

Government of India
 Directorate General of Health Services
 Central Drugs Standard Control Organisation
 Ministry of Health and Family welfare

FREE SALE CERTIFICATE

FSC Number : FSC/IVD/2021/000033

Dated : 15/04/2021

This is to certify that M/s. ZEPHYR BIOMEDICALS A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED situated at address PLOT NOS. M-46, 47, PHASE III-B, VERNA INDUSTRIAL ESTATE, VERNA ,South Goa Goa ,403722,08326624605, India is holding Manufacturing License no. MFG/IVD/2020/000043 issued on 28-APR-2020 Under this license, the said firm is permitted to manufacture the products for their manufacture and sale in domestic market as per Indian Law and for export as per law of importing country (ies):-

Name of the products with their product name and dimensions if any mentioned below :

S.NO	Medical Device Details
1	<p>1. Generic Name :Rapid test for detection of SARS-CoV-2 Antigen in human nasopharyngeal swab specimens (Device)</p> <p>2. Brand Name :COVIRAT (DEVICE)</p> <p>3. Notified Category :Other than above substancesRapid test for detection of SARS-CoV-2 Antigen in human nasopharyngeal swab specimens</p> <p>4. Class of Medical Device :Class C</p> <p>5. Shelf life :15 Months</p> <p>6. Sterile/Non-Sterile:Non-Sterilized</p> <p>7. Intended Use :COVIRAT is an invitro, rapid, qualitative immunoassay for the detection of nucleocapsid protein 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. This rapid antigen detection test takes 15-30 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 may need to be further confirmed with a molecular test.</p> <p>8. Material of Construction: Not Applicable</p> <p>9. Dimension: Not Applicable</p> <p>10. Model/Catalogue No./Name :NIL</p>

