UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

الإمارات العربية المتحدة
وزارة الصحة ووقاية المجتمع

**DRUG DEPARTMENT**

**Application No:** DRCLAS-2019-002545
**Issue Date:** 13/11/2019
**Expiry Date:** 12/11/2022
**M/S.:** Lifetastic FZ LLC,Dubai,United Arab Emirates

Dear Sirs,

This is to inform you that the Classification Committee M.No.: 43/2019 Dated 11/11/2019 has classified your products as mentioned below:

| PRODUCT NAME & FORM | MANUFACTURER NAME & COUNTRY | CLASSIFIED AS |
|---|---|---|
| CVI42,SOFTWARE | CIRCLE CARDIOVASCULAR IMAGING 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, 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 المسؤلية كاملة عن صحتها و لا تتحمل وزارة الصحة و وقاية المجتمع اي مسؤلية تجاه الغير.
* في حالة المنتجات غيرالطبية تكون مسؤلية 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 مسؤلية تجاه الغير بخصوص المنتجات المذكورة.
* في حالة المنتجات غير الطبية لا يسمح بوجود أي نوع من الادعاءات الطبية علي المنتجات.

Pass Code: 172532

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.

This certificate is generated by MOHAP Drug Department, it is official government document and does not require signature, it is strictly prohibited to imitate or amend to this certificate. Any attempt to change, delete, erase or add will cause this certificate to be rendered invalid. To verify this certificate validity, please scan the QR Code.

**DRUG DEPARTMENT**

**Application No:** DRCLAS-2022-005511

**Issue Date:** 04/11/2022

**M/S.:** LIFETASTIC FZ LLC, DUBAI, UNITED ARAB EMIRATES

# Subject : Notification

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

Dear Sirs,

This is to inform you that upon reviewing your request for Regulatory Advice for your product with below mentioned details:

**PRODUCT NAME & FORM :** **CVI42,SOFTWARE**

**MANUFACTURER NAME & COUNTRY :** **CIRCLE CARDIOVASCULAR IMAGING INC.,CANADA**

Based on the information provided by the above mentioned applicant, the product described above fits the designation of THE SOFTWARE AND ANY RELATED SYSTEMS OF YOUR SOFTWARE/ MOBILE APPLICATION/ HARDWARE SHOULD COMPLY 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. THIS SOFTWARE IS CONSIDERED AS A MEDICAL DEVICE BY INTERNATIONAL DEFINITION BUT IS NOT REQUIRED TO BE IMPORTED/SUPPLIED TO THE UAE VIA A MOHAP LICENSED MEDICAL STORE, IT IS ADVISABLE THAT THE HEALTHCARE FACILITY VERIFIES RELATED QUALITY CERTIFICATION OF THE SOFTWARE BEFORE USE, THIS LETTER COVERS ONLY THE MENTIONED SOFTWARE AND DOES NOT COVER ANY OTHER COMPONENTS OR RELATED HARDWARE, THIS LETTER CANNOT BE CONSIDERED AS AN ENDORSEMENT FROM MOHAP TOWARDS THE MENTIONED PRODUCT as per UAE regulations, **this notification should not be in any way be considered as an endorsement for the mentioned product and cannot be used for importation / distribution / selling / exportation of the product within the UAE, the applicant is fully liable to the information provided to generate the opinion mentioned regarding the product.**

**The applicant is required to generate relevant product licenses from the concerned UAE competent authority depending on the advice above as per applicable procedures.**

**Drug Department**

Issued on: ~~04/11/2022~~

THE EMIRATES

~~This~~ is a system-generated document and it doesn't require a signature. To verify certificate validity, please scan the QR Code.