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

Product Service

CERTIFICATE

No. Q5 17 11 58008 022

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

Facility(ies): GUANGZHOU WONDFO BIOTECH CO., LTD.
No. 8 Lizhishan Road, Science City, Luogang District, 510663 Guangzhou, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate: Design and Development, Production and Distribution of In Vitro Diagnostics for the Detection of Fertility, Pregnancy, Infectious Diseases, Drugs of Abuse, Tumor Markers, Cardiac Markers, Diabetes Makers, Renal Injury Markers, Autoimmune Diseases, Infection and Inflammation Markers and related instruments, Sperm Concentration Test, Fluorescence Immunoassay System, Blood Glucose Monitoring System Control materials for tumor makers, ECG Event Recorder

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
DIN EN ISO 13485:2016

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). See also notes overleaf.

Report No.: SH1714115
Valid from: 2018-02-01
Valid until: 2021-01-31

Date, 2018-01-15
Page 1 of 1

Stefan Preiß

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REPUBLICA MOLDOVA MUN. CHIȘINĂU PENTRU FACTURI S.R.L. "PROFILABDIAGNOSTIC" IDNO 1009600045502 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

Digitally signed by Varman Irina
Date: 2019.12.24 10:29:24 EET
Reason: MoldSign Signature
Location: Moldova

DAkkS CRT2 / A4 07.17 ZM

qarad
European Regulatory Services

DECLARATION

The undersigned, Mrs. Joke Doutreloigne, Consultant at Qarad b.v.b.a.,

hereby declares that Guangzhou Wondfo Biotech Co. Ltd. has signed the EC Declaration of Conformity in agreement with the Annex III of the European Directive 98/79/EC on In Vitro Diagnostic Medical Devices and has submitted the required technical documentation, for the following IVD products:

IVD name	Catalogue nr.
Finecare™ FIA Meter Plus Handheld Colloidal Gold Test Analyzer	FS-113 IP-101

The notification to the Belgian Competent Authorities has been carried out on June 21th, 2016 by Qarad b.v.b.a., the appointed Authorized Representative of Guangzhou Wondfo Biotech Co. Ltd.

Information on the notification to the competent Authorities of other European countries is available upon request.

Joke Doutreloigne.

Qarad b.v.b.a.
Authorized Representative

REPUBLICA MOLDOVA mun.CHIŞINĂU PENTRU FACTURI S.R.L. "PROFILABDIAGNOSTIC" IDNO 1009600045502 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

qarad
European Regulatory Services

DECLARATION

The undersigned, Mr. Dirk Stynen, President at Qarad b.v.b.a.,

hereby declares that Guangzhou Wondfo Biotech Co. Ltd. has signed the EC Declaration of Conformity in agreement with the Annex III of the European Directive 98/79/EC on In Vitro Diagnostic Medical Devices and has submitted the required technical documentation, for the following IVD products (for professional use only):

Finecare™ microalbumin Rapid Test	cat. nr. W206
Finecare™ HbA1c Rapid Test	cat. nr. W207

The notification to the Belgian Competent Authorities has been carried out on July the 14th, 2014 by Qarad b.v.b.a., the appointed Authorized Representative of Guangzhou Wondfo Biotech Co. Ltd.

Information on the notification to the competent Authorities of other European countries is available upon request.

Dirk Stynen, Ph.D.

President at Qarad b.v.b.a.
Authorized Representative

REPUBLICA MOLDOVA mun. CHIŞINĂU
PENTRU FACTURI
S.R.L.
"PROFILABDIAGNOSTIC"
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BTW/VAT nr. BE 0471.972.009 | IBAN BE72 7765 9763 8016 | BIC GKCCBEBB | RPR Turnhout

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DECLARATION

The undersigned, Mrs. Joke Doutreloigne, Consultant at Qarad b.v.b.a.,

hereby declares that Guangzhou Wondfo Biotech Co. Ltd. has signed the EC Declaration of Conformity in agreement with the Annex III of the European Directive 98/79/EC on In Vitro Diagnostic Medical Devices and has submitted the required technical documentation, for the following IVD products:

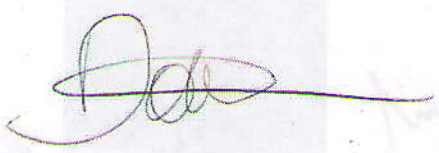
IVD name	Catalogue nr.
Finecare™ Carcino-embryonic Antigen Control	W820-L, W820-M, W820-H
Diagnostic Kit for IgM Antibody to Human Enterovirus71 (Immunochromatographic Assay)	W141-C, W141-S
Finecare™ Carcino-embryonic Antigen Quantitative Rapid Test (Lateral Flow Immunoassay)	W226
Finecare™ cTnI and NT-proBNP Quantitative Rapid Test (Lateral Flow Immunoassay)	W223
Finecare™ cTnI/NT-proBNP Multi-Control	W821-L, W821-M, W821-H

The notification to the Belgian Competent Authorities has been carried out on March 25th, 2016 by Qarad b.v.b.a., the appointed Authorized Representative of Guangzhou Wondfo Biotech Co. Ltd.

Information on the notification to the competent Authorities of other European countries is available upon request.

Joke Doutreloigne.

Qarad b.v.b.a.
Authorized Representative



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European Regulatory Services

DECLARATION

The undersigned, Mrs. Agnes Goris, Consultant at Qarad b.v.b.a.,

hereby declares that Guangzhou Wondfo Biotech Co. Ltd. has signed the EC Declaration of Conformity in agreement with the Annex III of the European Directive 98/79/EC on In Vitro Diagnostic Medical Devices and has submitted the required technical documentation, for the following IVD products (for professional use only):

Finecare™ cTnI/CK-MB/Myo Rapid Test	cat. nr. W216
Finecare™ D-Dimer Rapid Test	cat. nr. W211
Finecare™ H-FABP Rapid Test	cat. nr. W217

The notification to the Belgian Competent Authorities has been carried out on July the 28th, 2014 by Qarad b.v.b.a., the appointed Authorized Representative of Guangzhou Wondfo Biotech Co. Ltd.

Information on the notification to the competent Authorities of other European countries is available upon request.

Agnes Goris.

Qarad b.v.b.a.
Authorized Representative

REPUBLICA MOLDOVA mun. CHISINAU
PENTRU FACTURI
S.R.L.
"PROFILABDIAGNOSTIC"

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European Regulatory Services

DECLARATION

The undersigned, Mrs. Agnes Goris, Consultant at Qarad b.v.b.a.,

hereby declares that Guangzhou Wondfo Biotech Co. Ltd. has signed the EC Declaration of Conformity in agreement with the Annex IV of the European Directive 98/79/EC on In Vitro Diagnostic Medical Devices and has submitted the required technical documentation, for the following IVD products:

Finecare™ CRP PCT Rapid Test	W218
Finecare™ Cystatin C Rapid Test	W219
Finecare™ βhCG Rapid Test	W225
Finecare™ CRP Control	W806-L, W806-M, W806-H
Finecare™ Cystatin C Control	W816-L, W816-M, W816-H
Finecare™ Alpha-Fetoprotein Control	W815-L, W815-M, W815-H

The notification to the Belgian Competent Authorities has been carried out on March 2nd, 2015 by Qarad b.v.b.a., the appointed Authorized Representative of Guangzhou Wondfo Biotech Co. Ltd.

Information on the notification to the competent Authorities of other European countries is available upon request.

Agnes Goris.

Qarad b.v.b.a.
Authorized Representative

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S.R.L.
"PROFILABDIAGNOSTIC"

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European Regulatory Services

DECLARATION

The undersigned, Dr. Dirk Stynen, President of Qarad b.v.b.a.,
hereby declares that Guangzhou Wondfo Biotech Co. Ltd. has signed the EC Declaration of Conformity in agreement with the Annex III of the European Directive 98/79/EC on In Vitro Diagnostic Medical Devices and has submitted the required technical documentation, for the following IVD products (for professional use only):

Finecare™ FIA Meter	cat. nr. FS-131
Finecare™ hsCRP Rapid Test	cat. nr. W201
Finecare™ NT-proBNP Rapid Test	cat. nr. W202
Finecare™ Troponin I Rapid Test	cat. nr. W203
Finecare™ Myoglobin Rapid Test	cat. nr. W204
Finecare™ CK-MB Rapid Test	cat. nr. W205
Finecare™ PCT Rapid Test	cat. nr. W210

The notification to the Belgian Competent Authorities has been carried out on May the 17th, 2013 by Qarad b.v.b.a., the appointed Authorized Representative of Guangzhou Wondfo Biotech Co. Ltd.

Information on the notification to the competent Authorities of other European countries is available upon request.

Dirk Stynen, Ph. D.
President Qarad b.v.b.a.
Authorized Representative

REPUBLICA MOLDOVA mun. CHISINAU PENTRU FACTURI S.R.L. "PROFILABDIAGNOSTIC" SOCIETATEA CU RASPUNDERE LIMITATA

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