



Product Service

CERTIFICATE

No. Q1N 15 12 58008 018

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:



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
Makers 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 13485:2012 + AC:2012
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

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.: SH1514113
Valid from: 2016-03-09
Valid until: 2018-01-31

Date, 2016-03-08

Stefan Preiß



Page 1 of 1

