



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. 14

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	<p>Generic Name:Chip-based Real Time PCR Test for Isoniazid Resistant Mycobacterium tuberculosis</p> <p>Model No.:601360005 - Kit containing 5 Test ,601360020 - Kit containing 20 Test , 601360025 - Kit containing 25 Test ,601360050 - Kit containing 50 Test ,601360100 - Kit containing 100 Test ,601360200 - Kit containing 200 Test</p> <p>Intended Use:Truenat® MTB-INH is a Chip-based Real Time Polymerase Chain Reaction (PCR) Test for the detection of Isoniazid 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 Isoniazid. Truenat® MTB-INH 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:Individually sealed pouches, each containing: 1. Truenat® MTB-INH Micro PCR chip preloaded with dried down proprietary buffer and sealed with inert polymer. 2. Microtube with freeze dried Biomix comprising of oligonucleotides (primers and probes specific to Isoniazid Resistance in Mycobacterium tuberculosis and internal control), dNTPs containing dUTP and Taq polymerase in a proprietary buffer. 3. DNase & RNase free pipette tip. 4. Desiccant pouch 5. 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-INH</p>

Place:

Date 09-Jan-23

Central Licensing Authority

