



Product Service

Certificate

No. Q5 058008 0025 Rev. 02

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

Facility(ies): GUANGZHOU WONFDO BIOTECH CO., LTD.
No. 8 Lizhishan Road, Science City, Luogang District, 510663
Guangzhou, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

Certification Mark:

Scope of Certificate: Design and Development, Production and 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

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). 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. 02

Report No.: SH2014101
Valid from: 2021-02-01
Valid until: 2024-01-31

Date, 2021-01-21

Christoph Dicks
Head of Certification/Notified Body