Central Drugs Standard Control Organisation

Directorate General of Health Services

Ministry of Health & Family Welfare

(Medical Device & Diagnostic Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Phone No-011-23236965
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File No. : NZ/MD/2020/000032

Dated : 27-APR-2020

M/s Alpine Biomedicals Private Limited,
Plot No-348, Sector-2, IGC, HSIIDC
Saha, Ambala, Haryana (India) - 134118
Telephone No.: 9306252669,7876222226
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gaurav.g@alpinebiomedicals.com

Sub:- Licence to manufacture for Sale or for Distribution of Class C or Class D medical devices in Form MD-9 under Medical Device Rules, 2017- regarding.

Sir,

Manufacturing licence No. MFG/IVD/2020/000039 in Form MD-9 is hereby forwarded to you. This licence is subject to following conditions:

1. Licence shall be produced when requested by the Medical Device Officer or any other senior officer under the control of Central Licensing Authority.
2. The licence holder shall inform the Central Licensing Authority of the occurrence of any suspected unexpected serious adverse event and action taken thereon including any recall within fifteen days of such event coming to the notice of licence holder
3. The licence holder shall obtain prior approval from the Central Licensing Authority, before any major change as specified in the Sixth Schedule is carried out and the Central Licensing Authority shall indicate its approval or rejection within forty five days and in case where no communication is received within the stipulated time from such Authority, such change shall be deemed to have been approved
4. The licence holder shall inform any minor change as specified in the Sixth Schedule to the Central Licensing Authority within a period of thirty days after such minor change take place
5. The licence holder shall carry out test of each batch of product manufactured prior to its release for compliance with specifications either in his own laboratory or in any other laboratory registered under sub-rule (3) of rule 83;

6. The licence holder shall, on being informed by the Central Licensing Authority that any part of any lot of the medical device has been found not conforming with the provisions specified under the Act and these rules, and on being directed so to do by such licensing authority, withdraw the remainder of that lot from sale and, so far as may, in the particular circumstances of the case, be practicable, recall the issues already made from that lot;
7. The licence holder shall maintain an audit or inspection book in Form MD-11 to enable the Notified Body or Medical Device Officer to record his observations and non-conformity, if any;
8. The licence holder shall maintain at least one unit of sample from each batch of invasive medical device and in vitro diagnostic medical device manufactured for reference purpose for a period of one hundred and eighty days after the date of expiry of such batch;
9. The licence holder shall maintain records of manufacturing and sales which shall be open to inspection by a Medical Device Officer;
10. The medical device, when offered for sale, shall be accompanied by either its package insert or user manual, wherever applicable;
11. The manufacturing or testing activity of medical device shall be undertaken only under the direction and supervision of the competent technical staff;
12. If the manufacturer has stopped manufacturing activity or closed the manufacturing site for a period of thirty days or more, the same shall be intimated to the Central Licensing Authority.

13. This licence is being issued with condition that 1. In order to track the positive cases product shall be used at laboratories designated/ approved by ICMR or concerned State or Central Govt. 2. Licensee shall maintain the records of laboratories/qty of the test supplied to them & report to this office regarding suspected occurrence of false positive & false negative results & significant deviation from the established performance characteristic. 3. The licence issued due to emergency health situation in public interest & will be effective until control of COVID 19 outbreak in the country & will be evaluated for continuation based on the data emerging & firm shall also obtain MD-29.

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=173d03345df62d489632379a1471bfdae9f0b2bea56c83bfbbe2154e399b1af7, cn=VENUGOPAL GIRDHARILAL SOMANI
Date: 2020.04.27 14:58:52 +05'30'

Licensing Authority

Seal/Stamp