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/2020/000043

Endorsement No. 6

1. M/s TULIP DIAGNOSTICS PRIVATE LIMITED, GITANJALI, DR. ANTONIO DO REGO BAGH,ALTO SANTACRUZ, BAMBOLIMBAMBOLIM, North Goa, Goa (India) - 403202 Telephone No.: 8322454546 FAX: 8322454544 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s ZEPHYR BIOMEDICALS A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED, PLOT NOS. M-46, 47, PHASE III-B, VERNA INDUSTRIAL ESTATE, VERNA, South Goa, Goa (India) - 403722 Telephone No.: 08326624605 FAX: 08326680156

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 | Generic Name:Rapid test for detection of SARS-CoV-2 Antigen in human nasal swab (NS) and nasopharyngeal (NP) swab specimens<br>Model No.:NIL<br>Intended Use:PerkinElmer COVID-19 Antigen Test (NS, NP) is an invitro, rapid, qualitative immunoassay for the detection of specific antigens expressed by the SARS-CoV-2 virus present in human nasopharyngeal swab and nasal swab specimens. It is to be used for screening or to aid in the diagnosis of COVID-19 disease and exposure to the virus. This rapid antigen detection test takes 20-30 minutes for producing a positive or negative test result. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. The result of this test should not be the sole basis for the diagnosis. Presumptive positive or negative result with the Rapid Antigen. Test may need to be further confirmed with a molecular test, as needed.<br>Class of medical device:Class C<br>Material of construction:Not Applicable<br>Dimension(if any):Not Applicable<br>Shelflife:15 Months<br>Sterile or Non sterile:Non-Sterilized<br>Brand Name(if registered under the Trade Marks Act, 1999):PerkinElmer COVID-19 Antigen Test (NS, NP) |

VENUGOPAL GIRDHARILAL SOMANI

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
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Date: 2021.02.25 11:55:59 +05'30'

Place:

Date24-Feb-21

Central Licensing Authority