

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

Food & Drugs Administration Bhawan  
Kotla Road, New Delhi-110002  
Date : 15/04/2021

To,

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 ,  
403722,08326624605, India

Subject: Issue of Free Sale Certificate for Medical Devices for export purpose-reg.

Sir,

This is with reference to your file no FSC/IVD/2021/39166 dated 10-APR-2021 for Issue of Free Sale Certificate FSC/IVD/2021/000033 for Medical Devices for export purpose .

The Free Sale Certificate no FSC/IVD/2021/000033 with respect to medical devices under manufacturing license no. MFG/IVD/2020/000043 dated : 28-APR-2020 is enclosed herewith.

**This free sale certificate is issued with the condition that the firm shall comply with the current Export policy issued by the Government.**

Date: 15-Apr-21

Competent Authority

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	1. Generic Name :Rapid test for detection of SARS-CoV-2 Antigen in human nasopharyngeal swab specimens (Device) 2. Brand Name :COVIRAT (DEVICE) 3. Notified Category :Other than above substancesRapid test for detection of SARS-CoV-2 Antigen in human nasopharyngeal swab specimens 4. Class of Medical Device :Class C 5. Shelf life :15 Months 6. Sterile/Non-Sterile:Non-Sterilized 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. 8. Material of Construction: Not Applicable 9. Dimension: Not Applicable 10. Model/Catalogue No./Name :NIL

