Republic of Sudan
Federal Ministry of Health
National Medicines & Poisons Board
Secretariat General

Requirements for the registration of Medical Devices (Human and Veterinary)

A. General Requirements:

1. The manufacturing plants should be registered within the NMPB records.
2. The application form should be filled by the applicant.
3. The prescribed fees should be paid (if required).
4. All documents should be in English and/ or Arabic.

B. Specific Requirements:

1. **Registration requirements of human medical devices:**
   a) Submit one of the following certificates:
      i. EC certificate compatible with the classification of medical device,
      ii. US Food and Drug Administration (FDA approval),
      iii. Certificate of registration in a country with a stringent regulatory authority (IMDRF countries)
   b) Submit medical device description, specification, and intended use,
   c) Submit the internal and external label of medical device,

2. **Registration requirements of veterinary medical devices:**
   a) Submit one of the following certificates:
      i. Free sale certificate
      ii. Certificate of registration in a country with a stringent regulatory authority (IMDRF* countries)
   b) Submit medical device description, specification, and intended use,
   c) Submit the internal and external label of medical device (the label must clearly state that the medical device is for veterinary use only).

IMDRF* = International Medical Device Regulators Forum

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