



Certificate

No. Q5 058008 0025 Rev. 03

Holder of Certificate: **GUANGZHOU WONDFO BIOTECH CO., LTD.**

No. 8 Lizhishan Road, Science City
Luogang District
510663 Guangzhou
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design and Development, Production, Distribution, Installation and Service of In Vitro Diagnostics for the Detection of Fertility, Pregnancy, Infectious Diseases, Drugs of Abuse, Tumor Markers, Cardiac Markers, Diabetes Markers, Renal Injury Markers, Autoimmune Diseases, Infection, Inflammation, Coagulation Factors, Blood Gas Markers and Related Instruments, Sperm Concentration Tests, Fluorescence Immunoassay Systems, Blood Glucose Monitoring Systems, Control Materials for Tumor Markers, Biochemical Reagents and Instruments

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. 03

Report No.: SH2114101
Valid from: 2022-03-18
Valid until: 2024-01-31

Date, 2022-03-18



Christoph Dicks
Head of Certification/Notified Body



Product Service

Certificate

No. Q5 058008 0025 Rev. 03

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): GUANGZHOU WONDFO BIOTECH CO., LTD.
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 Guangzhou, PEOPLE'S REPUBLIC OF CHINA

Design and Development, Distribution of In Vitro Diagnostics for the Detection of Fertility, Pregnancy, Infectious Diseases, Drugs of Abuse, Tumor Markers, Cardiac Markers, Diabetes Markers, Renal Injury Markers, Autoimmune Diseases, Infection, Inflammation, Coagulation Factors, Blood Gas Markers and Related Instruments, Sperm Concentration Tests, Fluorescence Immunoassay Systems, Blood Glucose Monitoring Systems, Control Materials for Tumor Markers, Biochemical Reagents and Instruments

Production of In Vitro Diagnostic Reagents for the Detection of Fertility, Pregnancy, Infectious Diseases, Drugs of Abuse, Tumor Markers, Cardiac Markers, Diabetes Markers, Renal Injury Markers, Autoimmune Diseases, Infection, Inflammation, Coagulation Factors, Blood Gas Markers, Sperm Concentration, Control Materials for Tumor Markers, Biochemical Reagents

GUANGZHOU WONDFO BIOTECH CO., LTD.
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Design and Development, Production, Installation and Service of In Vitro Diagnostic Instruments for Blood Gas, Fluorescence Immunoassay, Blood Glucose and Biochemical