



Registration of a Medical Equipment

About the Service

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

Service Process

- Login to the MoHAP website or smart app using the UAE PASS
- Submit the request through the electronic service and complete the payment to meet all conditions
- The competent technical committees will deliberate the registration of products and recommendations shall be submitted to the competent ministerial committee
- Letters shall be addressed to the concerned companies stating the committee's decisions
- The customer shall follow up with the Analysis Section of at the Drug Department
- The company should complete the requirements and submit them via electronic service
- 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
- 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
- The pharmaceutical certificates (for locally manufactured pharmaceutical products) will be issued and be valid for one year effective the date of issuance

Required Documents

- Filling out the application form of registration completely and to be 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 Embassy of the United Arab Emirates.
- 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.
- Providing one samples, certificate of analysis (as per equipment type), external and internal covers and brochures.
- Acknowledgement 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.

Conditions & Requirements

1. Marketing Authorization Holder companies must be registered by MOHAP before they could register their products.

2. The marketing office or medical warehouse must be licensed by the Ministry of Health and have a valid license.

FAQ's

Service completion duration

- 45 working days

Service fees

Service channels

Service locations

- [Mohab Website](#)
- MOHAP Smart Application

Support

- smartservicessupport@mohap.gov.ae
- drugreg.inquiries@mohap.gov.ae

Payment channels

- E- Payment

Target audience

- Medical warehouses
- Local pharmaceutical manufacturers
- Marketing offices

Resources

- [Pricing Rules](#)
- [Drug Registration - External User Manual](#)
- [Help Manual](#)
- [Login User Manual](#)
- [Portal Manual](#)
- [Infographic - Registration of a Medical Equipment - PDF 420KB.pdf](#)

Department name

Drug

Sector name

Health Regulation

Main service

Medical, Pharmaceutical and Drug Licencing and Registration

Service Code

110-04-013-000

Service Classification

Transactional

Sub Service Type

Variation

Service Type

Government to Business

Related Services

- This service is not linked with other services

Service Bundle

This service is not linked with any service packages

Number of Users

83

Number of Transactions

468

Notes

Marketing Authorization Holder companies must be registered by MOHAP before they could register their products.

Sustainable Goals

Good Health And Well-Being