



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. 7

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 PCR Test for Nipah Virus</p> <p>Model No.:601390005 - Kit containing 05 Tests ,601390020 - Kit containing 20 Tests , 601390025 - Kit containing 25 Tests ,601390050 - Kit containing 50 Tests ,601390100 - Kit containing 100 Tests ,601390200 - Kit containing 200 Tests</p> <p>Intended Use:Truenat® Nipah is a chip-based Real Time Reverse Transcription Polymerase Chain Reaction (RT PCR) test for semiquantitative detection and the diagnosis of Nipah virus in throat swabs and aids in the diagnosis of infection with Nipah virus. Truenat® Nipah 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 Oligonucleotides (primers and probes specific to Nipah Virus and internal control), dNTPs, Taq. polymerase, Reverse Transcriptase in proprietary buffer. 3. DNase &amp; RNase free pipette tip. 4. Desiccant pouch B. Package insert</p> <p>Dimension(if any):</p> <p>Shelflife:6 months</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):Truenat® Nipah</p>

Place:

Date 07-Sep-21

VENUGOPAL  
GIRDHARILA  
L SOMANI

Digitally signed by VENUGOPAL  
GIRDHARILA SOMANI  
DN: c=IN, o=MINISTRY OF HOME AFFAIRS,  
ou=CDSCO DIGIS, postalCode=431401,  
st=Maharashtra,  
2.5.4.20=171d33345d82d489632379a1471  
b6d9e9b2b0e56c8b0b27154c9f9b1af7,  
cn=VENUGOPAL GIRDHARILA SOMANI  
Date: 2021.09.07 20:51:53 +05'30'

Central Licensing Authority



Directorate General of Health Services  
Central Drugs Standard Control Organisation  
Ministry of Health and Family Welfare  
(Medical Device and Diagnostic Division)

File No : IVD/PostAppr/2022/9132

FDA Bhawan, Kotla Road  
New Delhi-110002  
Phone No-011-23236965  
Fax: 23236973  
Date: 20-Mar-2024

To

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 Email: shonali@molbiodiagnostics.com

Sub: Post approval change in Manufacturing License No. MFG/IVD/2019/000018 dated :  
12/06/2019

Sir,

This is with reference to your application number IVD/PostAppr/2022/9132 dated : 11/02/2022  
regarding the above subject.

The Change in Manufacturing License Form MD-9 No. MFG/IVD/2019/000018 as mentioned below is  
approved with subject to the same condition of licence.

Change Description	Product Name(Brand Name)	In Place of	To be Read as
Change of the approved Shelf Life	Chip-based Real Time PCR Test for Nipah Virus (Truenat® Nipah)	6 months	24 months

Yours faithfully

RAJEEV SINGH  
RAGHUVANSHI

Digitally signed by RAJEEV SINGH RAGHUVANSHI  
DN: c=IN, o=CENTRAL DRUGS STANDARD CONTROL  
ORGANISATION, ou=RAJEEV SINGH RAGHUVANSHI,  
2.5.4.20=80c02f6823e4eafbb8a239774cdeb03c276904101  
5a06564fe67f54b765db1cb, postalCode=600034,  
st=TAMIL NADU,  
serialNumber=657F5E47D940985D8F03BDC902D0E1FE73  
CFA12A1A126EA94FA5701124A19013, cn=RAJEEV SINGH  
RAGHUVANSHI  
Date: 2024.03.20 17:22:36 +05'30'