



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. 8

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.: South Goa Goa 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.: South Goa Goa 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:Rapid cell lysis system for sample processing</p> <p>Model No.:950020001 - Device containing 1 unit</p> <p>Intended Use:The Truelyse - Bead buffer based system is designed to serve as a specialized medium for the collection and lysis of Tongue swab specimens. This device utilizes glass beads within a buffered solution to effective lyse the sample. The resulting lysed sample is then available for subsequent processing procedures.</p> <p>Class of medical device:Class A</p> <p>Material of construction:1.Bead buffer solution for sample collection 2.AC adapter with power cord 3.Electronic circuitry to aid a device performance for intended use 4. Battery</p> <p>Dimension(if any):</p> <p>Shelflife:NA</p> <p>Sterile or Non sterile:Non-Sterilized</p> <p>Brand Name(if registered under the Trade Marks Act, 1999):Truelyse™</p>

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

Date:10-Jun-24

State Licensing Authority