



सत्यमेव जयते

## FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/IVD/2021/000064

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. 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:Control Kit for Truenat™ Chip-based micro PCR Tests: MTB, MTB Plus, MTB-RIF Dx, Beta CoV, SARS CoV-2, COVID-19 and H1N1</p> <p>Model No.:80101008 - Kit containing 08 Tests</p> <p>Intended Use:Truenat™ Positive Control Kit - Panel I is a set of Positive and Negative control for validating the performance of Truenat™ chip based micro PCR tests - MTB, MTB Plus, MTB-RIF Dx, Beta CoV, SARS CoV-2, COVID-19 and H1N1 as well as Truelab® Real Time micro PCR Analyzers.</p> <p>Class of medical device:Class A</p> <p>Material of construction:A. Individually sealed pouch, containing 1. Positive Control: Microtube containing dried down mix of DNA comprising target nucleic acids of Truenat™ chip based micro PCR tests - MTB, MTB Plus, MTB-RIF Dx, Beta CoV, SARS CoV-2, COVID-19 and H1N1 2. Negative Control: Proprietary buffer also used as reconstitution buffer for Positive Control B.</p> <p>Package Insert.</p> <p>Dimension(if any):</p> <p>Shelflife:12 months</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):Truenat™ Positive Control Kit - Panel I</p>

2	<p>Generic Name:Control Kit for Truenat™ Chip-based micro PCR Tests: HBV, HCV, HIV-1, HLA-B27, Dengue, Chikungunya and Influenza A/B</p> <p>Model No.:80102008 - Kit containing 08 Tests</p> <p>Intended Use:Truenat™ Positive Control Kit - Panel II is a set of Positive and Negative control for validating the performance of Truenat™ chip based micro PCR tests - HBV, HCV, HIV-1, HLA-B27, Dengue, Chikungunya and Influenza A/B as well as Truelab® Real Time micro PCR Analyzers.</p> <p>Class of medical device:Class A</p> <p>Material of construction:A. Individually sealed pouch, containing 1. Positive Control: Microtube containing dried down mix of DNA comprising target nucleic acids of Truenat™ chip based micro PCR tests - HBV, HCV, HIV-1, HLA-B27, Dengue, Chikungunya and Influenza A/B 2. Negative Control: Proprietary buffer also used as reconstitution buffer for Positive Control B. Package Insert.</p> <p>Dimension(if any):</p> <p>Shelflife:12 months</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):Truenat™ Positive Control Kit - Panel II</p>
3	<p>Generic Name:Control Kit for Truenat™ Chip-based micro PCR Tests: CT, NG, Trich, HPV-HR, GBS and Salmonella</p> <p>Model No.:80103008 - Kit containing 08 Tests</p> <p>Intended Use:Truenat™ Positive Control Kit - Panel III is a set of Positive and Negative control for validating the performance of Truenat™ chip based micro PCR tests - CT, NG, Trich, HPV-HR, GBS and Salmonella as well as Truelab® Real Time micro PCR Analyzers.</p> <p>Class of medical device:Class A</p> <p>Material of construction:A. Individually sealed pouch, containing 1. Positive Control: Microtube containing dried down mix of DNA comprising target nucleic acids of Truenat™ chip based micro PCR tests - CT, NG, Trich, HPV-HR, GBS and Salmonella 2. Negative Control: Proprietary buffer also used as reconstitution buffer for Positive Control B. Package Insert.</p> <p>Dimension(if any):</p> <p>Shelflife:12 months</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):Truenat™ Positive Control Kit - Panel III</p>
4	<p>Generic Name:Control Kit for Truenat™ Chip-based micro PCR Tests: HAV, HEV, Rabies, LTS, Nipah and Malaria Pv/Pf</p> <p>Model No.:80104008 - Kit containing 08 Tests</p> <p>Intended Use:Truenat™ Positive Control Kit - Panel IV is a set of Positive and Negative control for validating the performance of Truenat™ chip based micro PCR tests - HAV, HEV, Rabies, LTS, Nipah and Malaria Pv/Pf as well as Truelab® Real Time micro PCR Analyzers.</p> <p>Class of medical device:Class A</p> <p>Material of construction:A. Individually sealed pouch, containing 1. Positive Control: Microtube containing dried down mix of DNA comprising target nucleic acids of Truenat™ chip based micro PCR tests - HAV, HEV, Rabies, LTS, Nipah and Malaria Pv/Pf 2. Negative Control: Proprietary buffer also used as reconstitution buffer for Positive Control B. Package Insert.</p> <p>Dimension(if any):</p> <p>Shelflife:12 months</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):Truenat™ Positive Control Kit - Panel IV</p>

5	<p>Generic Name:Sample preparation kit for nucleic acid extraction on Trueprep® AUTO</p> <p>Model No.:60203AR05 - Kit containing 05 Tests,60203AR25 - Kit containing 25 Tests, 60203AR50 - Kit containing 50 Tests,60203AR100 - Kit containing 100 Tests</p> <p>Intended Use:Trueprep® AUTO Universal Cartridge Based Sample Prep Kit works with Trueprep® AUTO Universal Cartridge Based Sample Prep Device and is used for extraction and purification of nucleic acids from a wide range of biological specimens.</p> <p>Class of medical device:Class A</p> <p>Material of construction:A. Reagent Pack 1. Wash Buffer A - Known volume of proprietary buffer dispensed into a plastic bottle with cap. 2. Wash Buffer B - Known volume of proprietary buffer dispensed into a plastic bottle with cap. 3. Elution Buffer - Known volume of proprietary buffer dispensed into a plastic bottle with cap. 4. Priming Waste - Empty plastic bottle with cap. B. Cartridge Pack Individually sealed pouch containing: 1. Cartridge containing immobilized Internal Control DNA (IPC) for extraction. 2. Elute Collection Tube - Capped empty plastic tube for collection and storage of extracted nucleic acids. 3. Disposable graduated transfer pipette 4. Elute Collection Tube label C. Disposable graduated transfer pipette. D. 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):Trueprep® AUTO Universal Cartridge Based Sample Prep Kit</p>
6	<p>Generic Name:Sample preparation kit for nucleic acid extraction on Trueprep® AUTO v2</p> <p>Model No.:60207AR05 - Kit containing 05 Tests,60207AR25 - Kit containing 25 Tests, 60207AR50 - Kit containing 50 Tests,60207AR100 - Kit containing 100 Tests</p> <p>Intended Use:Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit works with Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Device and is used for extraction and purification of nucleic acids from a wide range of biological specimens.</p> <p>Class of medical device:Class A</p> <p>Material of construction:A. Reagent Pack 1. Wash Buffer A - Known volume of proprietary buffer dispensed into a plastic pouch. 2. Wash Buffer B - Known volume of proprietary buffer dispensed into a plastic pouch. 3. Elution Buffer - Known volume of proprietary buffer dispensed into a plastic pouch. 4. Priming Waste - Empty plastic pouch. B. Cartridge Pack Individually sealed pouch containing: 1. Cartridge containing immobilized Internal Control DNA. (IPC) for extraction. 2. Elute Collection Tube - Capped empty plastic tube for collection and storage of extracted nucleic acids. 3. Disposable graduated transfer pipette 4. Elute Collection Tube label C. Disposable graduated transfer pipette. D. 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):Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit</p>

7	<p>Generic Name:Sample pre-treatment pack for MTB samples</p> <p>Model No.:60204AS05 - Kit containing 05 Tests,60204AS25 - Kit containing 25 Tests, 60204AS50 - Kit containing 50 Tests,60204AS100 - Kit containing 100 Tests</p> <p>Intended Use:Trueprep® AUTO MTB Sample Pre-treatment pack is used to liquefy and pretreat the pulmonary and EPTB specimen before proceeding for extraction and purification of nucleic acids using Trueprep® AUTO Trueprep® /AUTO v2 Universal Cartridge Based Sample Prep Kit and AUTO/AUTO v2 Universal Cartridge Based Sample Prep Device</p> <p>Class of medical device:Class A</p> <p>Material of construction:1. Liquefaction buffer - Known volume of proprietary buffer dispensed into a plastic bottle with cap. 2. Lysis buffer - Known volume of proprietary buffer dispensed into plastic tubes with cap. 3. Disposable graduated transfer pipettes. 4. 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):Trueprep® AUTO MTB Sample Pretreatment Pack</p>
8	<p>Generic Name:Universal Sample pre-treatment pack for Non MTB samples</p> <p>Model No.:60205AB05 - Kit containing 05 Tests ,60205AB25 - Kit containing 25 Tests , 60205AB50 - Kit containing 50 Tests ,60205AB100 - Kit containing 100 Tests</p> <p>Intended Use:Trueprep® AUTO Universal Sample Pre-treatment Pack is used to pre-treat the samples such as whole blood/ serum/plasma/urine/stool/swab specimens/other body fluids before proceeding for extraction and purification of nucleic acids using Trueprep® AUTO/Auto v2 Universal Cartridge Based Sample Prep Kit and Trueprep® AUTO/AUTO v2 Universal Cartridge Based Sample Prep Device.</p> <p>Class of medical device:Class A</p> <p>Material of construction:1. Lysis buffer - Known volume of proprietary buffer dispensed into plastic tubes with cap. 2. Disposable graduated transfer pipettes. 3. 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):Trueprep® AUTO Universal Sample Pre-treatment Pack</p>

9	<p>Generic Name:Medium for Collection, Decontamination and Transport of Swab Specimen for Trueprep® AUTO</p> <p>Model No.:60206TS05 - Kit containing 05 Tests,60206TS25 - Kit containing 25 Tests, 60206TS50 - Kit containing 50 Tests,60206TS100 - Kit containing 100 Tests</p> <p>Intended Use:Trueprep® AUTO Transport Medium for Swab Specimen Pack is intended for use with clinician-collected endocervical, vaginal, anorectal, nasal and throat swab specimens. The transport media is used as a medium for collection, decontamination and transport of various types of swabs specimens before proceeding for pre-treatment using Lysis buffer, extraction and purification of nucleic acids using Trueprep® AUTO/AUTO v2 Universal Cartridge Based Sample Prep Kit and Trueprep® AUTO/AUTO v2 Universal Cartridge Based Sample Prep Device.</p> <p>Class of medical device:Class A</p> <p>Material of construction:1.Transport Medium for Swab specimen tubes - Known volume of proprietary buffer dispensed into plastic tubes with cap. 2. 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):Trueprep® AUTO Transport Medium for Swab Specimen Pack</p>
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Place:

Date21-Jun-21



State Licensing Authority

Directorate of Food & Drugs Administration,  
Bambolim-Goa