DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

# Certificate

## No. Q5 058008 0025 Rev. 00

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

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

**Certification Mark:**

tuv-sud.com/ps-cert

**Scope of Certificate:** **Design, 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 Test, Fluorescence Immunoassay System, Blood Glucose Monitoring System, Control Materials for Tumor Markers, ECG Event Recorder**

**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). See also notes overleaf.

**Report No.:** SH1814116

**Valid from:** 2019-03-11
**Valid until:** 2021-01-31

**Date,** 2019-03-11

Stefan Preiß

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17


TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany