



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

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	<p>Generic Name: Rapid Double Antigen Screening test for the detection of IgM / IgG / IgA antibodies to COVID-19 in human serum/ plasma/ whole blood</p> <p>Model No.: NIL</p> <p>Intended Use: Coviscreen is an invitro, rapid, self performing, qualitative, Double Antigen sandwich immunoassay for the simultaneous detection of Total antibodies (IgM+IgG+IgA) to SARS-CoV-2 virus in serum, plasma and whole blood. It is to be used for screening or to aid in the diagnosis of COVID-19 disease and exposure to the virus. Double Antigen Sandwich assays are also known to detect the Antigen specific IgA isotype antibodies and contribute to detect the seroconversion in patients samples earlier as compared to the other tests as detection of total antibodies (IgM+IgG+IgA) is possible.</p> <p>Class of medical device: Class D</p> <p>Material of construction: 1. Membrane test assembly comprising of (a.) Test region (b.) Control region C (c.) Specimen port A for dispensing sample, (d.) buffer port B for dispensing buffer 2. Sample running buffer in dropper bottle.</p> <p>Dimension(if any): N.A.</p> <p>Shelflife: 18 MONTHS</p> <p>Sterile or Non sterile: Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999): COVISCREEN</p>

Place:

