



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. 4

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 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 Collection and Lysis Medium for Prep Free Swab Specimen</p> <p>Model No.:90101PF05 - Kit containing 05 Tests ,90101PF20 - Kit containing 20 Tests , 90101PF25 - Kit containing 25 Tests ,90101PF50 - Kit containing 50 Tests ,90101PF100 - Kit containing 100 Tests ,90101PF200 - Kit containing 200 Tests</p> <p>Intended Use:STABILYSE® Prep Free is intended to be used as sample collection and lysis medium for oropharyngeal and nasopharyngeal swab specimens.</p> <p>Class of medical device:Class A</p> <p>Material of construction:1. Lysis buffer - Known volume of proprietary buffer dispensed into plastic tubes with cap 2. 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):STABILYSE® Prep Free</p>

Place: Directorate of Food & Drugs Administration ,Bambolim Goa

Date:27-Oct-21

State Licensing Authority