Registration of a Medical Equipment

This services allows the registration of medical equipment with the purpose of importing and trading them in UAE.

Department Name
Drug

Sector
Health Regulation

Main Service
Medical, Pharmaceutical and Drug Licencing and Registration

Service Code
110-04-013-000

Service Classification
Transactional

Variation / Auxiliary
Variation

Service Type
Government to Business

Service Process

01 Login to the MOHAP website or smart app using the UAE PASS.

02 Submit the request through the e-service and complete the payment to meet all conditions.

03 The competent technical committees will deliberate the registration of products and recommendations shall be submitted to the competent ministerial committee.

04 Letters shall be addressed to the concerned companies stating the committee's decisions.

05 The customer shall follow up with the Analysis Section of at the Drug Department.

06 The company should complete the requirements and submit them via electronic service.

07 The relevant technical and ministerial committees will re-deliberate the registration of products that have been deferred in advance as soon as companies complete the requirements.

08 The certificates of registration of products that have been approved for registration will be issued, provided all conditions and requirements are fulfilled. Registration certificates are valid for five years effective the date of committee's approval.

09 The pharmaceutical certificates (for locally manufactured pharmaceutical products) will be issued and be valid for one year effective the date of issuance.

Required Documents

- Application form of registration signed and stamped by company
- A copy of valid registration certificate of the factory
- A valid certificate of free sale/registration issued by the competent authorities in the country of origin certified by the UAE Embassy
- A copy of the product agency contract signed between the company and the agent
- Certificate of quality conformity/ marketing authorization, such as EC (European Conformity), 510 K (Premarket Notification), PMA (Parts Manufacturer Approval) as per the classification of the equipment, i.e. Class I, II, III, IV
- Post-marketing monitoring requirements
- Product's information, including description, formulation, types, sizes, models, accessories, usages, side effects, contradictions, warnings, precautions, usage guidelines, photos of packaging covers, brochures and usage manuals
- Provide laboratory requirements and analysis, as well as pricing for certain medical equipment
- Provide one sample, certificate of analysis (as per equipment type)
- External and internal covers and brochures
- Acknowledgment of the company that equipment conforms to the specifications as per the Medical Equipment Manual (EC (European Conformity) -Declaration of Conformity)
- Safety and efficacy data (for products classified as Class III, IV)
- Special requirements: Certificate of conformity to equipment manufactured from animal products

Requirements & Conditions

- Marketing Authorization Holder companies must be registered by MOHAP before they could register their products.
- The marketing office or medical warehouse must be licensed by the Ministry of Health and have a valid license.

Service Channels

MOHAP Website: www.mohap.gov.ae

MOHAP Smart App

Resources

- Pricing Rules
- Drug Registration - External User Manual
- Help Manual
- Login User Manual
- Portal Manual

Average Service Time
45 working days

Payment channels
E-Payment

Target Audience
Medical warehouses, local pharmaceutical manufacturers, and marketing offices

Service Locations
- MOHAP Website www.mohap.gov.ae
- MOHAP Smart App

Related Services
This service is not linked to any other services

Service Bundle
This service is not linked to any bundles

Contact Details
Email
smartservicessupport@mohap.gov.ae

drugreg.inquiries@mohap.gov.ae

Service Fees

Application: AED 100

Registration of a medical device: AED 5000

Sustainable Development Goals

3 GOOD HEALTH AND WELL-BEING

Notes

None

FAQs

1. What is the fee for the registration of a medical device?

- Application: AED 100
- Registration of a medical device: AED 5000

2. What is the average length of time for the registration of a medical device?

- 45 working days

3. What channels are available to apply for the registration of a medical device?

- MOHAP Website and Smart Application

4. What are the conditions and requirements for obtaining a medical device?

- Marketing Authorization Holder companies and product manufacturing sites must be registered in MOHAP prior to the registration of their products.
- The applicant must be a medical warehouse or marketing office licensed by the Ministry of Health and Prevention and must hold a valid license.