qarad
European Regulatory Services

DECLARATION

Digitally signed by Varman Irina
Date: 2023.02.16 19:59:59 EET
Reason: MoldSign Signature
Location: Moldova

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.

REPUBLICA MOLDOVA S.R.L. PROFILABDIAGNOSTIC IDNO 1009600045502 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Joke Doutreloigne.

Qarad b.v.b.a.
Authorized Representative

qarad
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. CHIȘINĂU PENTRU FACTURI S.R.L. "PROFILABDIAGNOSTIC" SOCIETATE 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 S.R.L. PROFILABDIAGNOSTIC SOCIETATEA CU RĂSPUNDERE LIMITATĂ IDNO 1009600045502

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

Qarad b.v.b.a. | Cipalstraat 3, B-2440 Geel, Belgium | Tel. +32 (0)14 57 05 44 | Fax +32 (0)14 58 23 87 | qarad@qarad.com | www.qarad.com
BTW/VAT nr. BE 0471.972.009 | IBAN BE72 7765 9763 8016 | BIC GKCCBEBB | RPR Turnhout

qarad
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™ Alpha-fetoprotein Rapid Test	W208
	Finecare™ PCT Control	W805-L, W805-N, W805-H
	Finecare™ NT-proBNP Control	W807-L, W807-N, W807-H
	Finecare™ troponin I Control	W808-L, W808-N, W808-H
	Finecare™ Myoglobin Control	W809-L, W809-N, W809-H
	Finecare™ CK-MB Control	W810-L, W810-N, W810-H

The notification to the Belgian Competent Authorities has been carried out on September 18th, 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 S.R.L. PRO-LABDIAGNOSTIC IDNO 1009600045602 SOCIETATEA CU RASPUNDIERE LIMITATA

qarad
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. CHIŞINĂU PENTRU FACTURI S.R.L. "PROFILABDIAGNOSTIC" IDNO 1008600004502 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

qarad
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
V	Finecare™ Cystatin C Rapid Test	W219
V	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

REPUBLICA MOLDOVA S.R.L. PRO-LABDIAGNOSTIC IDNO 1009600045502 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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™ 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

REPUBLICA MOLDOVA S.R.L. PRO-LABDIAGNOSTIC SOCIETATEA CU RĂSPUNDERE LIMITATĂ 1009600045502

qarad
European Regulatory Services

DECLARATION

The undersigned, Mrs. Eline Heylen, 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™ BNP (B-type natriuretic) Rapid Quantitative Test	W222
Finecare™ SAA (Serum Amyloid A Protein) Rapid Quantitative Test	W221
Finecare™ T4 (Thyroxine) Rapid Quantitative Test	W232
Finecare™ TSH (Thyroid - stimulating hormone) Rapid Quantitative Test	W220
Finecare™ β 2-MG (Beta-2-microglobulin) Rapid Quantitative Test	W229
Finecare™ NGAL (Neutrophil gelastinase-associated lipocalin) Rapid Quantitative Test	W228

The notification to the Belgian Competent Authorities has been carried out on June 17th, 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.

Eline Heylen

Qarad b.v.b.a.
Authorized Representative

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™ T3 (Triidothyronine) Rapid Quantitative Test	W231
Finecare™ Progesterone Rapid Quantitative Test	W233
Wondfo One Step Multi-drug Urine Test Panel for Analyzer	W501-P to W510-P, Panel
One Step Barbiturates Urine Test (BAR200)	W008-S (200ng/ml), Strip W008-C (200ng/ml), Cassette W008-P (200ng/ml), Panel
One Step Benzodiazepines Urine Test (BZO100)	W009-S (100ng/ml), Strip W009-C (100ng/ml), Cassette W009-P (100ng/ml), Panel
One Step Marijuana Urine Test (THC25)	W019-S (25ng/ml), Strip W019-C (25ng/ml), Cassette W019-P (25ng/ml), Panel
Multi-drug Tests	W2002-P to W2016-P, Panel W2002-CU to W2012-CU, Cup W502-CU2 to W518-CU2, T-Cup W502-CU3 to W518-CU3, Q-Cup

The notification to the Belgian Competent Authorities has been carried out on September 22, 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 S.R.L. PROFI-LABDIAGNOSTIC IDNO 1009600045602 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

qarad
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™ H-FABP Control	W811-L, W811-N, W811-H
Finecare™ D-Dimer Control	W812-L, W812-N, W812-H
Finecare™ Microalbumin Control	W813-L, W813-N, W813-H

The notification to the Belgian Competent Authorities has been carried out on October 6th, 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. CHIȘINĂU 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

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:

- Diagnostic Kit for Rotavirus Antigen (Colloidal Gold): W112-S & W112-C

- Diagnostic Kit for Adenovirus Antigen (Immunochromatographic Assay): W133-S & W133-C

- Combined Diagnostic Kit for Adenovirus Antigen and Rotavirus Antigen

(Immunochromatographic Assay): W134

- Diagnostic Kit for IgM Antibody to Hepatitis A Virus (Colloidal Gold): W071-S & W071-C

- Diagnostic Kit for IgM Antibody to Hepatitis E Virus (Colloidal Gold): W072-S & W072-C

- Diagnostic Kit for Human IgM Antibody of Mycoplasma Pneumoniae (Immunochromatographic Assay): W113-S & W113-C

- Combined Diagnostic Kit for Dengue NS1 Antigen and IgG/IgM Antibody (Colloidal Gold): W111

- Finecare™ cTnI/CK-MB/Myo Multi-Control: W817

The notification to the Belgian Competent Authorities has been carried out on August 27th, 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.

Joke Doutreloigne.

Qarad b.v.b.a.
Authorized Representative

Wondfo

EC DECLARATION OF CONFORMITY

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

Document No.: DOC-W246(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:	Finecare™ Prolactin Rapid Quantitative Test
Cat. No.:	W246P0001
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 and Regulation (EC) No 1272/2008.

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 17511:2003		

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): Bin Yang, Senior Vice President of Regulatory Affairs

Place and date of issue: Guangzhou, P.R. China,

April 20, 2022

Wondfo

EC DECLARATION OF CONFORMITY

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

No.: DOC-W202(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:	Finecare™ NT-proBNP Rapid Quantitative Test
Cat. No.:	W202
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 and Regulation (EC) No 1272/2008.

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 17511:2003		

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): Senior President of Regulatory Affairs

Place and date of issue: Guangzhou, P.R. China,
March 11, 2022

Wondfo

EC DECLARATION OF CONFORMITY

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

No.: DOC-W203(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:	Finecare™ cTn I Rapid Quantitative Test
Cat. No.:	W203
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 and Regulation (EC) No 1272/2008.

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 17511:2003		

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):	Senior President of Regulatory Affairs
Place and date of issue:	Guangzhou, P.R. China, March 11, 2022

Wondfo

EC DECLARATION OF CONFORMITY

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

No.: DOC-W205(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:	Finecare™ CK-MB Rapid Quantitative Test
Cat. No.:	W205
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 and Regulation (EC) No 1272/2008.

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 17511:2003		

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): Senior President of Regulatory Affairs

Place and date of issue: Guangzhou, P.R. China,
March 11, 2022

Wondfo

EC DECLARATION OF CONFORMITY

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

No.: DOC-W206(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:	Finecare™ One Step MAU Rapid Quantitative Test
Cat. No.:	W206
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 17511:2003		

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): Senior President of Regulatory Affairs

Place and date of issue: Guangzhou, P.R. China,

March 11, 2022

Wondfo

EC DECLARATION OF CONFORMITY

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

No.: DOC-W207(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:	Finecare™ HbA1c Rapid Quantitative Test
Cat. No.:	W207
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 and Regulation (EC) No 1272/2008.

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 17511:2003		

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): Senior President of Regulatory Affairs

Place and date of issue: Guangzhou, P.R. China,

March 11, 2022

Wondfo

EC DECLARATION OF CONFORMITY

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

Document No.: DOC-W209(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:	Finecare™ PSA Rapid Quantitative Test
Cat. No.:	W209
IVDD Classification:	List B of Annex II, 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 and Regulation (EC) No 1272/2008.

The following (harmonized) standards have been applied:

EN ISO 13485:2016	EN ISO 18113-1:2011	EN 13612:2002
EN ISO 14971:2012	EN ISO 18113-2:2011	EN 13641:2002
EN ISO 23640:2015	EN ISO 15223-1:2016	EN 62366-1:2015
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 IV, excluding 4 and 6**

Notified Body (if consulted):	**TÜV SÜD Product Service GmbH (NB # 0123)**
Address:	Ridlerstraße 65, D-80339 München
EC Certificate(s):	V1 058008 0030 Rev.01
Expiry date of the Certificate(s):	2025-05-26

Signature of manufacturer

(Name and function): Bin Yang, Senior Vice President of Regulatory Affairs

Place and date of issue: Guangzhou, P.R. China,

April 20, 2022

Wondfo

EC DECLARATION OF CONFORMITY

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

Document No.: DOC-W210(2)-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:	Finecare™ PCT Rapid Quantitative Test
Cat. No.:	W210P0004
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 and Regulation (EC) No 1272/2008.

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 17511:2003		

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): Bin Yang, Senior Vice President of Regulatory Affairs

Place and date of issue: Guangzhou, P.R. China,

April 20, 2022

Wondfo

EC DECLARATION OF CONFORMITY

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

No.: DOC-W211(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:	Finecare™ D-Dimer Rapid Quantitative Test
Cat. No.:	W211
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 and Regulation (EC) No 1272/2008.

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 17511:2003		

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): Senior President of Regulatory Affairs

Place and date of issue: Guangzhou, P.R. China,
March 11, 2022

Wondfo

EC DECLARATION OF CONFORMITY

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

No.: DOC-W216(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:	Finecare™ cTnI/CK-MB/Myo Rapid Quantitative Test
Cat. No.:	W216
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 and Regulation (EC) No 1272/2008.

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 17511:2003		

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): Senior President of Regulatory Affairs

Place and date of issue: Guangzhou, P.R. China,

March 11, 2022

Wondfo

EC DECLARATION OF CONFORMITY

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

No.: DOC-W220(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:	Finecare™ TSH Rapid Quantitative Test
Cat. No.:	W220
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 and Regulation (EC) No 1272/2008.

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 17511:2003		

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): Senior President of Regulatory Affairs

Place and date of issue: Guangzhou, P.R. China,
March 11, 2022

Wondfo

EC DECLARATION OF CONFORMITY

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

No.: DOC-W223(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:	Finecare™ cTn I/NT-proBNP Rapid Quantitative Test
Cat. No.:	W223
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 and Regulation (EC) No 1272/2008.

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 17511:2003		

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):	Senior President of Regulatory Affairs
Place and date of issue:	Guangzhou, P.R. China, March 11, 2022

Wondfo

EC DECLARATION OF CONFORMITY

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

No.: DOC-W224(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:	Finecare™ One Step PCT Rapid Quantitative Test
Cat. No.:	W224
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 17511:2003		

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): Bin Yang, Senior Vice President of Regulatory Affairs

Place and date of issue: Guangzhou, P.R. China,

April 20, 2022

Wondfo

EC DECLARATION OF CONFORMITY

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

No.: DOC-W227(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:	Finecare™ One Step D-Dimer Rapid Quantitative Test
Cat. No.:	W227
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 17511:2003		

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): Bin Yang, Senior Vice President of Regulatory Affairs

Place and date of issue: Guangzhou, P.R. China,

April 20, 2022

Wondfo

EC DECLARATION OF CONFORMITY

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

No.: DOC-W231(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:	Finecare™ T3 Rapid Quantitative Test
Cat. No.:	W231
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 and Regulation (EC) No 1272/2008.

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 17511:2003		

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): Senior President of Regulatory Affairs

Place and date of issue: Guangzhou, P.R. China,

March 11, 2022

Wondfo

EC DECLARATION OF CONFORMITY

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

No.: DOC-W232(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: Finecare™ T4 Rapid Quantitative Test
Cat. No.: W232
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 and Regulation (EC) No 1272/2008.

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 17511:2003		

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): Senior President of Regulatory Affairs

Place and date of issue: Guangzhou, P.R. China,
March 11, 2022

Wondfo

EC DECLARATION OF CONFORMITY

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

Document No.: DOC-W240(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:	Finecare™ hsCRP Rapid Quantitative Test
Cat. No.:	W240
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 and Regulation (EC) No 1272/2008.

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 17511:2003		

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): Bin Yang, Senior Vice President of Regulatory Affairs

Place and date of issue: Guangzhou, P.R. China,

April 20, 2022

Wondfo

EC DECLARATION OF CONFORMITY

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

Document No.: DOC-W241(2)-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:	Finecare™ Vitamin D Rapid Quantitative Test
Cat. No.:	W241P0002, W241P0003
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 and Regulation (EC) No 1272/2008.

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 17511:2003		

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): Bin Yang, Senior Vice President of Regulatory Affairs

Place and date of issue: Guangzhou, P.R. China,

April 20, 2022

Wondfo

EC DECLARATION OF CONFORMITY

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

Document No.: DOC-W248(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:	Finecare™ Testosterone Rapid Quantitative Test
Cat. No.:	W248-C4P1-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 and Regulation (EC) No 1272/2008.

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 17511:2003		

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): Bin Yang, Senior Vice President of Regulatory Affairs

Place and date of issue: Guangzhou, P.R. China,

April 20, 2022

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

Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6) (List A and B and devices for self-testing)

No. V1 18 01 58008 024

Manufacturer:

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

EC-Representative:

Qarad b.v.b.a
Cipalstraat 3
B-2440 GEEL
BELGIUM

Product Category(ies):

Products for determination of tumor markers (PSA)
Chlamydia, Blood Glucose and self testing products

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

Report No.: SH18141EXT01

Valid from: 2018-04-09
Valid until: 2023-04-08

Date, 2018-02-01

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

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

Product Service

EC Certificate
Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 18 01 58008 024

Model(s):

One Step Prostate Specific Antigen (PSA) Serum/Plasma Test,
One Step Prostate Specific Antigen (PSA) Whole Blood/Serum/Plasma Test,
One Step FSH Urine Test,
Blood Glucose Monitoring System for Self Testing,
One Step Strep A Swab Test,
One Step Chlamydia Swab Test,
One Step Influenza A Test,
One Step Influenza B Test,
One Step Influenza A&B Test,
Digital Pregnancy Test,
PSA Rapid Quantitative Test,
Sperm Concentration Test,
One Step Fecal Occult Blood (FOB) Test
Prostate Specific Antigen Control,
Diagnostic kit for Human IgM Antibody of Chlamydia Pneumoniae(Immunochromatographic Assay),
Digital OvulationTest,
FPSA (Free Prostate Specific Antigen) Quantitative Rapid Test,
Digital Pregnancy Test with Conception Indicator

Facility(ies):

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

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

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