

APPLICATION FOR AUTHORIZATION TO IMPORT MEDICAL DEVICES IN BHUTAN

I/we.....hereby apply for a authorization to import following Medical Device(s) in Bhutan for Sale and distribution.

Sl. No.	Product Name	Registration No	Registration Validity	Manufacturer	Pack size	Quantity

Attach a separate list in case of multiple products

Address of the premises/Store:

Please attach the following documents

1. No Objection letter from the Market Authorization holder in case the importer is different from the Market Authorization holder.
2. Proforma invoice
3. Free sale certificate (for non-registered notified medical devices and list of additional medical devices notified by the Authority for import)
4. Purchase/supply order (for non-registered notified medical devices and list of additional medical devices notified by the Authority for import)

Declaration (please tick the boxes):

- I hereby declare that the documents submitted above/all information provided is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.
- If my application is granted, I shall abide by the Medicines Act and Regulations and any other standards set by the Authority.
- I /we shall submit the record of medical devices imported half yearly in the prescribed format.

Signature of applicant:
Name and Address:

Date: