APPLICATION FOR ABRIDGE REGISTRATION OF MEDICAL DEVICE

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

Basis for Abridge registration (tick whichever applicable)

- The product is WHO prequalified
- The product has obtained at least one regulatory agency approval from WHO recognized SRAs or IMDRF member countries.

Name of the SRA/IMDRF member countries…….

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 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: