



Product Service

# CERTIFICATE

No. Q5 17 11 58008 022

**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

**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 Makers, Renal Injury Markers,  
Autoimmune Diseases,  
Infection and Inflammation  
Markers and related instruments,  
Sperm Concentration Test,  
Fluorescence Immunoassay System,  
Blood Glucose Monitoring System  
Control materials for tumor makers,  
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.:**

SH1714115

**Valid from:**

2018-02-01

**Valid until:**

2021-01-31

**Date,** 2018-01-15

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Stefan Preiß

