

No. IVD/NOC/010/19
Government of India
Central Drugs Standard Control Organization
Directorate General of Health Services
(Diagnostic Division)

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

22 FEB 2019

To,

M/s. Arogyam Medisoft Solution Pvt. Ltd.
B – 7/3 TRIPARNA 39A Gobinda Auddy Road Kolkata,
West Bengal (India) – 700027

Sub: - Issuance of NOC for the product i.e. HaemurEx - Reg.

Sir,

Please refer to your letter no. nil dated 17/01/2019 received by this office vide diary no. 756 dated 18/01/2019 on the above cited subject.

The matter has been examined in the light of document submitted by you. In this connection, it is to inform that the proposed product HaemurEx which is Equipment / Analyzer, using approved test strips/reagents, presently may not be regulated under the provision of Medical Device Rules 2017.

Further, Strips and reagents intended for the In-Vitro Diagnostic purpose are being regulated as per the provision of Drugs & Cosmetics Act and Medical Device Rules 2017.

Yours faithfully,



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