



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/2021/000071

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, PLOT NO. L-42, PHASE II B, VERNA INDUSTRIAL ESTATE, VERNA GOA , South Goa, Goa (India) - 403722 Telephone No.: 083 26724888 FAX: 083 26724888
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 Mycobacterium tuberculosis Model No.:601030005 - Kit containing 05 Tests,601030025 - Kit containing 25 Tests, 601030050 - Kit containing 50 Tests,601030100 - Kit containing 100 Tests,601030200 - Kit containing 200 Tests Intended Use:Truenat® MTB is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the quantitative detection and diagnosis of Mycobacterium tuberculosis (MTB) in human pulmonary and EPTB specimen and aids in the diagnosis of infection with MTB. Class of medical device:Class C 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 of Oligonucleotides (primers and probes specific to MTB and internal control), dNTPs, Taq. polymerase in 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® MTB</p>

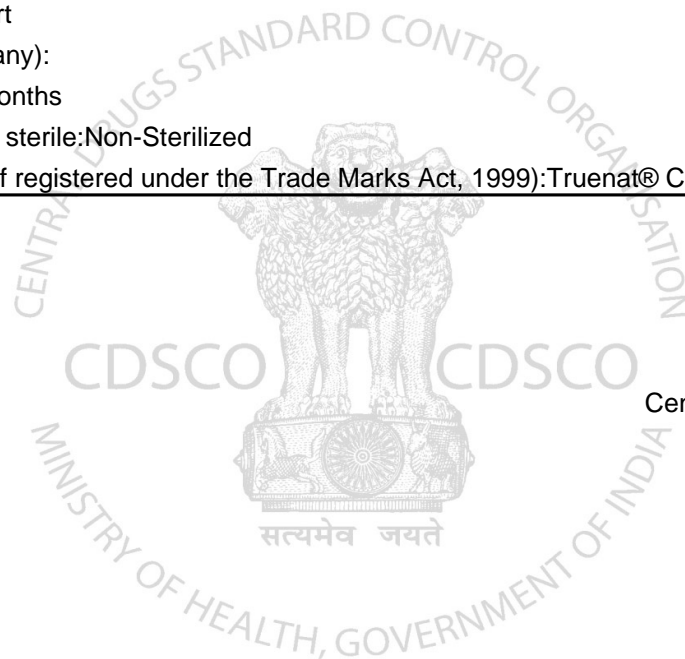
2	<p>Generic Name:Chip-based Real Time PCR Test for Mycobacterium tuberculosis</p> <p>Model No.:601130005 - Kit containing 05 Tests,601130025 - Kit containing 25 Tests, 601130050 - Kit containing 50 Tests,601130100 - Kit containing 100 Tests,601130200 - Kit containing 200 Tests</p> <p>Intended Use:Truenat® MTB Plus is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the semiquantitative detection and diagnosis of Mycobacterium tuberculosis (MTB) in human pulmonary (sputum/non-sputum) and EPTB specimen and aids in the diagnosis of infection with MTB.</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 of Oligonucleotides (primers and probes specific to Mycobacterium tuberculosis and internal control), dNTPs, Taq. 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® MTB Plus</p>
3	<p>Generic Name:Chip-based Real Time PCR Test for Rifampicin resistant Mycobacterium tuberculosis</p> <p>Model No.:601210005 - Kit containing 05 Tests,601210025 - Kit containing 25 Tests, 601210050 - Kit containing 50 Tests,601210100 - Kit containing 100 Tests,601210200 - Kit containing 200 Tests</p> <p>Intended Use:Truenat™ MTB-RIF Dx is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the detection of Rifampicin resistance in Mycobacterium tuberculosis (MTB) in Truenat™ MTB/MTB Plus positive human specimen and aids in the diagnosis of MDR-TB. This test detects the presence of major mutations (SNPs) in the MTB genome that are known to cause resistance to rifampicin. Truenat™ MTB-RIF Dx runs on the Truelab® Real Time Quantitative micro PCR Analyzers. This is a follow on test, to be performed only on the extracted DNA from Truenat™ MTB/MTB Plus positive sample.</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 of Oligonucleotides (primers and probes specific wild type rpoB gene of Mycobacterium tuberculosis, which covers mutation prone regions of rpoB gene specific to rifampicin resistance and internal control), dNTPs, Taq. 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® MTB-RIF Dx</p>

4	<p>Generic Name:Chip-based Real Time PCR Test for Hepatitis C Virus Model No.:601180005 - Kit containing 05 Tests,601180025 - Kit containing 25 Tests, 601180050 - Kit containing 50 Tests,601180100 - Kit containing 100 Tests,601180200 - Kit containing 200 Tests</p> <p>Intended Use:Truenat® HCV is a chip-based Real Time Reverse Transcription Polymerase Chain Reaction (RT-PCR) test for the quantitative detection of Hepatitis C virus (HCV) RNA in human plasma, serum and whole blood samples. Truenat® HCV aids in the diagnosis and confirmation of HCV infection (in conjunction with HCV antibody test) and in estimation of viral load. It is not intended as a blood donor screening test. Truenat® HCV runs on the Truelab® Real Time micro 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 of Reverse Transcriptase, Oligonucleotides (primers and probes specific to Hepatitis C Virus and internal control), dNTPs, Taq. 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® HCV</p>
5	<p>Generic Name:Chip-based Real Time PCR Test for Chlamydia trachomatis Model No.:601140005 - Kit containing 05 Tests,601140025 - Kit containing 25 Tests, 601140050 - Kit containing 50 Tests,601140100 - Kit containing 100 Tests,601140200 - Kit containing 200 Tests</p> <p>Intended Use:Truenat® CT is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the semiquantitative detection of Chlamydia trachomatis in female endocervical and vaginal swab specimens, male urethral swab specimen and male and female Urine specimen. It aids in the diagnosis of symptomatic or asymptomatic infection with Chlamydia trachomatis. Truenat® CT runs on the Truelab® Real Time micro 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 of Oligonucleotides (primers and probes specific to Chlamydia trachomatis and internal control), dNTPs, Taq. 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® CT</p>

6	<p>Generic Name:Chip based Real Time Duplex PCR Test for COVID-19</p> <p>Model No.:601430005 - Kit containing 05 Tests ,601430025 - Kit containing 25 Tests , 601430050 - Kit containing 50 Tests ,601430100 - Kit containing 100 Tests ,601430200 - Kit containing 200 Tests</p> <p>Intended Use:Truenat® COVID-19 is a chip-based Real Time duplex Reverse Transcription Polymerase Chain Reaction (RT PCR) test for the semi quantitative detection of SARS CoV-2 RNA in human oropharyngeal and nasopharyngeal swab specimen and aids in detection and confirmation of SARS CoV-2 infection and diagnosis of COVID-19. The test detects the E and Orf1a genes of the virus. Truenat® COVID-19 runs on Truelab® Real Time Quantitative micro 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, Taq Polymerase in a 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® COVID-19</p>
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Place:

Date27-Jul-21



Central Licensing Authority