Digitally signed by Iurchevici Valeriu
Date: 2024.06.14 12:39:06 EEST
Reason: MoldSign Signature
Location: Moldova

Zhongjian Certification Co., Ltd.

CERTIFICATE OF CONFORMITY OF QUALITY MANAGEMENT SYSTEM CERTIFICATION

No:0070023Q54381R7L

This is to certify that the quality system of

GUANGZHOU WONDFO BIOTECH CO., LTD

REGISTER/OFFICE ADDRESS: NO.8, LIZHISHAN ROAD, SCIENCE CITY, HUANGPU DISTRICT, GUANGZHOU CITY, GUANGDONG PROVINCE

SITE ADDRESS 1: NO.8, LIZHISHAN ROAD, SCIENCE CITY, HUANGPU DISTRICT, GUANGZHOU CITY, GUANGDONG PROVINCE SITE ADDRESS 2: NO.501, 5F, BUILDING 1, NO.8, LIANHUAYAN ROAD, HUANGPU DISTRICT, GUANGZHOU CITY, GUANGDONG PROVINCE

SITE ADDRESS 3: NO.268, SHENZHOU ROAD, HUANGPU DISTRICT, GUANGZHOU CITY, GUANGDONG PROVINCE

Organization Code: 91440101618640472W

is in conformity with

GB/T 19001-2016/ISO9001:2015 Standard

This system is valid for the

DESIGN, DEVELOPMENT AND PRODUCTION OF Ⅰ, Ⅱ, Ⅲ KIND OF 6840 IN VITRO DIAGNOSTIC REAGENT, DESIGN, DEVELOPMENT AND PRODUCTION OF Ⅰ KIND OF 22-14 TRAINING AND INCUBATION EQUIPMENT, Ⅱ, Ⅲ KIND OF 6840 CLINICAL LABORATORY ANALYTICAL INSTRUMENTS

(This certificate only covers the sites listed. If the covered scope involves pre-approval of administration permit or compulsory certification requirement,the scope only covers products and services within the permit license or compulsory certification scope)

Date of issue:2023-11-20

Term of validity of this certificate:from 2023-11-20 to 2026-11-19 inclusive

This certificate remains valid only if the certified organization accepts and passes regular surveillance audits.

Representative of The Company

中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C007-M

The validity of this certificate could be confirmed via official Website Of CNCA (www.cnca.gov.cn)
Further to the certificate applicability, please enquire the certified organization: visit www.gzcc.org.cn or contact GZCC 020-66390902
4/F, Huajing Building, Guangzhou Dadaozhong, Guangzhou City, Guangdong Province, China (510600) Zhongjian Certification Co., Ltd.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 058008 0025 Rev. 05

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

Certification Mark:

TÜV SÜD
EN ISO 13485
tuvsud.com/ps-cert

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

"TEHNIPAMED-PLUS" SOCIETATEA CU RASPUNDERE LIMITATA IDNO 1003600077677 REPUBLICA

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TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
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.

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Wondfo

EC DECLARATION OF CONFORMITY

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

No.: DOC-W451(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 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 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
EN ISO 17511:2021		

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

Wondfo

EC DECLARATION OF CONFORMITY

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

No.: DOC-BGAcard(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 Test Card
Cat. No.:	W459-C7P4-M, W460-C7P4-M, W461-C7P4-M, W462-C7P4-M, W463-C7P4-M, W464-C7P4-M, W465-C7P4-M, W466-C7P4-M, W459-C7P4-E, W460-C7P4-E, W461-C7P4-E, W462-C7P4-E, W463-C7P4-E, W464-C7P4-E, W465-C7P4-E, 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 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
EN ISO 17511:2021		

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

Wondfo

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