



Guangzhou Wondfo Biotech Co., Ltd.

No. 8 Lizhishan Road, Science City, Huangpu District, Guangzhou, Guangdong, P.R. China 510663

Tel: (+86)-20-32299999 / (+86) 400-830-8768

Website: en.wondfo.com E-mail: sales@wondfo.com.cn

To whom it may concern

Manufacturer's Authorization

Date: 25.12.2025

We *Guangzhou Wondfo Biotech Co., Ltd.*, who are official manufacturers of *POCT under In-Vitro-Diagnosis medical products*, having factories at *No.8, Lizhishan Road, Science City, Huangpu District, 510663, Guangzhou, China*, do hereby declare that

ECHIPAMED PLUS SRL
str. Valea Trandafirilor 24 "B", of. 2-7
MD-2001, Chisinau
Republic of Moldova

is our official distributor and local representative in the territory of the Republic of Moldova.

We declare that above mentioned company is authorized to quote, sell, subsequently negotiate and sign contracts, as well as to perform registration, installation and after sales service of products manufactured by us.

We hereby extend our full warranty with respect to the Goods offered by the above company.

This authorization letter will remain valid until 31.12.2026.

Guangzhou Wondfo Biotech Co., Ltd.

Zhang Yue
Regional Manager





Product Service

Certificate

No. Q5 058008 0025 Rev. 05

Holder of Certificate: **GUANGZHOU WONFDO 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

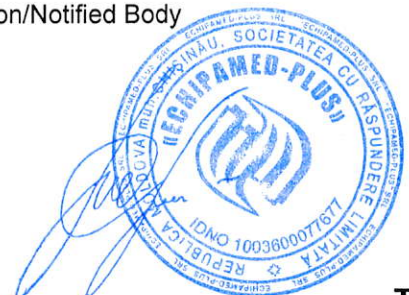
Report No.: SH2314101/SH2314101_CN

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

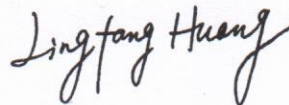
Notified Body (if consulted): Not Applicable

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

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **09 100 89004**

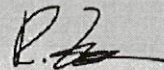
Certificate Holder: **SYSMEX CORPORATION**
1-5-1 Wakino-hama-Kaigandori, Chuo-ku, Kobe 651-0073 Japan
including the locations according to annex

Scope: Development, design, production, sales and servicing of in-vitro diagnostic medical devices, laboratory equipment, reagents, laboratory information system and gene variants analysis set (for cancer genome profiling)

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2024-08-01 until 2027-07-31.
First certification 1998

2024-07-19



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com



Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 1254782-1

Certificate Holder: SYSMEX CORPORATION
1-5-1 Wakinohama-Kaigandori,
Chuo-ku, Kobe
651-0073 Japan

Scope: Design and development, manufacture, distribution,
installation and service of blood analyzer, urine analyzer,
related reagents and accessories and gene variants analysis
set (for cancer genome profiling)
Product categories: Analyzers and reagents for hematological
test, blood coagulation test, immune serum test, biochemical
test, genetic test, bacteriological test and urine test

Installation is not applicable for reagents and gene variants
analysis set (for cancer genome profiling)

In accordance with EN ISO 13485:2016 Medical devices -
Quality management systems - Requirements for regulatory
purposes (ISO 13485:2016)

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies
a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality
management system is subject to yearly surveillance.

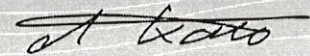
Report No.: 150287325-301

Effective date: 2024-08-01

Expiry date: 2027-07-31

Issue date: 2024-07-04

Replaces certificate SX 1254782-1 issued 2023-08-28



Atsushi Kato

TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on <https://www.certipedia.com>

