UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

CLASSIFICATION OF A PRODUCT - GUIDLINES

Service description

This service allows the classification of products of all types and forms based on Presentation /Composition / Use and Design; Requirements may vary based on the Nature of the Product, Risk Class, and Regulatory Status.

Conditions and requirements

1. The purpose of the Classification letter is to inform you about the laws governing your products within UAE.

2. The classification letter identifies the product classification if the product needs or does not need registration by MOHAP. If it is determined that it needs registration by MOHAP, it must be registered in MOHAP according to the class identified in the classification letter.

3. Classification is available for all types of Companies and for Individuals.

4. Registration in MOHAP should be only for Medical Warehouses licensed by MOHAP.

5. If the result of classification is "Does not require MOHAP registration", the product is subject to procedures of other competent authorities within UAE. It is the applicant's responsibility to contact such authorities and to abide by the regulations governing their work. Examples of these authorities include Dubai Municipality, Ministry of industry and Advanced Technology, Ministry of Environment and Water and other official UAE authorities.

6. In case of non-medicinal products no medical claims are allowed on the products.

7. The Classification letter is not a registration certificate and doesn’t imply the MOHAP approval to market the product in the UAE.

8. The Classification letter is given for the purpose of preliminary classification upon data submitted by the applicant, the applicant alone bears the responsibility of the truth of his submitted data, MOHAP doesn’t bear any responsibility.

9. MOHAP did not analyse the product and doesn’t guarantee the quality, efficacy & safety of the product.

10. This letter is valid for Three years only from the date of issue.

11. To classify products of Medical Equipment and Devices, the above terms are applicable along with the following additional steps:

11.1: In the case of Medical Device that have a large number of accessories/ supplies, a list of these accessories should be presented in the form of a table showing the names of these accessories and their code numbers (if any). This list is to be stamped by the manufacturer/ supplier abroad as well as the stamp of the local agent. If the list is long one and needs multiple pages, each page is to be stamped and the list is to be attached to the classification application.

11.2: If product contains multiple sizes, then all the sizes can be submitted in one application, Similar Products with difference in models/Configurations/uses/ dosage forms are considered as different application.

11.3: As for devices, each device and its accessories will be dealt with as one product. Fees will be applied accordingly.

11.4: Supporting items of different areas of the body of the device are considered different products. Fees will be applied accordingly.

11.5: As for first aid bags and kits, each item within the group is considered a different product. Fees will be applied accordingly.

11.6: Dentistry kits for the use of specialized doctors are classified as follows: Tools and Equipment of the same group are classified within one application and products with Pharmaceutical and Chemical substances are considered as separate applications. Fees will be applied accordingly.

11.7: Laboratory Reagents: Reagent linked to a specific system / analyser are considered one application, separate individual reagents/ rapid test kits are handled in separate applications.

11.8: For products granted the status of "Clearance from UAE MOHAP as Medical Device, restricted to use by professionals", then the applicant have to approach the Importation section/ Drug Department at the UAE MOHAP (Online) for clearance of the products as per applicable procedures after submitting a copy of this letter along with copies of quality related documents e.g.:ISO,CE etc., Such products will only be cleared for Medical Stores licensed by the UAE MOHAP, such products can only be supplied to MOHAP/DOH/DHA licensed healthcare facilities within the UAE, supply of such products to patients within the UAE is not allowed and is considered as violation of the UAE laws and will result in cancellation of any permits granted for the products along with other legal procedures. In case of any adverse effects or malfunction or pharmacovigilance reports resulting from the cleared Medical Devices then the Agent/Applicant is responsible to notify MOHAP immediately, failing to do so will hold the Agent/Applicant liable.

11.9: For products granted the status of “Clearance from UAE MOHAP as over the counter medical device” then all mentioned above applies with the exception that it is allowed to be placed in pharmacies for OTC use.

11.10: For Medical Devices containing Software that processes patient data, it is mandatory to be in compliance with UAE Federal Law No.2 of 2019 (https://www.mohap.gov.ae/FlipBooks/PublicHealthPolicies/PHP-LAW-EN-77/mobile/index.html) that regulates handling/processing/transferring of patient data and the MOHAP Ministerial Decree 51/2021 related to this law

12. Classification Letter Formats:

12.1: Classification Letter: User Account Type; Medical Stores (warehouse)/ Local Manufacturer licensed by the UAE MOHAP

12.2: Notification Letter: User Account Type; Individuals or other facilities except the above mentioned

Required documents

1. Emirates ID or Applicant Passport or Trade License or Drug Store License (Depends on the user type)

2. Certificate from Country-of-Origin Regulatory Authority related to the Submitted Product (Copy of the CPP/Free Sale Certificate/CFG/CE/ISO) along with English or Arabic Translation

[CPP: Certificate of Pharmaceutical Product. CFG: Certificate to Foreign Government. CE: European Conformity. ISO: International Organization for Standardization with submitted Product Name]

3. Product Picture

4. Leaflet/Product Information in English/ Arabic

5. Product Catalogue for Medical Devices

6. Inner Pack Label with Clear and Readable Product Name and Information (Artwork)

7. Outer Pack Label with Clear and Readable Product Name and Information (Artwork)

8. Composition Certificate (Active/ Inactive ingredient list with each ingredients quantity)/ MSDS (applicable for product that have Medicinal/Chemical Ingredients in it) MSDS: Material Safety Data Sheet.

9. Registration and Marketing Status in other Countries (Copy of the Certificates along with English or Arabic Translation from Reference Countries approved by UAE MOHAP (Reference Country List Attached Above) / CE Certificate from EU approved Notified Body for the submitted Product) [CE: European Conformity. EU: European Union.]

10. Product Sample in their Final Original Pack (Upon Request)

11. MOHAP Quality Control Lab Analysis Report (Upon Request)

12. Letter of Authorisation from Marketing Authorization Holder (Upon Request)

Service Link

https://mohap.gov.ae/en/services/classification-of-a-product