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No.1157(9)/MFG/DFDA/2023/2328
Government of Goa,
Dte. Of Food & Drugs Admn.,
"DHANWANTARI"
Opposite Shrine of the Holy Cross
Bambolim -Goa, 403 202

Dated: 24/09/2023

To,
M/s, Molbio Diagnostics Private Limited
Plot no. L-42, Phase II B,
Verna Industrial Estate,
Verna, Salcete, South Goa, Goa.

Sub: Application for endorsement of additional product permission under manufacturer
Licence No. MFG/IVD/2019/000003 for sale and distribution of Class A
Medical Device under MD-3 of The Medical Device Rules 2017.

Ref: Your inward application vide Inward No. **MFG/IVD/2023/70649** dated 18/09/2022

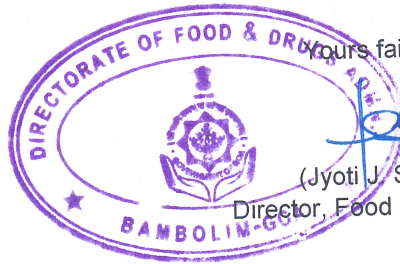
Sir,

With reference to your inward application No. MFG/IVD/2021/39723 dated 26/04/2021 I am inform you that the said application is approved and permission is granted to manufacture the below listed Class A Medical Device under license No. **MFG/IVD/2019/000003 with endorsement NO. 7 dated 15/09/2023** granted in Form MD-5 of The Medical Device Rules, 2017 on the premises situated at Plot No. L-46, Phase II D, Verna Industrial Estate, Verna, Goa.

Name of the Medical Devices:

1. Reagent Pack for Liquefaction of Samples
Trueprep AUTO Liquefaction Reagent

Pack Size: 5T, 20T, 25T, 50T, 100T, 200T
Shelf Life – 24 months



Yours faithfully

(Jyoti J. Sardesai)
Director, Food & Drugs Admn.



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. 7

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. 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: Reagent Pack for Liquefaction of Samples</p> <p>Model No.: 60204AL20 - Kit containing 20 Test , 60204AL25 - Kit containing 25 Test , 60204AL50 - Kit containing 50 Test , 60204AL100 - Kit containing 100 Test , 60204AL05 - Kit containing 5 Test , 60204AL200 - Kit containing 200 Test</p> <p>Intended Use: Trueprep® AUTO Liquefaction Reagent is used to liquefy and pretreat the pulmonary and EPTB specimen before proceeding for extraction and purification of nucleic acids using Trueprep® AUTO/AUTO v2 Universal Cartridge Based Sample Prep Kit and Trueprep® AUTO v2 Universal Cartridge Based Sample Prep Device.</p> <p>Class of medical device: Class A</p> <p>Material of construction: Trueprep® AUTO Liquefaction Reagent consists of the following components: A. Liquefaction buffer (dropper bottle) B. 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 Liquefaction Reagent</p>

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

Date: 15-Sep-23

**JYOTI
JAIWANT
SARDESAI**

Digitally signed by
JYOTI JAIWANT
SARDESAI
Date: 2023.09.15
15:57:45 +05'30'

State Licensing Authority