



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/2019/000003

Endorsement No. 3

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 Pvt. Ltd., Plot No. L-46, Phase II D, Verna Industrial Estate, Verna, South Goa, Goa (India) - 403722 Telephone No.: 09960590604 FAX: 0832 2783267

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.:NIL</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.:NIL</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.:NIL</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.:NIL</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>

Place: Directorate of Food & Drugs Administration, Bambolim-Goa.

Date:15-Dec-20

State Licensing Authority

