



CERTIFICATE

No. QS6 084208 0005 Rev. 02

Certificate Holder: **Molbio Diagnostics Limited**
 Plot No. L-46, Phase II D
 Verna Industrial Estate
 Verna, Goa 403722
 INDIA

Certification Mark:



Scope of Certificate: **Design and Development, Manufacture, Distribution, Installation and Servicing of In-Vitro Diagnostic Test Kit and Reagents, Sample Preparation and Real Time PCR Based In-Vitro Diagnostic Kits and Devices with Embedded Software (including Near Patient / Point of Care In-Vitro Diagnostics Medical Devices) Used in the Diagnosis and Detection of Disease Status and Transmissible Agents, Genetic Testing, Clinical Chemistry Reagents Test Kit Used in the Detection of Alcohol in Saliva**

Standard(s): **ISO 13485:2016**
Regulatory Authority(ies): **Brazil ANVISA, Health Canada, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6_084208_0005_Rev.02
 TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F006644**
Report No.: **TPS11624**
Effective Date: **2026-07-26**
Expiry Date: **2029-07-25**

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 Date of Issue: 2026-05-28

(Renee Walker)
 Director, US Certification Body, MHS

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Regulatory Requirements: Audit/Certification Criteria

Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

Canada

- Medical Device Regulations – Part 1- SOR 98/282

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):

Molbio Diagnostics Limited

Plot No. L-46, Phase II D, Verna Industrial Estate, Verna, Goa
403722, INDIA

Bigtec Private Limited

2nd Floor, Golden Heights, 59th 'C' Cross, 4th M Block, Rajaji
Nagar, Bengaluru 560010, INDIA

Molbio Diagnostics Limited

Plot No, L-61 A, Phase II-D, Verna Industrial Estate, Verna Goa
403722, INDIA

Molbio Diagnostics Limited

Plot no, L-42, Phase IIB, Verna Industrial Estate, Verna Goa
403722, INDIA

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Facility Scopes:

Molbio Diagnostics Limited

Plot No. L-46, Phase II D, Verna Industrial Estate, Verna, Goa 403722, INDIA

Manufacture, Formulation, Marketing and Sale of In-Vitro Diagnostics Reagents and Kits including Real Time PCR Tests, Clinical Chemistry Reagents

REPs Facility ID: F006644

Bigtec Private Limited

2nd Floor, Golden Heights, 59th 'C' Cross, 4th M Block, Rajaji Nagar, Bengaluru 560010, INDIA

Design and Development of In-Vitro Diagnostics Reagents and Kits including Real Time PCR Tests, Instruments, Clinical Chemistry Reagents

REPs Facility ID: F006644

Molbio Diagnostics Limited

Plot No, L-61 A, Phase II-D, Verna Industrial Estate, Verna Goa 403722, INDIA

Packaging, Quality Control, Installation and Servicing of In-Vitro Diagnostic Instruments for Nucleic Acid Testing including Real Time PCR and Sampling Processing System for the Purpose of In-Vitro Diagnostic Examination

REPs Facility ID: F006644

Molbio Diagnostics Limited

Plot no, L-42, Phase IIB, Verna Industrial Estate, Verna Goa 403722, INDIA

Manufacture, Formulation, Marketing and Sale of In-Vitro Diagnostics Reagents and Kits Including Real Time PCR Tests, Clinical Chemistry Reagents

REPs Facility ID: F006644

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