SERVICE NAME / CLASSIFICATION OF A PRODUCT

DEPARTMENT NAME
Drug Department

SERVICE FEES
AED500

SECTOR NAME
Public Health and Licensing Sector

SERVICE DESCRIPTION
This service enables clients to submit their applications for the classification of products of all types and forms, based on Presentation, Composition, Usage and Design.

SERVICE CHANNELS
Website

CONDITIONS AND REQUIREMENTS

The purpose of the classification letter is to inform you about the laws that govern your products within the UAE

The classification letter identifies the product classification (whether or not the product requires registration) according to MOHAP. If it is decided that the product needs to be registered in MOHAP, then it will be registered as per the class identified in the classification letter

Classification is available for all types of companies and individuals

Only medical warehouses licensed by MOHAP will be registered in MOHAP

If the result of classification is "Does not require MOHAP registration", then the product will be subject to the requirements of other competent authorities (such as Dubai Municipality, Emirates Authority for Standardization and Metrology, Ministry of Environment and Water and other official authorities) within the UAE. It is the applicant's responsibility to contact such authorities and to abide by the regulations governing their work

No medical claims are permitted on non-medicinal products

A classification letter should not be considered the equivalent of a registration certificate and in no way implies MOHAP's approval to market the product in the UAE

A classification letter is submitted for the purpose of preliminary classification based upon data submitted by the applicant and, accordingly, the applicant bears full responsibility for the validity of such data, while MOHAP bear no liability whatsoever

It is understood that MOHAP has not analyzed the product and cannot guarantee the quality, efficacy or safety of the product

A classification letter is valid for three years from the date of issue

The classification of medical equipment and devices also requires the following additional steps:

a. In the case of medical devices that include a large number of accessories/supplies, a list of such accessories must be submitted in the form of a schedule listing the names of such accessories and their code numbers (if any). This list is to be stamped by the manufacturer/supplier abroad as well by the local agent. If the list is too long and needs multiple pages, each page must be stamped and the list must be attached to the classification application

b. Where the product includes multiple sizes, all sizes can be submitted in one application. Similar products with different models/configurations/uses/dosages will be regarded as separate applications

c. Individual devices and their accessories will be regarded as one product. Fees will be applied accordingly

d. Supporting items for different parts of the device body will be regarded as separate products. Fees will be applied accordingly

e. Each item included in a first aid bag or kit will be regarded as a separate product. Fees will be applied accordingly

f. Dentistry kits for use by specialized doctors will be classified as follows:
- Tools and equipment of the same group will be classified within one application. Fees will be applied accordingly
- Products containing pharmaceutical and chemical substances will be considered separate applications. Fees will be applied accordingly

g. Laboratory reagents: a reagent linked to a specific system/analyzer will be considered one application, while separate individual reagents will be regarded as separate applications

h. For products granted the status of “Clearance from UAE MOHAP as a medical device restricted to use by professionals”, the applicant must approach the Importation section/Drug Department at the UAE MOHAP (online) for clearance of the products as per applicable procedures, following the submission of a copy of this letter along with copies of quality related documents (such as ISO or CE). Such products will only be cleared for medical stores licensed by the UAE MOHAP and can only be supplied to MOHAP/HAAD/DHA-licensed healthcare facilities within the UAE. Supply of such products to patients within the UAE is not allowed and will be considered a violation of the UAE laws, resulting in the cancellation of any licenses granted for the products along with other legal procedures. Should any adverse effects, malfunctions or pharmacovigilance reports result from the cleared medical devices, the agent/applicant will be liable to notify MOHAP immediately and failure to do so will result in the full liability of the agent/applicant

i. For products granted the status of “Clearance from UAE MOHAP as an over-the-counter medical device”, all abovementioned stipulations apply with the exception that such devices may be placed in pharmacies for OTC use

REQUIRED DOCUMENTS

01 Emirates ID, Trade License or Drug Warehouse License (per user)
02 Product catalogue for medical devices
03 Product photographs for medical devices
04 Certificate from the authorities in the country of origin related to the product (CPP/Free Sale Certificate/CE/ISO)
05 Registration and marketing status in other countries (attach copies of certificates), if applicable
06 Leaflet/product information in English/Arabic
07 Artwork: inner label
08 Artwork: outer design
09 Composition certificate/MSDS (applicable for products containing medicinal/chemical ingredients)

SERVICE STEPS

01
User Account Creation:
Select the account type:
- **Agent** (linked with your existing account)**:** If you have a valid drug warehouse license issued by UAE MOHAP Licensing Department, select this account type
- **Third Party:** Other facilities with licensed authority including trade license and free zone license etc. (the facility's name and the city shall conform to the trade license and free zone license etc.)
- **Individuals:** If you do not have any facility license in the UAE (Applicant Name must conform to the Emirates ID/passport)

02
Ensure that the applicant/establishment name and city are correctly entered as mentioned above (this is a one-time process upon creating the user account). To fill out or correct the user details, head to top left corner of the screen, click on ‘account’, settings, account details, complete or correct the information and press ‘save’ button

03
Enter the “Product name/Trade name” (product name must conform to the artwork (product pack/ catalogue/certificate of origin issued by the country of origin)

04
Select a suitable “Form/Product form” from the drop down list, if it is not available in the drop down list, select “others” and write the exact description in the pop-up box

05
Enter “Product description/details”

06
Select Yes/No in “Multiple size/Accessories” field. If your selection is "Yes", attach the documents as explained below: (“Product sizes/Accessories” list attachment option is only applicable for products that have multiple sizes or accessories). The attached document must include a list with the product name and sizes/name of the product and names and codes of accessories. The list must be on the manufacturer’s letterhead along with its logo. If the list is too large and needs several pages, each page must be stamped (the acceptable format is an A4 PDF) in addition to any other documents eg: artwork lists/catalogues/product lists that are not accepted in this field. If there are no multiple sizes/accessories for your product, select the "No" option

07
Enter the manufacturer's name and country

08
Enter the active ingredients as per the composition certificate (only applicable for products with pharmaceutical/chemical substances)

09
Attach the required documents in the “Attachments” field

10
Pay the fees and submit the application

11
Print the classification letter directly after its approval

SERVICE LOCATIONS
Website