



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/2019/000018

Endorsement No. 2

1. M/s MOLBIO DIAGNOSTICS PVT. LTD, PLOT NO L-46, PHASE II-D VERNA INDUSTRIAL AREA, VERNA, SALCETE SOUTH GOA , South Goa, Goa (India) - 403722 Telephone No.: 08322783267 FAX: 08322783139 has been licenced to manufacture for sale or for distribution the below listed medical device(s) at the premises situated at M/s Molbio Diagnostics Pvt. Ltd., Plot No. L-46, Phase II D, Verna Industrial Estate, Verna, South Goa, Goa (India) - 403722 Telephone No.: 09960590604 FAX: 0832 2783267

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:Chip based Real Time PCR Test for COVID-19</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat™ SARS CoV-2 is a point-of-care, disposable chip based Real Time Reverse Transcription PCR test for qualitative detection and confirmation of COVID 19 in Truenat™ Beta CoV positive human specimen. The intended clinical specimen is extracted nucleic acids from human throat or nasal swab. The intended testing population is the clinically symptomatic general population. Even the peripheral laboratories with the minimal infrastructure and minimally trained technician can easily perform these tests routinely in their facilities and report PCR results in less than an hour. Truenat™ SARS CoV-2 runs on Truelab® Real Time Quantitative micro PCR Analyzer and the assay targets RdRp gene of COVID 19. Even the peripheral laboratories with the minimal infrastructure and minimally trained technician can easily perform these tests routinely in their facilities and report PCR results in less than an hour.</p> <p>Class of medical device:Class C</p> <p>Material of construction:A. Individually sealed pouches, each containing: 1. Micro PCR chip preloaded with dried down proprietary buffer and sealed with inert polymer. 2. Microtube containing freeze dried biomix comprising Oligonucleotides (primers and probes specific to COVID 19 and internal control DNA), dNTPs, DNA polymerase in proprietary buffer. 3. DNase & RNase free pipette tip. 4. Desiccant pouch B. Package insert</p> <p>Dimension(if any):</p> <p>Shelflife:24 months</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):Truenat™ SARS CoV-2</p>

Place:

Date 26-May-20

Central Licensing Authority

