Guangzhou Wondfo Biotech Co., Ltd.
No. 8 Lizhishan Road, Science City, Luogang 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

Manufacturer's Authorization

To whom it may concern

Date: January 29, 2024

We Guangzhou Wondfo Biotech Co., Ltd., who are official manufacturers of Blood Gas Analyzer and its compatible reagent pack & test card, having factories at No. 8 Lizhishan Road, Science City, Luogang District, Guangzhou, Guangdong, P.R. China 510663, do hereby authorize

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

to submit a bid by the Tender No. ocds-b3wdp1-MD-1705498196128 dated January 30th, 2024, organized by the "IMSP Spitalul Clinic Municipal de Ftiziopneumologie", the purpose of which is to provide the following Goods, manufactured by us Blood Gas Analyzer and its compatible reagent pack & test card, and to subsequently negotiate and sign the Contract, as well as to perform installation and after sales Service.

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

Yue Zhang
Regional Director
Guangzhou Wondfo Biotech Co., Ltd.
Date: January 29, 2024

广州万孚生物技术股份有限公司 Guangzhou Wondfo Biotech Co., Ltd. 国际业务章 for International Business only (1)

Digitally signed by Iurchevici Valeriu
Date: 2024.01.29 19:44:16 EET
Reason: MoldSign Signature
Location: Moldova

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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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-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

Wondfo

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

Lingfang Huang, Vice-President of Regulatory Affairs

Issue date: 2021-6-22