



America

# CERTIFICATE

No. QS6 084208 0005 Rev. 01

**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, 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**

**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.01](http://www.tuvsud.com/ps-cert?q=cert:QS6.084208.0005.Rev.01)

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:**

**F006644**

**Report No.:**

**TPS1408**

**Effective Date:**

**2025-07-11**

**Expiry Date:**

**2026-07-25**

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**Date of Issue:** 2025-07-22

( 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 Diagnostic 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  
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  
REPs Facility ID: F006644

**Molbio Diagnostics Limited**

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

Instrument and Instrument Services of Sample Preparation and  
Real Time PCR Based In-Vitro Diagnostics Devices With  
Embedded Software  
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  
REPs Facility ID: F006644



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Director, US Certification Body, MHS