



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/2019/000040

1. M/s MOLBIO DIAGNOSTICS PVT. LTD, H.NO. 13, SAGAR SOCIETY, DONA PAULA, PANAJI NORTH GOA, 403 004TISWADI, South Goa, Goa (India) - 403004 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	Generic Name:Chip-based Real Time PCR Test for Hepatitis C Virus Model No.:NIL Intended Use:Truenat™ HCV is a chip-based Real Time Reverse Transcription Polymerase Chain Reaction (RT PCR) test for the quantitative detection of Hepatitis C virus (HCV) RNA in human plasma, serum and whole blood samples. Truenat™ HCV aids in the diagnosis and confirmation of HCV infection (in conjunction with HCV antibody test) and in estimation of viral load. It is not intended as a blood donor screening test. Truenat™ HCV runs on the Truelab™ Real Time micro PCR Analyzers. Class of medical device:Class C Material of construction:A. Individually sealed pouches, each containing: 1. Micro PCR chip pre-loaded with dried down proprietary buffer and sealed with inert polymer. 2. Microtube containing freeze dried biomix comprising Reverse Transcriptase, Oligonucleotides (primers and probes specific to Hepatitis C Virus and internal control DNA), dNTPs, DNA 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™ HCV

Place:

Date12-Sep-19

Central Licensing Authority