Digitally signed by Iurchevici Valeriu
Date: 2022.09.15 13:45:44 EEST
Reason: MoldSign Signature
Location: Moldova

To whom it may concern

Manufacturer's Authorization

Date: 15.09.2022

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 for ***Blood gas analyzer and reagents*** of ***Guangzhou Wondfo Biotech Co., Ltd.***, 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 ***Blood gas analyzer and reagents***, 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 31.12.2023.

Guangzhou Wondfo Biotech Co., Ltd.

Zhang Yue
Regional Manager

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

"ECHIPAMED-PLUS" SOCIETATEA CU RASPUNDERE LIMITATA IDNO 1003600077677 REPUBLICA MOLDOVA MUN. CHISINAU

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. 03

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

Certification Mark:

Scope of Certificate: **Design and Development, Production, Distribution, Installation and Service of In Vitro Diagnostics for the Detection of Fertility, Pregnancy, Infectious Diseases, Drugs of Abuse, Tumor Markers, Cardiac Markers, Diabetes Markers, Renal Injury Markers, Autoimmune Diseases, Infection, Inflammation, Coagulation Factors, Blood Gas Markers and Related Instruments, Sperm Concentration Tests, Fluorescence Immunoassay Systems, Blood Glucose Monitoring Systems, Control Materials for Tumor Markers, Biochemical Reagents and Instruments**

The Certification Body of TÜV SÜD Product Service GmbH certif
ies 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. 03

Report No.:	SH2114101
Valid from:	2022-03-18
Valid until:	2024-01-31

Date, 2022-03-18

Christoph Dicks
Head of Certification/Notified Body

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

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
Model No.:	BGA-102
REF:	W966
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, RoHS Directive 2011/65/EU and (EU) 2015/863, Radio Equipment Directive (2014/53/EU).

The following (harmonized) standards have been applied:

EN ISO 13485: 2016	EN ISO 14971: 2019	EN 13612: 2002
EN ISO 15223-1: 2016	EN ISO 18113-1: 2011	EN ISO 18113-3: 2011
EN 62304: 2006	EN 62366-1: 2015	EN 61010-1: 2010
EN 61010-1: 2010+A1: 2019	EN 61010-2-101: 2002	EN 61010-2-101: 2017
EN IEC 61010-2-010: 2020	EN 61326-1: 2013	EN 61326-2-6: 2006
EN 61326-2-6: 2013	EN 300 328 V2.2.2	EN 301 489-1 V2.2.3
EN 301 489-17 V3.2.4	EN IEC 62311: 2020	EN 62479: 2010
EN 62133-2: 2017	EN 50665: 2017	EN 50663: 2017

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: 2021-10-10