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. 15

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 Private Limited, L - 46, Phase II-D, Verna Industria Estate, Verna, South Goa, Goa (India) - 403722 Telephone No.: 08322783267 FAX: 08322783267

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	Generic Name:Chip-based Real Time Duplex PCR Test for Influenza A,B and COVID-19 Model No.:601720005 - Kit containing 5 Test ,601720020 - Kit containing 20 Test , 601720025 - Kit containing 25 Test ,601720050 - Kit containing 50 Test ,601720100 - Kit containing 100 Test ,601720200 - Kit containing 200 Test Intended Use:Truenat® Inf A,B/COVID-19 is a Chip-based Real Time Duplex Reverse Transcription Polymerase Chain Reaction (RT-PCR) test for the semi-quantitative detection of Influenza A,B & COVID-19 in human oropharyngeal and nasopharyngeal swab specimens and aids in the differential diagnosis of infection with Influenza A,B and/or COVID-19 virus. Truenat® Inf A,B/COVID-19 runs on Truelab® Real Time Quantitative micro PCR Analyzers. Class of medical device:Class C Material of construction:A. Individually sealed pouches, each containing: 1. Truenat® Inf A, B/COVID-19 Micro PCR chip preloaded with dried down proprietary buffer and sealed with inert polymer. 2. Microtube with freeze dried Biomix comprising of Reverse Transcriptase, Oligonucleotides (primers and probes specific to Inf A,B/COVID-19 and internal control), dNTP containing dUTP and Taq polymerase in a proprietary buffer. 3. DNase & RNase free pipette tip. 4. Desiccant pouch B. Package insert Dimension(if any): Shelflife:24 months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Truenat® Inf A,B/COVID-19

RAJEEV SINGH RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL ORGANIZATION, ou=RAJEEV SINGH RAGHUVANSHI, 2.5.4.20=80c62f6a23e4eafbe8a239774cdeb03c2769041015a06564fe67f54b765db1cb, postalCode=600034, st=TAMIL NADU, serialNumber=657F5E47D940985D8F03BDC902D0E1FE73CFA12A1A126EA94FA5701124A19013, cn=RAJEEV SINGH RAGHUVANSHI
Date: 2024.02.21 16:37:00 +05'30'

Place:

Date21-Feb-24

Central Licensing Authority