DRUG DEPARTMENT

Application No: DRCLAS-2025-001078

Issue Date: 26/03/2025

M/S.: MEDTECH SERVICES FZE LLC, SHARJAH, 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 (EXAMPLE: HOSPITAL/CLINICS) 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: 26/03/2025

الإمارات
THE EMIRATES

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MINISTRY OF HEALTH & PREVENTION
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