FDA GHANA **FOOD AND DRUGS AUTHORITY**

Your Well-being, Our Priority.

Certificate No: FDA-GH-38271416

CERTIFICATE OF REGISTRATION *of a* MEDICAL DEVICE

This is to certify that

HEALTHCUBE DIAGNOSTIC DEVICE

is registered for use in Ghana and is subject to the provisions of the Public Health Act, 2012, Act 851

Active Ingredient (s)/ Strength: N/A

Applicant: HEALTHCUBED INDIA PVT LTD SITE NO. 38 & 39 BEGUR HOBLI HONGASANDRA DHAKLE, GARVEBHAVI PALYA BENGALURU (BANGALORE) URBAN KARNATAKA INDIA

Manufacturer: HEALTHCUBED INDIA PVT LTD SITE NO. 38 & 39 BEGUR HOBLI HONGASANDRA DHAKLE, GARVEBHAVI PALYA BENGALURU (BANGALORE) URBAN KARNATAKA INDIA

Local Agent: CAREL LOGISTICS LIMITED, TAMARA BUILDING, H NO. C621, TESANO, ACCRA, GHANA

Registration No: FDA/D.23-7804

Date of Registration: 11-07-2023

The validity of this certificate shall continue until 01-04-2026
Unless otherwise suspended, revoked or varied as to the period of validity.

Dated this 11TH **of** JULY, 2023

DR. DELESE A.A DARKO
CHIEF EXECUTIVE OFFICER

FOOD & DRUGS AUTHORITY

Terms & Conditions Apply.

FOOD AND DRUGS AUTHORITY
FDA
GHANA
Your Well-being, Our Priority.

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FDA/HPT/MCH/MDD/DU2/23/0633

11th July 2023

The Managing Director
Healthcubed India Pvt Ltd
Site No. 38 & 39 Begur hobli
Hongasandra Dhakle, Garvebhavi Palya
Bengaluru (Bangalore) Urban Karnataka
India

Dear Sir,

RE-REGISTRATION OF MEDICAL DEVICE

This is to inform you that the Food and Drugs Authority (FDA) has completed the review of your medical device application for the re-registration of **HEALTHCUBE DIAGNOSTIC DEVICE** pursuant to Section 118, Part 7 of the Public Health Act, 2012 (Act 851).

Based upon the information presented to date, the FDA has concluded that the medical device is safe for use as recommended in the submitted labeling, subject to the conditions in this letter.

Your application has, therefore, been approved and issued with the registration number **FDA/D.23-7804.**

This registration is valid for three (3) years and expires on **April 1, 2026**.

A certificate of registration has been issued with respect to the above.

The conditions which apply are as follows:

- The medical device must conform to all the details submitted in your application and as modified in subsequent correspondence.
- The product cannot be advertised via promotional material/product launch unless the advertisement has been vetted and approved by the FDA.
- No changes may be made to the intended uses of the medical device without prior approval from the FDA.
- Importation of the product is not permitted after the period of validity of the registration has expired.

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Please note that it is your responsibility to apply for variation of the registration (as per the FDA's variation guidelines) and also renewal of the registration in due time (not later than three months prior to the expiry date of the registration).

Post Market Surveillance activities into the quality of the product are ongoing and any adverse findings will be brought to your immediate attention and the necessary regulatory measures taken.

Please ensure that you promptly communicate any change in the safety information on the product to the FDA.

Yours faithfully,

DR. DELESE A. A. DARKO
CHIEF EXECUTIVE OFFICER

cc: Carel Logistics Limited, Tamara Building, H No. C621, Tesano, Accra, Ghana,
Tel: 0502605435/ 0244932270 (Local Agent)

DCEO, Technical Operations Division, FDA

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