



CERTIFICATE

No. QS6 058008 0029 Rev. 00

Certificate Holder:

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, Service, Installation, and Distribution of In-Vitro Diagnostics for the Detection of Fertility, Pregnancy, Infectious Diseases, Drugs of Abuse, Tumor Markers, Cardiac Markers, Renal Injury Markers, Autoimmune Diseases, Infection and Inflammation Markers and Related Instruments, Sperm Concentration Test, Fluorescence Immunoassay

System, Blood Glucose Monitoring System

Standard(s):

(ISO 13485:2016)

Regulatory Authority(ies):

Australia TGA, Brazil ANVISA, Health Canada, USA FDA. See attachment page for listing of specific regulatory

requirements

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website https://www.tuev-sued.de/product-testing/certificates

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DUNS No:

53-014-8055

Effective Date:

2019-02-04

Expiry Date:

2022-02-03

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Date of Issue: 2019-02-18

(Arie Henkin)

Manager, Certification Body MHS

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Regulatory Requirements:

Australia

Therapeutic Goods (Medical Devices) Regulations 2002

- Schedule 3, Part 1

Brazil

- RDC ANVISA n. 16/2013

- RDC ANVISA n. 23/2012

- RDC ANVISA n. 67/2009

Canada

- Medical Device Regulations SOR/98-282, Part 1

United States

- 21 CFR Part 803

- 21 CFR Part 806

- 21 CFR Part 807

- 21 CFR Part 820

Facility(ies):

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Guangzhou, PEOPLE'S REPUBLIC OF CHINA

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Fluorescence Immunoassay System, Blood Glucose

Monitoring System

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