Central Drugs Standard Control Organisation

Directorate General of Health Services

Ministry of Health & Family Welfare

(Medical Device and Diagnostic Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Phone No-011-23236965
Fax: 23236973

File No: HQ/MD/2021/000002

Date: 16-Aug-2021

To,

Shiva Analyticals (India) Private Limited
Plot Nos. 24D (P) & 34D, KIADB Industrial
Area, Hoskote, Bangalore Hoskote (India)
- 562114

Sub: Certificate of registration to Medical Device Testing Laboratory for carry out Test or Evaluation of a medical device on behalf of manufacturer under Medical Device Rules, 2017- regarding.

Sir,

Registration No. TL/MD/2021/000005 in Form MD-40 is hereby forwarded to you. This registration is subject to following conditions.

1. The registration certificate shall be kept on the approved premises and shall be produced at the request of the medical device officer.
2. The person holding registration certificate shall provide and maintain necessary qualified staff, adequate premises and equipment.
3. The person holding registration certificate shall provide proper facilities for storage so as to preserve the properties of samples picked up for testing.
4. The person holding registration certificate shall maintain records of tests for evaluation and performance carried out on all samples of medical devices and the results thereof together with protocols of tests and the reports showing readings and calculations and such records shall be retained, in case of substances for which an expiry date is assigned, for a period of two years beyond the expiry date, and in the case of other substances, for a period of six years.
5. The person holding registration certificate shall allow the medical device officer and regulatory officials of Central Licensing Authority, to enter, with or without prior notice, the premises where the testing is carried out and to inspect the premises and the equipment used for test and the testing procedures employed.
6. The person holding registration certificate shall allow the medical device officer to inspect records maintained and shall make available such information as may be required for ascertaining whether the provisions of the Act and these rules have been complied with.
7. The registration holder shall inform forthwith, any change of existing expert staff or person-in-charge of the testing or evaluation to the Central Licensing Authority for its approval.
8. In case, any sample of a medical device is found on test, to be not of standard quality, the person in-charge of the registered medical device testing laboratory shall furnish a copy of the test or evaluation report on the sample with the protocols of tests applied to the Central Licensing Authority.
9. The person holding registration certificate shall maintain an inspection book to enable the Medical Device Officer to record non-compliance with the provisions of the Act and these rules.
10.The registered medical device testing laboratory shall inform to the Central Licensing Authority in writing in the event of any change in its constitution and where such change in the constitution takes place, the current registration shall be deemed to be valid for a maximum period of ninety days from the

date on which the change took place unless, in the meantime, a fresh approval has been taken from the Central Licensing Authority with the changed constitution.

Yours Faithfully,

VENUGOPAL GIRDHARILAL SOMANI

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
DN: c=IN, o=MINISTRY OF HOME AFFAIRS, ou=CDSCO DGHS, postalCode=431401, st=Maharashtra, 2.5.4.20=173d03345d9b2d489632379a1471bfdae9f8b2bea56c835dfbbe2154e399b1af7, cn=VENUGOPAL GIRDHARILAL SOMANI
Date: 2021.08.16 15:45:13 +05'30'

Licensing Authority