CLASSIFICATION LETTER

DRUG DEPARTMENT

Application No: DRCLAS-2021-005094

Issue Date: 07/10/2021

Expiry Date: 06/10/2024

M/S.: AL ZAHRAWI MEDICINES TRADING ,DUBAI,UNITED ARAB EMIRATES

Dear Sirs,

This is to inform you that the Classification Committee M.No.: 43/2021 Dated 07/10/2021 has classified your products as mentioned below:

PRODUCT NAME & FORM	MANUFACTURER NAME & COUNTRY	CLASSIFIED AS
XCITE IFES CLINICAL STATION,DEVICE	RESTORATIVE THERAPIES, INC,UNITED STATES OF AMERICA	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 UAE FEDERAL LAW NO.2 OF 2019 AND MOHAP MINISTERIAL DECREE 51/2021, 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 (https://www.mohap.gov.ae/FlipBooks/PublicHealthPolicies/PHP-LAW-EN-77/mobile/index.html) that regulates handling/processing/ transferring of patient data 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 أي مسوؤلية تجاه الغير بخصوص المنتجات المذكورة.
* في حالة المنتجات غير الطبية لا يسمح بوجود أي نوع من الادعاءات الطبية علي المنتجات.

Issued on: 07/10/2021

الإمارات
THE EMIRATES

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Main Device Unit Name: Xcite FES System

Item Name	Item Code
Xcite Clinical Station	FA216218
XciteV2 Stimulator	SA220070
XciteV2 Cart	SA220063
Xcite Power Kit	Xcite PWR
Stimulation Cable	PP217417
Electrode 2x2	PP100418
Electrode 3x4	PP100419
Electrode 3x5	PP100420
Electrode 1.25 Round	PP107289
Electrode sensitive 2x2	PP100421
Electrode sensitive 1.5x3.5	PP102738
Electrode sensitive 2x4	PP220276