

UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION



الإمارات العربية المتحدة
وزارة الصحة ووقاية المجتمع

DRUG DEPARTMENT

INSTANCE ID : 30987

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M/S., ABT GLOBLE FZE , AJMAN , UAE

Dear Sirs,

This is to inform you that the Classification Committee M.No.: 10/2019 Dated 13/03/2019 has Classified your products as mentioned below:

PRODUCT NAME & FORM	MANUFACTURER NAME & COUNTRY	CLASSIFIED AS
BIOTAB7 , DISINFECTANT TABLET	ADVANCED BIOCIDETECHNOLOGIES INC. , USA	CLEARANCE FROM UAE MINISTRY OF HEALTH & PREVENTION AS MEDICAL DEVICE, RESTRICTED TO USE BY PROFESSIONALS, 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 will 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 the 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 Device" 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 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 products other concerned government bodies have to make sure that the product is safe and fit for consumption according to law and approved procedures, MOHAP doesn't bear any responsibility regarding the above mentioned products.
- In case of non-medicinal products no medical claims are allowed on the products.

- هذه الرسالة ليست شهادة تسجيل ولا تعني موافقة وزارة الصحة ووقاية المجتمع على تسويق هذا المنتج داخل الدولة
- وزارة الصحة ووقاية المجتمع لم يتم بتحليل المنتج ولاضمن جودة , فاعلية ,أمان المنتج.
- أعطيت هذه الرسالة لغرض التصنيف المبدئي للمنتج بناءا على معلومات قدمها طالب الرسالة ويحمل وحده المسؤولية كاملة عن صحتها, ولاتحمل وزارة الصحة ووقاية المجتمع أي مسؤولية تجاه الغير
- في حالة المنتجات غير الطبية تكون مسؤولية الجهات الرسمية الاخرى المعنية التاكيد من محرويات المنتج وسلامته طبقا للنظم والقوانين المعمول بها لديها ولاتحمل وزارة الصحة ووقاية المجتمع أي مسؤولية تجاه الغير بخصوص المنتجات المذكورة.
- في حالة المنتجات غير الطبية لايسمح بوجود أي نوع من الادعاءات الطبية على المنتجات



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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