CLASSIFICATION LETTER

This document is not a registration certificate هذه الوثيقة ليست شهادة تسجيل

DRUG DEPARTMENT

Application No: DRCLAS-2023-002444

Issue Date: 04/05/2023

Expiry Date: 03/05/2026

Applicant Type: Business - Medical Store

M/S.: PHARMA SOLUTION DRUG STORE LLC, DUBAI, UNITED ARAB EMIRATES

Dear Sirs,

This is to inform you that the Classification Committee M.No.: 17/2023 Dated 04/05/2023 has classified your products as mentioned below:

PRODUCT NAME & FORM	MANUFACTURER NAME & COUNTRY	CLASSIFIED AS
NAVIDENT,DEVICE	CLARONAV INC,CANADA	CLEARANCE FROM UAE MINISTRY OF HEALTH & PREVENTION AS MEDICAL DEVICE, RESTRICTED TO USE BY PROFESSIONALS, IMPORT/EXPORT ONLY BY MOHAP LICENSED MEDICAL STORE, IN CASE OF MEDICAL DEVICE CONTAINING SOFTWARE THAT PROCESSES PATIENT DATA IT IS MANDATORY TO BE IN COMPLIANCE WITH THE UAE FEDERAL LAW NO. (2) OF 2019 CONCERNING THE USE OF INFORMATION AND COMMUNICATION TECHNOLOGY (ICT) IN HEALTH FIELDS AND THE MOHAP MINISTERIAL DECREE 51/2021 RELATED TO THIS LAW, READ THE BELOW INSTRUCTIONS

- **This letter is used only to classify a Product in order to guide the applicant to which regulatory path to follow in the UAE.**
- **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. For Medical Devices containing Software that processes patient data, it is mandatory to be in compliance with UAE Federal Law No.2 of 2019 Concerning the use of Information and Communication Technology (ICT) in Health Fields (https://mohap.gov.ae/app_content/legislations/php-law-en-77/mobile/index.html) and the MOHAP Ministerial Decree 51/2021 related to this law.**
- **For products granted the status of "Clearance from UAE MOHAP as over the Counter Medical Devices" then all mentioned above applies with the exception that it is allowed to be placed in pharmacies for OTC use.**
- **This is not marketing authorization certificate and doesn't imply the MOHAP approval to market the product in the UAE.**
- **MOHAP did not analyze the product and doesn't guarantee the quality, efficacy & safety of the product.**
- **This letter was 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.**
- **In case of non-medicinal (Registration not applicable in MOHAP) products other concerned government bodies have to make sure that the products is safe and fit for consumption according to the law and approved procedures, MOHAP doesn't bear any responsibility regarding the above mentioned products.**
- **In case of non-medicinal (Registration not applicable in MOHAP) products, no medical claims are allowed on the products.**

* هذه الرسالة ليست شهادة تسجيل ولا تعني موافقة وزارة الصحة و وقاية المجتمع علي تسويق هذا المنتج داخل الدولة.
* وزارة الصحة و وقاية المجتمع لم تقم بتحليل المنتج و لا تضمن جودة و فاعلية و امان المنتج.
* أعطيت هذه الرسالة لغرض التصنيف المبدئي للمنتج بناءا علي معلومات قدمها طالب الرسالة و يتحمل وحده المسوؤلية كاملة عن صحتها و لا تتحمل وزارة الصحة و وقاية المجتمع اي مسوؤلية تجاه الغير.
* في حالة المنتجات غيرالطبية تكون مسوؤلية الجهات الرسمية الاخري المعنية التأكد من محتويات المنتج و سلامته طبقا للنظم و القوانين المعمول بها لديها و لا تتحمل وزارة الصحة و وقاية المجتمع أأي مسوؤلية تجاه الغير بخصوص المنتجات المذكورة.
* في حالة المنتجات غير الطبية لا يسمح بوجود أي نوع من الادعاءات الطبية علي المنتجات.

Issued on: 04/05/2023

THE EMIRATES

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