



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. 12

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 - 46, Phase II-D, Verna Industrial Estate, Verna, South Goa, Goa (India) - 403722 Telephone No.: 083 26724888 FAX: 083 26724888

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 Clostridium difficile</p> <p>Model No.:601620005 - Kit Contains 5 Test ,601620020 - Kit Contains 20 Test ,601620025 - Kit Contains 25 Test ,601620050 - Kit Contains 50 Test ,601620100 - Kit Contains 100 Test , 601620200 - Kit Contains 200 Test</p> <p>Intended Use:Truenat® CDI is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the semi-quantitative detection and diagnosis of Clostridium difficile infections in stool samples. Truenat® CDI runs on the Truelab® Real Time Quantitative micro PCR Analyzers. Truenat® CDI is an in vitro diagnostics test meant for professional use only.</p> <p>Class of medical device:Class C</p> <p>Material of construction:Individually sealed pouches, each containing: 1.Truenat® CDI Micro PCR chip preloaded with dried down proprietary buffer and sealed with inert polymer</p> <p>2. Microtube with freeze dried Biomix comprising of oligonucleotides (primers and probes specific to CDI and internal control), dNTP containing dUTP and Taq polymerase in a proprietary buffer 3. DNase &amp; RNase free pipette tip 4. Desiccant pouch 5. 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® CDI</p>

Place:

Date:11-Oct-22

Central Licensing Authority