



सत्यमेव जयते

## FORM MD-5

[See sub-rule (4) of rule 20 and sub-rule (6) of rule 20]

Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device

Licence Number: MFG/IVD/2019/000003

Endorsement No. 2

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. 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:Sample preparation kit for nucleic acid extraction on Trueprep® AUTO v2</p> <p>Model No.:NIL</p> <p>Intended Use:Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit works with Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Device and is used for extraction and purification of nucleic acids from a wide range of biological specimens.</p> <p>Class of medical device:Class A</p> <p>Material of construction:A. Reagent Pack 1. Wash Buffer A - Known volume of proprietary buffer dispensed into a plastic pouch. 2. Wash Buffer B - Known volume of proprietary buffer dispensed into a plastic pouch. 3. Elution Buffer - Known volume of proprietary buffer dispensed into a plastic pouch. 4. Priming Waste - Empty plastic pouch. B. Cartridge Pack Individually sealed pouch containing: 1. Cartridge containing immobilized Internal Control DNA. (IPC) for extraction. 2. Elute Collection Tube - Capped empty plastic tube for collection and storage of extracted nucleic acids. 3. Disposable graduated transfer pipette 4. Elute Collection Tube label C. Disposable graduated transfer pipette. D. 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):Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Kit</p>

Place: Directorate of Food & Drugs Administration,  
Bambolim- Goa.

