



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/2021/000064

Endorsement No. 1

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-42, PHASE II B, VERNA INDUSTRIAL ESTATE, VERNA GOA , South Goa, Goa (India) - 403722 Telephone No.: 083 26724888 FAX: 083 26724888

2. Details of medical device(s) [Annexed]

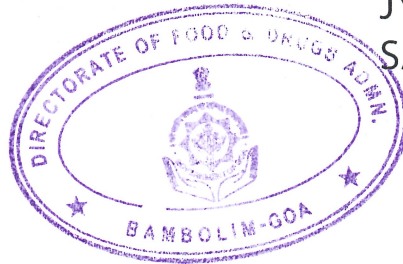
3. This licence is subject to the provisions of the Medical Devices Rules, 2017 and conditions prescribed therein.

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:

Date:17-Feb-22



**JYOTI JAIWANT
SARDESAI**

Digitally signed by JYOTI
JAIWANT SARDESAI
Date: 2022.02.17
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State Licensing Authority

Directorate of Food & Drugs Administration ,Bambolim Goa