



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 084208 0004 Rev. 03

Holder of Certificate: **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, Manufacturing, Distribution of In-Vitro Diagnostic Reagents and Reagent Kits for Infectious Diseases, Genetic Testing (Including Real Time PCR Tests) and Clinical Chemistry.

Design and Development, Manufacturing, Distribution, Installation and Servicing of In-Vitro Diagnostic Instruments for Nucleic Acid Testing including Real Time PCR and Sample Processing System for the purpose of In-Vitro Diagnostic examination.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 084208 0004 Rev. 03

Report No.: TPS1408_CN
Valid from: 2025-07-09
Valid until: 2026-04-26

Date, 2025-07-09

Christoph Dicks
Head of Certification/Notified Body



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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Molbio Diagnostics Limited**
Plot No. L-46, Phase II D, Verna Industrial Estate, Verna, Goa
403722, INDIA

Manufacturing, marketing, and sale of in-vitro diagnostic reagents, reagent kits for infectious diseases, genetic testing, (including real-time PCR tests) and Clinical Chemistry.

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

Design and development of in-vitro diagnostic reagents and reagent kits for infectious diseases, genetic testing and Clinical Chemistry, in-vitro diagnostic instruments for nucleic acid testing (including real-time PCR), sample processing systems for in-vitro diagnostic examination.

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

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.

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

Manufacturing, marketing, and sale of in-vitro diagnostic reagents, reagent kits for infectious disease, genetic testing (including real-time PCR tests) and Clinical Chemistry.

Molbio Diagnostics Limited
Plot No MU - 2A, AMTZ, Nadupuru - Village, Pedagantyada-Mandal, Campus, Pragati-Maidan, VM Steel Project, Visakhapatnam 530031, INDIA

Manufacturing of In-Vitro Diagnostic Instruments for Nucleic Acid Testing including Real Time PCR and Sample Processing System for the purpose of In-Vitro Diagnostic examination. Assembly of Consumables of Sampling Processing System for the purpose of In-Vitro Diagnostic examination (Cartridge).

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