



Certificate

No. Q5 001708 0001 Rev. 04

Holder of Certificate: **Zybio Inc.**
Floor 1 to Floor 5, Building 30
No. 6 of Taikang Road
Block C of Jianqiao Industrial Park
Dadukou District
400082 Chongqing
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Clinical Chemistry Diagnostic Kit, Immunochromatography Diagnostic Kit, Nucleic Acid Isolation Reagent, Hematology Analysis Reagent, Chemiluminescence Reagent, Nucleic Acid Detection Kit, Microbial Sample Treatment Kit, Disposable Virus Sampling Tube, Blood Culture Reagent Kit, Pathological Reagent Kit, Urine Test Strip, Mass Spectrometry System, Blood Culture System, Urine Analyzer, Immune Quantitative Analyzer, Fully Automatic Chemistry Analyzer, Nucleic Acid Isolation System, Hematology Analyzer, Chemiluminescence Immunoassay Analyzer, Immunohistochemistry Autostainer**

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 001708 0001 Rev. 04

Report No.: SH21101401 / SH21101401-CN
Valid from: 2022-02-25
Valid until: 2025-02-24

Date, 2022-02-24



Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 001708 0001 Rev. 04

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):

Zybio Inc.
Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C
of Jianqiao Industrial Park, Dadukou District, 400082
Chongqing, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Blood Culture System, Urine Analyzer, Immune Quantitative Analyzer, Fully Automatic Chemistry Analyzer, Nucleic Acid Isolation Systems, Hematology Analyzer, Chemiluminescence Immunoassay Analyzer

Design and Development of Nucleic Acid Isolation Reagent, Nucleic Acid Detection Kit, Mass Spectrometry System, Immunohistochemistry Autostainer

Zybio Inc.
Floor 1 to Floor 4, Building 27/28, No. 10 of Taikang Road,
Block C of Jianqiao Industrial Park, Dadukou District, 400082
Chongqing, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Clinical Chemistry Diagnostic Kit, Immunochromatography Diagnostic Kit, Nucleic Acid Isolation Reagent, Hematology Analysis Reagent, Chemiluminescence Reagent, Nucleic Acid Detection Kit, Microbial Sample Treatment Kit, Disposable Virus Sampling Tube, Blood Culture Reagent Kit, Pathological Reagent Kit, Urine Test Strip

Zybio Inc.
Floor 2, Building 24-25, No. 3 of Taikang Road, Block C of
Jianqiao Industrial Park, Dadukou District, 400082 Chongqing,
PEOPLE'S REPUBLIC OF CHINA

Production and Distribution of Nucleic Acid Isolation Reagent



Product Service

Certificate

No. Q5 001708 0001 Rev. 04

Facility(ies):

Zybio Inc.
Floor 3, Building 35, No. 1 of No. 17 of Shilin Avenue,
Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC
OF CHINA

Production and Distribution of Disposable Virus Sampling Tube

Zybio Inc.
Floor 1 to Floor 5, Building 38, No. 5 of Taikang Road, Block C
of Jianqiao Industrial Park, Dadukou District, 400082
Chongqing, PEOPLE'S REPUBLIC OF CHINA

Production and Distribution of Pathological Reagent,
Chemiluminescence Reagent, Microbial Sample Treatment Kit,
Mass Spectrometry System, Immunohistochemistry Autostainer



America

CERTIFICATE

No. QS5 001708 0003 Rev. 03

Certificate Holder:

Zybio Inc.
Floor 1 to Floor 5, Building 30
No. 6 of Taikang Road
Block C of Jianqiao Industrial Park
Dadukou District
400082 Chongqing
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

See Page 2 for Overall Scope Statement.

Standard(s):

ISO 9001:2015

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.:

SH21101401

Effective Date:

2022-01-24

Expiry Date:

2025-01-23

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Date of Issue: 2022-02-03

(Michael Ogunleye)
Manager, US Certification Body,
Medical and Health Services



America

CERTIFICATE

No. QS5 001708 0003 Rev. 03

Overall Scope Statement: Design and Development, Production and Distribution of Clinical Chemistry Diagnostic Kit, Immunochromatography Diagnostic Kit, Nucleic Acid Isolation Reagent, Hematology Analysis Reagent, Chemiluminescence Reagent, Nucleic Acid Detection Kit, Microbial Sample Treatment Kit, Disposable Virus Sampling Tube, Blood Culture Reagent Kit, Pathological Reagent Kit, Urine Test Strip, Mass Spectrometry System, Blood Culture System, Urine Analyzer, Immune Quantitative Analyzer, Fully Automatic Chemistry Analyzer, Nucleic Acid Isolation System, Hematology Analyzer, Chemiluminescence Immunoassay Analyzer, Immunohistochemistry Autostainer

Facility(ies): **Zybio Inc.**
Floor 1 to Floor 5, Building 30, No. 6 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA

Facility Scopes: Design and Development, Production and Distribution of Blood Culture System, Urine Analyzer, Immune Quantitative Analyzer, Fully Automatic Chemistry Analyzers, Nucleic Acid Isolation Systems, Hematology Analyzers, Chemiluminescence Immunoassay Analyzers; Design and Development Nucleic Acid Isolation Reagent, Nucleic Acid Detection Kit, Mass Spectrometry System, Immunohistochemistry Autostainer

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Date of Issue: 2022-02-03

(Michael Ogunleye)
Manager, US Certification Body,
Medical and Health Services



America

CERTIFICATE

No. QS5 001708 0003 Rev. 03

Facility(ies):	Zybio Inc. Floor 1 to Floor 4, Building 27/28, No. 10 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA
Facility Scopes:	Design and Development, Production and Distribution of Clinical Chemistry, Immunochromatography Diagnostic Kit, Nucleic Acid Isolation Reagent, Hematology Analysis Reagent, Chemiluminescence Reagent, Nucleic Acid Detection Kit, Microbial Sample Treatment Kit, Disposable Virus Sampling Tube, Pathological Reagent Kit, Urine Test Strip
Facility(ies):	Zybio Inc. Floor 2, Building 24-25, No. 3 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA
Facility Scopes:	Production and Distribution of Nucleic Acid Isolation Reagent
Facility(ies):	Zybio Inc. Floor 3, Building 35, No. 1 of No. 17 of Shilin Avenue, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA
Facility Scopes:	Production and Distribution of Disposable Virus Sampling Tube
Facility(ies):	Zybio Inc. Floor 1 to Floor 5, Building 38, No. 5 of Taikang Road, Block C of Jianqiao Industrial Park, Dadukou District, 400082 Chongqing, PEOPLE'S REPUBLIC OF CHINA
Facility Scopes:	Production and Distribution of Pathological Reagent, Chemiluminescence Reagent, Microbial Sample Treatment Kit, Mass Spectrometry System, Immunohistochemistry Autostainer

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(Michael Ogunleye)
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Medical and Health Services