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

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

TÜV®

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-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

AYSET
Tıbbi Ürünler

17/05/2024

MANUFACTURER'S DECLARATION

Regarding Regulation (EU) No 2023/607 amending Regulation (EU) No 2017/745 on transitional provisions for medical devices:

As a manufacturer of medical devices subject to the certificate numbered M.2016.106.6922 specified in the table below within the scope of Council Directive 93/42/EEC (MDD) on Medical Devices

Manufacturer name	Ayset Tıbbi Ürünler Ve Plastik Tekstil Elektronik Gıda Temizlik Maddeleri İnşaat Müteahhitlik San. A.Ş.
Manufacturer address and contact information	Sarıhamzalı Mahallesi 47007 Sokak No:36/A Seyhan Adana TURKEY Phone: +90 322 441 12 99 Fax: +90 322 441 12 98 Web: www.ayset.com E-mail: info@ayset.com
Individual Identification Number-SRN (if available)	TR-MF-000016409

Name of Authorized Representative (if applicable)	Not applicable
Address and contact information of the Authorized Representative	Not applicable
Individual Identification Number-SRN	Not applicable

Name of notified body (if any)	Udem Uluslararası Belgelendirme Denetim Eğitim Merkezi Sanayi Ve Ticaret Anonim Şirketi
Identification number of the notified body (if available)	2292
Directive Certificate number(s) under which this approval was made (if any)	M.2016.106.6922
Original expiration date (if any) stated in the Directive Certificate before extension of validity	27 May 2024
Extended validity/transitional period end date	31 December 2028
Contract Number and contract date with the Notified Body	CNT_UDEM.0330/P1/R0 13 May 2024
Devices within the Scope of Application	Sterile, Disposable 3-Piece Blood Gas Syringe with Needle
	Sterile, Disposable 3-Piece Syringes (Without Needle, Luer Slip/ Luer Lock)
	Sterile, Disposable 2-Piece Syringes (Without Needle, Luer Slip/ Luer Lock)
	Sterile, Disposable 3-Piece Syringes (With Needle, Luer Slip/ Luer Lock)

AYSET TIBBİ ÜRÜNLER SAN. A.Ş.
Sarıhamzalı Mah. 47007 Sk. No:36/A Seyhan / Adana / TÜRKİYE
Tel.: +90 (322) 441 12 99 Fax: +90 (322) 441 12 98 e-mail:info@ayset.com web:www.ayset.com

	Sterile, Disposable 2-Piece Syringes (With Needle, Luer Slip/ Luer Lock)
	Sterile, Disposable U-100 Insulin Syringe (Without Needle)
	Sterile, Disposable U-100 Insulin Syringe (With Needle)
	Sterile, Disposable Tuberculin Syringe (Without Needle)
	Sterile, Disposable Tuberculin Syringe (With Needle)
	Sterile, Disposable Hypodermic Needles
	Sterile, Disposable Vacuum Blood Collection Needles
	Sterile, Disposable Vacuum Blood Collection Needle Butterfly Set Type
	Sterile, Disposable Insulin Pen Injector Needles

Related devices; We continue to comply with Council Directive 93/42/EEC,

Related devices; There is no significant change in its design and intended use,

Related devices; does not pose an unacceptable risk to the health or safety of patients, users or other persons or to other matters relevant to the protection of public health,

As the manufacturer of the relevant devices, we have implemented a quality management system (QMS) in our company in accordance with MDR Article 10(9) before May 26, 2024,

As the manufacturer of the relevant devices, it is bound to the notified body of Udem International Certification Audit Training Center Industry and Trade Joint Stock Company (Approved Body Identifier Number: 2292) in accordance with the first subparagraph of Article 4.3 of MDR Annex VII before 26 May 2024, with our certificate numbered M.2016.106.6922. We declare that an official application has been made for medical devices and an MDR certification agreement numbered CNT_UDEM.0330/P1/R0 has been signed with the Notified Body on 13 May 2024.

Özgül UYAN
Chemistry
Legislative Compliance Responsible
E-mail: ozgulcankurt@ayset.com

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