

DEPARTMENT NAME OOO Drug Department



SERVICE FEES

AED500



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



governing their work

safety of the product

accordingly

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

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



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

A classification letter is submitted for the purpose of preliminary classification based upon data



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:

implies MOHAP's approval to market the product in the UAE



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
- 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

h. For products granted the status of "Clearance from UAE MOHAP as a medical device restricted to use

- q. 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
- 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

device", all abovementioned stipulations apply with the exception that such devices may be placed in

i. For products granted the status of "Clearance from UAE MOHAP as an over-the-counter medical

1 Emirates ID, Trade License or Drug Warehouse License (per user)

REQUIRED DOCUMENTS

03 Product photographs for medical devices O4 Certificate from the authorities in the country of origin related to the product (CPP/Free Sale Certificate/CE/ISO)

pharmacies for OTC use

05 Registration and marketing status in other countries (attach copies of certificates), if applicable

02 Product catalogue for medical devices

- 06 Leaflet/product information in English/Arabic **07** Artwork: inner label
- Osmposition certificate/MSDS (applicable for products containing medicinal/chemical ingredients)

08 Artwork: outer design

SERVICE STEPS

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

- Third Party: Other facilities with licensed authority including trade

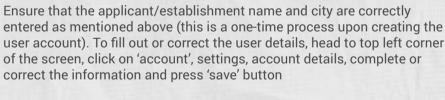
license and free zone license etc. (the facility's name and the city shall conform to the trade license and free zone license etc.)

- Individuals: If you do not have any facility license in the UAE (Applicant Name must conform to the Emirates ID/passport)

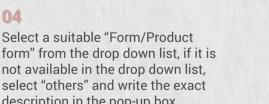
this account type

User Account Creation:

02



04





Enter the "Product name/Trade name" (product name must conform to the artwork (product pack/

03

issued by the country of origin) description in the pop-up box Select Yes/No in "Multiple size/Accessories" field. If your

accessories. The list must be on the manufacturer's letterhead along with its logo. If the list is too large and needs several

catalogue/certificate of origin

Enter "Product selection is "Yes", attach the documents as explained below: description/details" ("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

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,

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Enter the

manufacturer's

name and country

select the "No" option 80

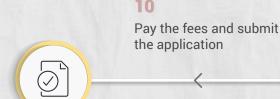
Attach the required

"Attachments" field

documents in the

Print the classification

approval



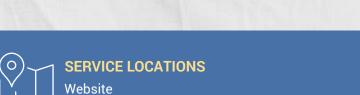
Enter the active ingredients as

per the composition certificate

with pharmaceutical/chemical

(only applicable for products

substances)



letter directly after its

