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2025/07/31

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证明书

CERTIFICATE



中国国际贸易促进委员会

中国国际商会

China Council for the Promotion of International Trade

China Chamber of International Commerce

中国国际贸易促进委员会
中国国际商会

China Council for the Promotion of International Trade
China Chamber of International Commerce

证明书
CERTIFICATE



号码 No. 251100B0/H34525

兹证明：所附文件的影印件与原件相符。

THIS IS TO CERTIFY THAT: the annexed photostated copy of
DOCUMENT is in conformity with the original.



China Council for the Promotion
of International Trade
商事证明专用章
CCPIT

签证员:
Authorized
Official: Zhang Hanrong

日期: 2025年07月28日
(Date: Jul. 28, 2025)

证 询网址 Website for verifying the certificate: <http://www.rzccpit.com/validate.html>



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 058008 0025 Rev. 06

Holder of Certificate: **GUANGZHOU WONFO BIOTECH CO., LTD.**
No. 8 Lizhishan Road, Science City
Huangpu District
510663 Guangzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostics Reagents and Control Materials for Clinical Chemistry, Immunology, Haemostasis and Infectious Diseases, Histology**
Design and Development, Production, Distribution, Installation and servicing of In Vitro Diagnostics Instrument for Clinical Chemistry, Immunochemistry, Infectious Immunology, Nucleic Acid Testing and Histology

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 058008 0025 Rev. 06

Report No.: SH2414102/SH2414102_CN

Valid from: 2025-05-06
Valid until: 2027-01-31

Date, 2025-05-06

Christoph Dicks
Head of Certification/Notified Body



Product Service

Certificate

No. Q5 058008 0025 Rev. 06

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): **GUANGZHOU WONDFO BIOTECH CO., LTD.**
No. 8 Lizhishan Road, Science City, Huangpu District, 510663
Guangzhou, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production of In Vitro Diagnostics
Reagents for Fertility, Pregnancy, Infectious Diseases, Drugs of
Abuse, Tumor Markers, Cardiac Markers, Diabetes Markers, Renal
Injury Markers, Autoimmune Diseases, Inflammation, Sperm
Concentration Tests, Thyroid Function Hormones, Vitamin Test,
Anemia, Control Materials for Tumor Markers

GUANGZHOU WONDFO BIOTECH CO., LTD.
Building 1, No.2 Huangqi Street, Songshan Lake Park, 523787
Dongguan, PEOPLE'S REPUBLIC OF CHINA

Design and Development of In Vitro Diagnostics Instruments for
Blood Gas, Coagulation Factors, Fluorescence Immunoassay,
Clinical Chemistry, Chemiluminescence Immunoassay, Nucleic
Acid Test, Histology

GUANGZHOU WONDFO BIOTECH CO., LTD.
NO. 268 Shenzhou Road, Huangpu District, 510663 Guangzhou,
PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of In Vitro
Diagnostics Reagents for Fertility, Pregnancy, Infectious Diseases,
Drugs of Abuse, Tumor Markers, Cardiac Markers, Diabetes
Markers, Renal Injury Markers, Autoimmune Diseases,
Inflammation, Coagulation Factors, Blood Gas Markers, Sperm
Concentration Tests, Thyroid Function Hormones, Vitamin Test,
Anemia, Histology, Control Materials for Tumor Markers, Clinical
Chemistry

Production, Installation and Servicing, Distribution of In Vitro
Diagnostics Instruments for Blood Gas Coagulation Factors,
Fluorescence Immunoassay, Clinical Chemistry,
Chemiluminescence Immunoassay, Nucleic Acid Test, Histology



ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICATE ◆



本附加证明书仅证明公文书上的签名、签署人签名时的身份，需要时可证明公文书上的印鉴属实。附加证明书不对公文书内容予以证明。
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1. 文书出具国: 中华人民共和国
Country: People's Republic of China

本公文书 This public document

2. 签署人
has been
signed by 张瀚蓉
Zhang Hanrong

3. 签署人身份
acting in the
capacity of 签证员
Authorized Official

4. 印鉴名称
bears the
seal/stamp of 中国国际贸易促进委员会
China Council for the Promotion of International Trade

证明 Certified

5. 签发地
at 北京
Beijing

6. 签发日期
the 2025年07月30日
July 30, 2025

7. 签发人
by 龚晴, 二等秘书/ Gong Qing, Second Secretary
外交部领事司
Department of Consular Affairs of the Ministry of Foreign Affairs



8. 附加证明书编号
No 认字第250000340648号

9. 签发机关印鉴:
Seal/Stamp:



10. 签名:
Signature:

龚晴