



# Certificate

No. Q5 003027 0001 Rev. 02

**Holder of Certificate:** **Nanjing Vazyme Medical Technology Co.,Ltd.**  
F1-F3, Building C2  
Red Maple Park of Technological Industry  
State Economy & Technology Development Zone  
210038 Nanjing  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Distribution of In-vitro Diagnostic Test Kits based on Latex Particle-enhanced Turbidimetric Immunoassay, Quantum Dot Immunofluorescence, Rapid test for the detection of SARS-COV-2 infection marker, Fluorescence Immunity Analyzer and Specific Protein Analyzer.**

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 003027 0001 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5 003027 0001 Rev. 02)

**Report No.:** SH21128101

**Valid from:** 2021-05-09

**Valid until:** 2024-05-08

**Date,** 2021-05-07



Christoph Dicks  
Head of Certification/Notified Body

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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):** **Nanjing Vazyme Medical Technology Co.,Ltd.**  
**F1-F3, Building C2, Red Maple Park of Technological Industry,**  
**State Economy & Technology Development Zone, 210038**  
**Nanjing, PEOPLE'S REPUBLIC OF CHINA**

Design and Development, Production and Distribution of In-vitro Diagnostic Test Kits based on Latex Particle-enhanced Turbidimetric Immunoassay, Quantum Dot Immunofluorescence, Rapid test for the detection of SARS-COV-2 infection marker, Fluorescence Immunity Analyzer and Specific Protein Analyzer.

**Nanjing Vazyme Medical Technology Co.,Ltd.**  
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**PEOPLE'S REPUBLIC OF CHINA**

Production and Distribution of In-vitro Diagnostic Test Kits based on Quantum Dot Immunofluorescence, Rapid test for the detection of SARS-COV-2 infection marker.