UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

الإمارات العربية المتحدة
وزارة الصحة ووقاية المجتمع

# Renewal of Registration of Medical Equipment

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

## Main service

Medical, Pharmaceutical and Drug Licencing and Registration

## Service code

110-04-013-013

## Service classification

- Government to business

## Service type

Transactional

## Service process

1. Login to the MoHAP website or smart app using the UAE PASS.
2. Submit the request online and complete the payment to meet all conditions.
3. The competent technical committees will deliberate the registration of products and recommendations shall be submitted to the competent ministerial committee.
4. Letters are to be addressed to the concerned companies stating the committee's decisions.

## Service completion duration

15 working days

## Payment channels

E-payment

## Target audience

Medical warehouses
Local pharmaceutical manufacturers

## Service locations

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

## Support

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

## Service fees

Application: 100 AED
Renewal of the registration of a medical device: 2,500 AED

## SDGs Goals

5 The customer will follow up with the Analysis Section of at the Drug Department.

6 The company should complete the requirements and submit them online.

7 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.

8 The certificates of registration of products that have been approved for registration will be issued, provided all the conditions and requirements are met. Registration certificates are valid for five years effective the date of last expiry date of the previous certificate.

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

## Required documents

1. The application form of renewing the registration of medical equipment and reagents
2. The original registration certificate of the product issued previously by the Drug Control Department
3. A valid manufacturing certificate of the factory issued by MOHAP
4. Certificate of free sale/ registration issued by the competent authorities in the country of origin
5. A copy of all minor changes certificates issued by the Drug Control Department and certificates of quality conformity/ marketing authorization, such as EC, 510 (K), PMA as per the classification of the equipment, i.e. Class I, II, III, IV
6. Post-marketing monitoring requirements
7. Providing 3 samples (as per equipment type), certificate of analysis (as per equipment type), external and internal covers and brochures
8. Acknowledgment of the company that equipment conforms to the specifications as per the Medical Equipment Manual (EC-Declaration of Conformity)

## Conditions and requirements

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

## Service channels

1. MOHAP website: www.mohap.gov.ae
2. MOHAP smart app

## Resources

- Infographic - Renewal of Registration of Medical Equipment - 417KB.pdf
- Drug Registration - External User Manual-403.pdf
- Help Manual-642.pdf
- Login User Manual-653.pdf
- Portal Manual-666.pdf
- Pricing Rules.pdf