



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

Endorsement No. 1

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

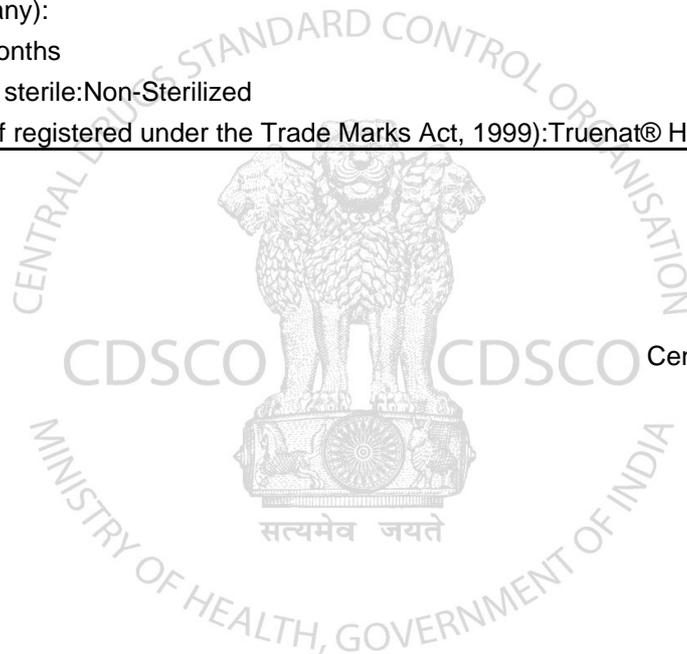
S.No.	Details Of Device(s)
1	<p>Generic Name:Chip-based Real Time PCR Test for Hepatitis B Virus Model No.:601090005 - Kit containing 05 Tests,601090020 - Kit containing 20 Tests, 601090025 - Kit containing 25 Tests,601090050 - Kit containing 50 Tests,601090100 - Kit containing 100 Tests,601090200 - Kit containing 200 Tests Intended Use:Truenat® HBV is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the quantitative estimation of the Hepatitis B Virus (HBV) in human blood /serum/ plasma specimen and aids in the diagnosis of infection with Hepatitis B Virus and in the estimation of viral load. Truenat® HBV runs on the Truelab® Real Time Quantitative micro PCR Analyzers. 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 HBV 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® HBV</p>

2	<p>Generic Name:Chip-based Real Time Duplex PCR Test for Human Papillomavirus High Risk Types 16, 31 and 18, 45</p> <p>Model No.:601220005 - Kit containing 05 Tests,601220020 - Kit containing 20 Tests, 601220025 - Kit containing 25 Tests,601220050 - Kit containing 50 Tests,601220100 - Kit containing 100 Tests,601220200 - Kit containing 200 Tests</p> <p>Intended Use:Truenat® HPV-HR is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the semiquantitative detection of high risk Human Papillomavirus (HPV) types 16, 18, 31 and 45 in female cervical specimens collected by a clinician. It aids in the differential diagnosis of symptomatic or asymptomatic infection with high risk HPV types 16, 31 and 18, 45. Truenat® HPV-HR runs on the 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 of Oligonucleotides (primers and probes specific to high risk Human Papillomavirus (HPV) types 16, 18, 31 and 45 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® HPV- HR</p>
3	<p>Generic Name:Chip-based Real Time PCR Test for Hepatitis A Virus</p> <p>Model No.:601320005 - Kit containing 05 Tests ,601320020 - Kit containing 20 Tests , 601320025 - Kit containing 25 Tests ,601320050 - Kit containing 50 Tests ,601320100 - Kit containing 100 Tests ,601320200 - Kit containing 200 Tests</p> <p>Intended Use:Truenat® HAV is a chip-based Real Time Reverse Transcription Polymerase Chain Reaction (RT PCR) test for the quantitative detection and diagnosis of Hepatitis A Virus in human blood /serum/ plasma specimen and aids in the diagnosis of infection with Hepatitis A Virus. This test is also intended for qualitative detection and diagnosis of Hepatitis A virus in stool sample. Truenat® HAV runs on the 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. Micro tube containing dried down Reverse Transcriptase, Oligonucleotides (primers and probes specific to Hepatitis A Virus 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® HAV</p>

4	<p>Generic Name:Chip-based Real Time PCR Test for Hepatitis E Virus</p> <p>Model No.:601330005 - Kit containing 05 Tests ,601330020 - Kit containing 20 Tests , 601330025 - Kit containing 25 Tests ,601330050 - Kit containing 50 Tests ,601330100 - Kit containing 100 Tests ,601330200 - Kit containing 200 Tests</p> <p>Intended Use:Truenat® HEV is a chip-based Real Time Reverse Transcription Polymerase Chain Reaction (RT PCR) test for the quantitative detection and diagnosis of Hepatitis E virus in human blood /serum/ plasma specimen and aids in the diagnosis of infection with Hepatitis E Virus. This test is also intended for qualitative detection and diagnosis of Hepatitis E virus in stool sample. Truenat® HEV runs on the 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. Micro tube containing dried down Reverse Transcriptase, Oligonucleotides (primers and probes specific to Hepatitis E Virus 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® HEV</p>
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Place:

Date08-Aug-22



Central Licensing Authority