

CLASSIFICATION LETTER

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

DRUG DEPARTMENT

Application No: DRCLAS-2025-005365

Issue Date: 17/11/2025

Expiry Date: 16/11/2028

Applicant Type: Business - Local Manufacture

M/S.: AMEYA (FZC), SHARJAH, UNITED ARAB EMIRATES

Dear Sirs,

This is to inform you that the Classification Committee M.No.: 37/2025 Dated 17/11/2025 has classified your products as mentioned below:

PRODUCT NAME & FORM	MANUFACTURER NAME & COUNTRY	CLASSIFIED AS
AMEYA ISOPROPYL ALCOHOL 70%, LIQUID	AMEYA (FZC), UNITED ARAB EMIRATES	SHOULD BE REGISTERED IN EMIRATES DRUG ESTABLISHMENT AS GENERAL SALE LIST PRODUCT. SERVICE CARD AVAILABLE AT: HTTPS://EDE.GOV.AE/EN/SERVICES (REGISTRATION OF PHARMACEUTICAL PRODUCT FOR GENERAL SALE)

- 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 EDE as Medical Device, restricted to use by professionals", then the applicant have to approach the Importation section/ Drug Department at the UAE EDE (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 EDE, such products can only be supplied to EDE/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 EDE 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 EDE Ministerial Decree 51/2021 related to this law.
- For products granted the status of "Clearance from UAE EDE 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 EDE approval to market the product in the UAE.
- EDE 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, EDE doesn't bear any responsibility.
- In case of non-medicinal (Registration not applicable in EDE) 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, EDE doesn't bear any responsibility regarding the above mentioned products.
- In case of non-medicinal (Registration not applicable in EDE) products, no medical claims are allowed on the products.

* هذه الرسالة ليست شهادة تسجيل ولا تعني موافقة مؤسسة الإمارات للدواء على تسويق هذا المنتج داخل الدولة.

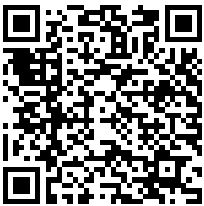
* مؤسسة الإمارات للدواء لم تقوم بتحليل المنتج ولا تضمن جودة و فاعلية و امان المنتج.

* أعطيت هذه الرسالة لغرض التصنيف المبدئي للمنتج بناء على معلومات قدمها طالب الرسالة و يتحمل وحده المسؤولية كاملة عن صحتها و لا تتحمل مؤسسة الإمارات للدواء اي مسؤولية تجاه الغير.

* في حالة المنتجات غير الطبية تكون مسؤولية الجهات الرسمية الاخرى المعنية التأكد من محتويات المنتج و سلامته طبقا للنظم و القوانين المعمول بها لديها و لا تتحمل مؤسسة الإمارات للدواء أي مسؤولية تجاه الغير بخصوص المنتجات المذكورة.

* في حالة المنتجات غير الطبية لا يسمح بوجود أي نوع من الادعاءات الطبية علي المنتجات.

Issued on: 17/11/2025



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AMEYA FZC

Product Name: ISOPROPYL ALCOHOL 70%

S.No	Product Code	Pack Size
1	AM055	100 mL with CAP
2	AM056	100 mL with SPRAY
3	AM057	200 mL with cap
4	AM058	200 mL with SPRAY
5	AM059	250 mL with SPRAY
6	AM060	500 mL with cap
7	AM061	500 mL with SPRAY
8	AM062	5 Ltr

FOR AMEYA FZC

SUBHADRA RAO

AUTHORISED SIGNATORY

PLACE – SAIF ZONE – SHARJAH, UAE