



DRA/D1/31-Med-Device/21-22/ 107

31 August, 2022

NOTIFICATION

Notification on Requirement of Technical Authorization for sales, distribution of Medical Devices and Registration of Medical Devices

“The medicines Act of the Kingdom of Bhutan 2003”, mandated the Drug Regulatory Authority to develop policies, guidelines and standards on the regulation of medicinal products including medical devices to ensure the safety, quality and efficacy/performance of these products in the market. Furthermore, pursuant to the provisions of the same law, a Technical Authorization is required for establishments engaged in the sale, distribution and manufacturing of any medical device including in-vitro diagnostic device henceforth. Medical devices requiring Technical Authorization from DRA for sales and distribution incorporates the list of the medical devices published by the DRA (The Medical Device list would be updated and notified from time to time). Additionally the products listed must also be registered by the wholesalers prior to obtaining Import Authorization from the DRA. Authorizing the medical device suppliers, manufacturers and retailers and registering the products will ensure access to safe, quality and effective medical devices. The Guidelines for registration and Import Authorization has been uploaded on the DRA website (www.dra.gov.bt) for access.

Therefore, all the concerned individuals are requested to comply with this regulatory notification and visit the DRA office for registration of your firm and medical devices and clear the stocks (unregistered medical devices) within 6 months of this notification as per section 16.2.3 of The Medicines Act of The Kingdom of Bhutan, 2003.

This notification is issued for immediate compliance.

For any further clarification & queries kindly contact DRA officials at +975-2-337074/337075


DRUG CONTROLLER

Copy to:

1. Director General, Department of Trade Ministry of Economic Affairs
2. Director General, Department of Medical Supplies and Health Infrastructure
3. Retailers and Wholesalers of medical devices



Requirements for Obtaining Technical Authorization (Both Retailers and Wholesalers) from DRA

1. A competent person with following qualification:
 - a. Health Professionals registered with Bhutan Medical Health Council, or any other allied science and technology courses relevant to the device to be distributed or imported.
 - (or)
 - b. Diploma in any field with minimum of three years' of experience in the field of medical devices.
2. Suitable premise for storage and distribution of medical devices.

Note: Prior to obtaining Technical Authorization, the Competent Person must be registered with the DRA. The requirements are specified in the Application forms which are uploaded in the website.

List of Medical Devices Requiring Registration and Technical Authorization for Sale and Distribution (List based on market prevalence and risk)

1. All catheters
2. All types of cannula
3. Blood bags
4. Blood pressure Monitor
5. Blood transfusion sets
6. Cotton for surgical purposes
7. Endotracheal tubes
8. Gauze
9. Glucometer
10. Hearing aid
11. IV set
12. Medical syringes
13. Nebulizer
14. Oxygen Concentrator
15. Pregnancy Test Kit
16. Prolene mesh
17. Surgical stapler
18. Surgical blade
19. Surgical gloves
20. Suture (absorbable and nonabsorbable)
21. TTI Te

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