



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. 4

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 Duplex PCR Test for COVID-19 Model No.:NIL</p> <p>Intended Use:Truenat™ COVID-19 is a point-of-care, disposable chip based in-vitro diagnostic medical device for semiquantitative detection and confirmation of COVID-19. Truenat™ COVID-19 RT PCR test uses E gene and Orf1a as gene target. The intended clinical specimen is human throat and nasal swab. The intended testing population is 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™ COVID-19 RT PCR Kit runs on Truelab® Real Time PCR analyzers</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), dUTPs, Reverse Transcriptase, RNase Inhibitor, Platinum Taq Polymerase in a proprietary buffer. 3. DNase &amp; 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™ COVID-19</p>

Place:

Date 08-Sep-20

Central Licensing Authority

