



सत्यमेव जयते

FORM MD-9

[See sub-rule (1) rule 25]

Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device

Licence Number: MFG/IVD/2020/000039

1. M/s Alpine Biomedicals Private Limited, Plot No-348, Sector-2, IGC, HSIIDCSaha, Ambala, Haryana (India) - 134118 Telephone No.: 9306252669,7876222226 FAX: 9306252669 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Alpine Biomedicals Private Limited, Plot No-348, Sector-2, IGC, HSIIDC, Ambala, Haryana (India) - 133104 Telephone No.: 9306252669 FAX: 9306252669

2. Details of medical device(s) [Annexed]

3. The names, qualifications and experience of the competent technical staff responsible for the manufacture and testing of the above mentioned medical device(s): As per records maintain by the manufacturer

4. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

ANNEXURE

S.No.	Details Of Device(s)
1	<p>Generic Name:Novel Coronavirus (COVID-19) IgG/IgM antibody detection rapid test kit Model No.:NIL Intended Use:COVID-19 Antibody IgG/IgM Kit will be a rapid, qualitative and convenient immunochromatographic in vitro assay for the differential detection of IgM & IgG antibodies to COVID-19 virus in human serum, plasma and/or whole blood samples obtained from patient with signs and symptoms of respiratory infection. The device is designed to aid in the rapid differential diagnosis of COVID-19 Virus infection Class of medical device:Class C Material of construction:Lateral Flow Immunochromatographic rapid test device with clear buffer Dimension(if any):NA Shelflife:1 year Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Alpine Let's Confirm it</p>

Place:

Date27-Apr-20

Central Licensing Authority