DRUG DEPARTMENT

Application No: DRCLAS-2019-001919
Issue Date: 08/10/2019
Expiry Date: 07/10/2022
M/S.: PRIME MEDICAL SUPPLIES EST,Abu Dhabi,United Arab Emirates

Dear Sirs,

This is to inform you that the Classification Committee M.No.: 39/2019 Dated 07/10/2019 has classified your products as mentioned below:

PRODUCT NAME & FORM	MANUFACTURER NAME & COUNTRY	CLASSIFIED AS
NAVIDENT,DEVICE	CLARONAV,CANADA	CLEARANCE FROM UAE MINISTRY OF HEALTH & PREVENTION AS MEDICAL DEVICE, RESTRICTED TO USE BY PROFESSIONALS, IMPORT/EXPORT ONLY BY MOHAP LICENSED MEDICAL STORE, READ THE BELOW INSTRUCTIONS

- **This letter is used only to classify a Pharmaceutical Product in order to guide the applicant to which criteria of registration should be followed to register this product in UAE Ministry of Health & Prevention (MOHAP).**
- **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/ HAAD/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 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 a registration certificate and doesn't imply the MOHAP approval to market the product in the UAE.**
- **MOHAP did not analyze the product and doesn't gurantee 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 المسؤولية كاملة عن صحتها و لا تتحمل وزارة الصحة و وقاية المجتمع اي مسؤولية تجاه الغير.
* في حالة المنتجات غيرالطبية تكون مسؤولية 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 أي مسؤولية تجاه الغير بخصوص المنتجات المذكورة.
* في حالة المنتجات غير الطبية لا يسمح بوجود أي نوع من الادعاءات الطبية علي المنتجات.

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هذه الشهادة صادرة من وزارة الصحة ووقاية المجتمع وتعتبر من الوثائق الحكومية الرسمية ولا تحتاج إلى توقيع، ويحظر قطعيا تقليدها أو إدخال أي تعديلات عليها سواءً بالإضافة أو الحذف أو التغيير في بياناتها أو غير ذلك من أنواع التعديل، وتعد الشهادة لاغية إذا شابهها شيء من ذلك. للتأكد من صلاحية الشهادة يرجى المسح الضوئي للرمز ثنائي الأبعاد.

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