



Product Service

CERTIFICATE

No. Q5 18 02 03027 001

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

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



Certification Mark:



Scope of Certificate: **Design and Development,
Production and Distribution of
In-vitro Diagnostic Test Kits
based on Latex Particle-enhanced
Turbidimetric Immunoassay and
Quantum Dot Immunofluorescence
Assay, Dry-type Fluorescence
Immunity Analyzer**

**Applied
Standard(s):**

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

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). See also notes overleaf.

Report No.: SH17128101

Valid from: 2018-05-09

Valid until: 2021-05-08

Date, 2018-05-09

Stefan Preiß



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