



Certificate

No. Q5 058008 0025 Rev. 05

Holder of Certificate:

GUANGZHOU WONDFO 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.

Design and Development, Production, Distribution, Installation and servicing of In Vitro Diagnostics Instrument for Clinical Chemistry, Immunochemistry, Infectious Immunology and Nucleic Acid Testing.

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 058008 0025 Rev. 05

Report No.:

SH2314101/SH2314101_CN

Valid from:

2024-02-01

Valid until:

2027-01-31

Date,

2024-01-24

Christoph Dicks

Head of Certification/Notified Body

Certificate

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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, Control Materials for Tumor Markers.

GUANGZHOU WONDFO BIOTECH CO., LTD.

501 Room, 5F Self-edited Building 1, No.8 Lianhuayan Road,
Huangpu District, 510663 Guangzhou, PEOPLE'S REPUBLIC OF
CHINA

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

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; Control Materials for Tumor Markers, Clinical
Chemistry.

Distribution of In Vitro Diagnostics Instruments for Blood Gas,
Coagulation Factors, Fluorescence Immunoassay, Clinical
Chemistry, Chemiluminescence Immunoassay, Nucleic Acid Test.