



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. 10

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 Shigella spp. Model No.:601470005 - Kit Contains 5 Test ,601470020 - Kit Contains 20 Test , 601470025 - Kit Contains 25 Test ,601470050 - Kit Contains 50 Test ,601470100 - Kit Contains 100 Test ,601470200 - Kit Contains 200 Test Intended Use:Truenat® Shigella is a chip-based Real Time Polymerase Chain Reaction (PCR) test for the semi quantitative detection of Shigella spp. in human stool specimen and aids in the diagnosis of infection with Shigella. Truenat® Shigella runs on the Truenat® Real Time Quantitative micro PCR Analyzers. Truenat® Shigella is an in vitro diagnostics test meant for professional use only. Class of medical device:Class C 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 Shigella and internal control), dNTPs, Taq Polymerase in proprietary buffer. 3) DNase & RNase free pipette tip 4) Desiccant pouch 5) Plastic packaging sleeve Dimension(if any): Shelflife:24 months Sterile or Non sterile:Non-Sterilized Brand Name(if registered under the Trade Marks Act, 1999):Truenat® Shigella</p>

Place:

Date 05-Aug-22

Central Licensing Authority