



Product Service

# Certificate

No. Q5 058008 0025 Rev. 05

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

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Distribution of In Vitro Diagnostics Reagents and Control Materials for Clinical Chemistry, Immunology, Haemostasis and Infectious Diseases.**

**Design and Development, Production, Distribution, Installation and servicing of In Vitro Diagnostics Instrument for Clinical Chemistry, Immunochemistry, Infectious Immunology and Nucleic Acid Testing.**

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. 05](http://www.tuvsud.com/ps-cert?q=cert:Q5 058008 0025 Rev. 05)

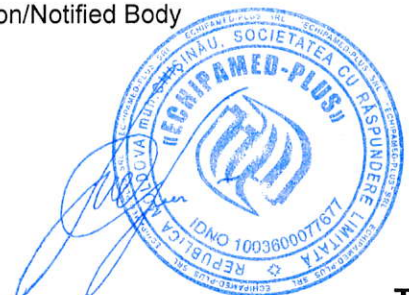
**Report No.:** SH2314101/SH2314101\_CN

**Valid from:** 2024-02-01

**Valid until:** 2027-01-31

**Date,** 2024-01-24

Christoph Dicks  
 Head of Certification/Notified Body





Product Service

# Certificate

No. Q5 058008 0025 Rev. 05

**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems -  
Requirements for regulatory purposes

**Facility(ies):** **GUANGZHOU WONDFO BIOTECH CO., LTD.**  
No. 8 Lizhishan Road, Science City, Huangpu District, 510663  
Guangzhou, PEOPLE'S REPUBLIC OF CHINA  
  
Design and Development, Production of In Vitro Diagnostics  
Reagents for Fertility, Pregnancy, Infectious Diseases, Drugs of  
Abuse, Tumor Markers, Cardiac Markers, Diabetes Markers, Renal  
Injury Markers, Autoimmune Diseases, Inflammation, Sperm  
Concentration Tests, Control Materials for Tumor Markers.

**GUANGZHOU WONDFO BIOTECH CO., LTD.**  
501 Room,5F Self-edited Building 1, No.8 Lianhuayan Road,  
Huangpu District, 510663 Guangzhou, PEOPLE'S REPUBLIC OF  
CHINA

Design and Development, Production, Installation and Servicing of  
In Vitro Diagnostics Instruments for Blood Gas, Coagulation  
Factors, Fluorescence Immunoassay, Clinical Chemistry,  
Chemiluminescence Immunoassay, Nucleic Acid Test.

**GUANGZHOU WONDFO BIOTECH CO., LTD.**  
NO. 268 Shenzhou Road, Huangpu District, 510663 Guangzhou,  
PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of In Vitro  
Diagnostics Reagents for Fertility, Pregnancy, Infectious Diseases,  
Drugs of Abuse, Tumor Markers, Cardiac Markers, Diabetes  
Markers, Renal Injury Markers, Autoimmune Diseases,  
Inflammation, Coagulation Factors, Blood Gas Markers, Sperm  
Concentration Tests; Control Materials for Tumor Markers, Clinical  
Chemistry.

Distribution of In Vitro Diagnostics Instruments for Blood Gas,  
Coagulation Factors, Fluorescence Immunoassay, Clinical  
Chemistry, Chemiluminescence Immunoassay, Nucleic Acid Test.

## EC DECLARATION OF CONFORMITY

According to the *In Vitro* Diagnostic Medical Device Directive 98/79/EC

No.: DOC-BGAcontrol(1)-01

Version: 00

**Manufacturer:** Guangzhou Wondfo Biotech Co., Ltd.  
**Address:** No.8, Lizhishan Road, Science City, Luogang District,  
510663, Guangzhou, P.R. China

**EC Authorised Representative:** Qarad BV  
**Address:** Cipalstraat 3, 2440 Geel, Belgium

### ***In Vitro* Diagnostic Medical Device(s):**

**Product Name:** Wondfo Blood Gas Analyzer Control  
**Cat. No.:** W847-L, W847-M, W847-H, W848, W849-L, W849-H  
**IVDD Classification:** Other, for professional use

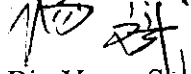
This declaration of conformity is issued under the sole responsibility of the manufacturer that the above product(s) meet(s) the provisions of the European Directive 98/79/EC for *In Vitro* Diagnostic Medical Devices.

The following (harmonized) standards have been applied:

EN ISO 13485:2016	EN ISO 18113-1:2011	EN 13612:2002
EN ISO 14971:2019	EN ISO 18113-2:2011	EN 13641:2002
EN ISO 23640:2015	EN ISO 15223-1:2016	EN 62366-1:2015

The conformity with the requirements of the Directive has been assessed following the procedure(s) outlined in the following annexes of the Directive: **Annex III, excluding 6**

**Notified Body (if consulted):** Not Applicable  
**Address:** /  
**EC Certificate(s):** /  
**Expiry date of the Certificate(s):** /

**Signature of manufacturer**   
**(Name and function):** Bin Yang, Senior Vice President of Regulatory Affairs

**Place and date of issue:** Guangzhou, P.R. China,  
April 25, 2022



## EC DECLARATION OF CONFORMITY

According to the *In Vitro* Diagnostic Medical Device Directive 98/79/EC

**Manufacturer:** Guangzhou Wondfo Biotech Co., Ltd.  
**Address:** No.8, Lizhishan Road, Science City, Luogang District,  
510663, Guangzhou, P.R. China

**EC Authorised Representative:** Qarad BV  
**Address:** Cipalstraat 3, 2440 Geel, Belgium

### *In Vitro* Diagnostic Medical Device(s):

**Product Name:** Wondfo Blood Gas Analyzer Reagent Pack  
**Cat. No.:** W451-Z0P4-G, W451-Z0P4-I  
**IVDD Classification:** Other, for professional use

This declaration of conformity is issued under the sole responsibility of the manufacturer that the above product(s) meet(s) the provisions of the European Directive 98/79/EC for *In Vitro* Diagnostic Medical Devices.

The following (harmonized) standards have been applied:

EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 15223-1:2016
EN 13641:2002	EN ISO 13485:2016	EN ISO 14971: 2019
EN 13612:2002	EN ISO 23640:2015	EN ISO 17511:2003

The conformity with the requirements of the Directive has been assessed following the procedure(s) outlined in the following annexes of the Directive: Annex III, excluding 6

**Notified Body (if consulted):** Not Applicable

**Address:** /

**EC Certificate(s):** /

**Expiry date of the Certificate(s):** /

**Signature of manufacturer (Name and function):**

Lingfang Huang, Vice-President of Regulatory Affairs

**Issue date:** 2021-6-22

## EC DECLARATION OF CONFORMITY

According to the *In Vitro* Diagnostic Medical Device Directive 98/79/EC

**Manufacturer:** Guangzhou Wondfo Biotech Co., Ltd.  
**Address:** No.8, Lizhishan Road, Science City, Luogang District,  
510663, Guangzhou, P.R. China

**EC Authorised Representative:** Qarad BV  
**Address:** Cipalstraat 3, 2440 Geel, Belgium

### ***In Vitro* Diagnostic Medical Device(s):**

**Product Name:** Wondfo Blood Gas Analyzer Test Card  
**Cat. No.:** W459-C7P4-M, W459-C7P4-E, W460-C7P4-M, W460-C7P4-E, W461-C7P4-M, W461-C7P4-E, W462-C7P4-M, W462-C7P4-E, W463-C7P4-M, W463-C7P4-E, W464-C7P4-M, W464-C7P4-E, W465-C7P4-M, W465-C7P4-E, W466-C7P4-M, W466-C7P4-E

**IVDD Classification:** Other, for professional use

This declaration of conformity is issued under the sole responsibility of the manufacturer that the above product(s) meet(s) the provisions of the European Directive 98/79/EC for *In Vitro* Diagnostic Medical Devices.

The following (harmonized) standards have been applied:

EN ISO 18113-1:2011	EN ISO 18113-2:2011	EN ISO 15223-1:2016
EN 13641:2002	EN ISO 13485:2016	EN ISO 14971: 2019
EN 13612:2002	EN ISO 23640:2015	EN ISO 17511:2003

The conformity with the requirements of the Directive has been assessed following the procedure(s) outlined in the following annexes of the Directive: Annex III, excluding 6

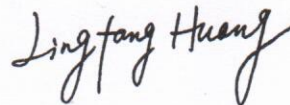
**Notified Body (if consulted):** Not Applicable

**Address:** /

**EC Certificate(s):** /

**Expiry date of the Certificate(s):** /

**Signature of manufacturer (Name and function):**



Lingfang Huang, Vice-President of Regulatory Affairs

**Issue date:** 2021-6-22