



Certificate

No. Q5 084208 0004 Rev. 02

Holder of Certificate: **Molbio Diagnostics Private 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 and Genetic Testing (Including Real Time PCR Tests)**

Design and Development, Manufacturing, Distribution, 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

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 and certification regulation of 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._02

Report No.: IND2023075
Valid from: 2023-05-09
Valid until: 2026-04-26

Date, 2023-05-09

Christoph Dicks
Head of Certification/Notified Body

Certificate

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Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Molbio Diagnostics Private Limited

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

Manufacturing, Marketing and Sale of In-Vitro Diagnostic Reagents
and Reagent Kits for Infectious Diseases and Genetic Testing
(Including Real Time PCR Tests)

Molbio Diagnostics 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 and Genetic Testing, 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 Diagnostics Private 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 Private Limited

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

Manufacturing, Marketing and Sale of In-Vitro Diagnostic Reagents
and Reagent Kits for Infectious Diseases and Genetic Testing
(Including Real Time PCR Tests)

Molbio Diagnostics Private 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 Sampling 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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