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: