

No. IVD/Misc/151/DCGI/18
Government of India
Central Drugs Standard Control Organization
Directorate General of Health Services
(Diagnostic Division)

FDA Bhawan, Kotla Road,
New Delhi – 110002, Dated: -

10 DEC 2018

To,
M/s. HealthCubed India Pvt.Ltd
B-221, Okhla Industrial Area,
Phase -1, Delhi (India) – 110020

Sub: - Issuance of the no objection certificate of HealthCube-XL & HealthCube-SE in India – Reg

Sir,

Please refer to your letter no. Nil date 31/08-2018 received by this office vide Diary no. 31584 dated 04/09/2018 on the subject cited above

The matter has been examined in the light of document submitted by you. In this connection, you are hereby inform that the proposed products HealthCube-XL and HealthCube-SE integrated system has cloud-based data system paired with an android application intended for performing multiparameter diagnostics such as vitals and point of care testing by trained professional on adult population is not regulated presently under the provision of Drugs and Cosmetics Act, 1940 and Rules there under.

Yours faithfully,



(Dr.V.G. Somani)
Joint Drugs Controller (I)