



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. 8

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. 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 Duplex PCR Test for HIV-1/HIV-2</p> <p>Model No.:NIL</p> <p>Intended Use:Truenat® HIV-1/HIV-2 is a Chip based Real Time Duplex PCR Test (RT-PCR) for the quantitative detection and diagnosis of Human Immunodeficiency Virus Type 1 & 2 (HIV-1 & 2) in whole Blood / Plasma / Serum and aids in the monitoring of the HIV-1 & 2 viral load of patients with infection. Truenat® HIV-1/HIV-2 duplex 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 HIV-1 and HIV-2 and internal control DNA), dNTPs, Taq. polymerase in proprietary buffer. 3. DNase & RNase free pipette tip. 4. Desiccant pouch 5. Packaging sleeve</p> <p>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® HIV-1/HIV-2</p>

Place:

Date 21-Mar-22

Central Licensing Authority