

Zhongjian Certification Co., Ltd.
**CERTIFICATE OF CONFORMITY OF QUALITY
MANAGEMENT SYSTEM CERTIFICATION**

No:0070023Q54381R7L

This is to certify that the quality system of
GUANGZHOU WONDFO BIOTECH CO., LTD

REGISTER/OFFICE ADDRESS: NO.8, LIZHISHAN ROAD, SCIENCE CITY, HUANGPU DISTRICT,
GUANGZHOU CITY, GUANGDONG PROVINCE
SITE ADDRESS 1: NO.8, LIZHISHAN ROAD, SCIENCE CITY, HUANGPU DISTRICT, GUANGZHOU CITY, GUANGDONG PROVINCE
ADDRESS 2: NO.501, 5F, BUILDING 1, NO.8, LIANHUAYAN ROAD, HUANGPU DISTRICT, GUANGZHOU CITY, GUANGDONG PROVINCE
SITE ADDRESS 3: NO.268, SHENZHOU ROAD, HUANGPU DISTRICT, GUANGZHOU CITY, GUANGDONG PROVINCE

Organization Code: 91440101618640472W

is in conformity with

GB/T 19001-2016/ISO9001:2015 Standard

This system is valid for the

DESIGN, DEVELOPMENT AND PRODUCTION OF I, II, III KIND OF 6840 IN
VITRO DIAGNOSTIC REAGENT, DESIGN, DEVELOPMENT AND PRODUCTION OF
I KIND OF 22-14 TRAINING AND INCUBATION EQUIPMENT, II, III KIND OF
6840 CLINICAL LABORATORY ANALYTICAL INSTRUMENTS

(This certificate only covers the sites listed. If the covered scope involves pre-approval of administration permit or compulsory certification requirement, the scope only covers products and services within the permit license or compulsory certification scope.)

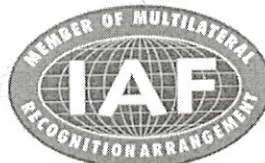
Date of issue: 2023-11-20

Term of validity of this certificate: from 2023-11-20 to 2026-11-19 inclusive

This certificate remains valid only if the certified organization accepts and passes regular surveillance audits.



Representative of The Company



中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C007-M

The validity of this certificate could be confirmed via official Website Of CNCA (www.cnca.gov.cn)
Further to the certificate applicability, please enquire the certified organization: visit www.gzcc.org.cn or contact GZCC 020-66390902
4/F, Huajing Building, Guangzhou Dadaozhong, Guangzhou City, Guangdong Province, China (510600) Zhongjian Certification Co., Ltd.





Product Service

Certificate

No. Q5 058008 0025 Rev. 05

Holder of Certificate: **GUANGZHOU WONFO BIOTECH CO., LTD.**

No. 8 Lizhishan Road, Science City
Huangpu District
510663 Guangzhou
PEOPLE'S REPUBLIC OF CHINA

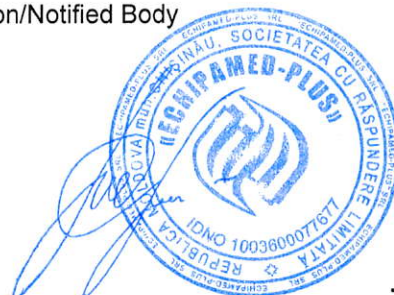
Certification Mark:**Scope of Certificate:** **Design and Development, Production and Distribution of In Vitro Diagnostics Reagents and Control Materials for Clinical Chemistry, Immunology, Haemostasis and Infectious Diseases.****Design and Development, Production, Distribution, Installation and servicing 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



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.

DECLARATION OF NOTIFICATION

Date: March 5, 2024

The undersigned, Teresa Batet i Solà, Authorized Representative Expert of Qarad EC-REP BV, hereby declares that:

Guangzhou Wondfo Biotech Co. Ltd.
No. 8 Lizhishan Road, Science City Huangpu District, 510663 Guangzhou,
PR China

has signed the EC Declaration of Conformity in agreement with the Annex III or 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 (for professional use or self-testing):

see attached list

The notification of the manufacturer address change to the Belgian Competent Authorities has been carried out on February 27 2024 by Qarad EC-REP BV, the appointed Authorized Representative of Guangzhou Wondfo Biotech Co. Ltd.

BATET SOLA
MARIA TERESA -
90001246S

Firmado digitalmente por BATET
SOLA MARIA TERESA -
90001246S
Fecha: 2024.03.05 09:07:44
+01'00'

Teresa Batet i Sola
Authorized Representative Expert
Qarad EC-REP BV
Authorized Representative

Annex IV

List of Devices covered by the Authorized Representative agreement of Guangzhou Wondfo Biotech Co. Ltd.

This document is an attachment to the Agreement for Services as Authorized Representative between Guangzhou Wondfo Biotech Co. Ltd. and Qarad BV.

The table below lists all Devices covered by the Agreement under the current IVD Directive 98/79/EC. This list is valid from the date of signature by both Parties.

1. For IVD products

a. Self-declared IVD products

No.	Name Device	Catalogue number Device
1	One Step Alcohol Saliva Test	W53-S
2	One Step Alcohol Urine Test	W59-S, W59-C
3	Alpha-Thalassemia(--SEA) Zeta Globin Chain Test	W114-S, W114-C
4	One Step Troponin I Whole Blood / Serum / Plasma Test	W46-C4P, W046P0011
5	One Step Dengue IgG/IgM Whole Blood/Serum/Plasma Test	W109-C, W109P0010
6	One Step Dengue NS1 Antigen Whole Blood/Serum/Plasma Test	W041-C, W041P0007
7	Diagnostic Kit for Adenovirus Antigen (Immunochromatographic Assay)	W133-C, W133P0003
8	Combined Diagnostic Kit for Dengue NS1 Antigen and IgG/IgM Antibody (Colloidal Gold)	W111-C, W111P0005
9	Diagnostic Kit for IgM Antibody to Hepatitis A Virus (Colloidal Gold)	W071-C, W071P0005
10	Diagnostic Kit for IgM Antibody to Hepatitis E Virus	W072-C, W072P0003
11	Diagnostic Kit for IgM Antibody to Human Enterovirus71 (Immunochromatographic Assay)	W141-C, W141P0002
12	Diagnostic Kit for Human IgM Antibody of Mycoplasma Pneumoniae (Immunochromatographic Assay)	W113-C, W113P0003
13	Combined Diagnostic Kit for Adenovirus Antigen and Rotavirus Antigen (Immunochromatographic Assay)	W134
14	Diagnostic Kit for Rotavirus Antigen (Colloidal Gold)	W112-C, W112P0004
15	One Step Cotinine (COT) Urine Test	W139-S, W139-C, W139-P
16	One Step Amphetamine Urine Test	W7-S, W7-C
17	One Step Amphetamine Urine Test (AMP500)	W007-C1G5001(25T), W007-C1G5001(40T), W007-P1G5001(25T), W007-P1G5001(40T), W007-S1G5001(100T), W007-S1G5001(50T)
18	One Step Barbiturates Urine Test	W8-S, W8-C

19	One Step Barbiturates Urine Test (BAR200)	W008-S (200ng/ml), W008-C (200ng/ml), W008-P (200ng/ml)
20	One Step Benzodiazepine Urine Test	W9-S, W9-C
21	One Step Benzodiazepines Urine Test (BZO100)	W009-S (100ng/ml), W009-C (100ng/ml), W009-P (100ng/ml)
22	One Step Buprenorphine Urine Test	W13-S, W13-C
23	One Step Cocaine Urine Test	W10-S, W10-C
24	One Step Cocaine Urine Test (COC150)	W010-C1G1501(25T), W010-C1G1501(40T), W010-P1G1501(25T), W010-P1G1501(40T), W010-S1G1501(100T), W010-S1G1501(50T)
25	One Step EDDP Urine Test	W074-S, W074-C, W074-P
26	One Step Ethyl Glucuronide (EtG) Urine Test	W140-S, W140-C, W140-P
27	One Step Fentanyl Urine Test	W087-C1G1(25T), W087-C1G1(40T), W087-P1G1(25T), W087-P1G1(40T), W087-S1G1(50T), W087-S1G1(100T)
28	One Step Ketamine Urine Test	W55-S, W55-C
29	One Step Marijuana Urine Test	W19-S, W19-C
30	One Step Marijuana Urine Test (THC25)	W019-S (25ng/ml), W019-C (25ng/ml), W019-P (25ng/ml)
31	One Step Metamphetamine Urine Test	W11-S, W11-C
32	One Step Methadone Urine Test	W15-S, W15-C
33	One Step Methamphetamine Urine Test (MET500)	W011-C1G5001(25T), W011-C1G5001(40T), W011-P1G5001(25T), W011-P1G5001(40T), W011-S1G5001(100T), W011-S1G5001(50T)
34	One Step Methylenedioxymetamphetamine Urine Test	W12-S, W12-C
35	One Step Morphine Urine Test	W14-S, W14-C
36	One Step Multi-Drug Urine Q-Cup	W502-CU3, W503-CU3, W504-CU3, W505-CU3, W506-CU3, W507-CU3, W508-CU3, W509-CU3, W510-CU3, W511-CU3, W512-CU3, W513-CU3, W514-CU3, W515-CU3, W516-CU3, W517-CU3, W518-CU3

37	One Step Multi-Drug Urine T-Cup	W502-CU2, W503-CU2, W504-CU2, W505-CU2, W506-CU2, W507-CU2, W508-CU2, W509-CU2, W510-CU2, W511-CU2, W512-CU2, W513-CU2, W514-CU2, W515-CU2, W516-CU2, W517-CU2, W518-CU2
38	One Step Multi-Drug Urine Test (+Adulteration+Alcohol) Panel	W55102-P, W55103-P, W55104-P, W55105-P, W55106-P, W55107-P, W55108-P, W55109-P, W55110-P, W55111-P, W55112-P
39	One Step Multi-Drug Urine Test (+Adulteration+Alcohol) Q-cup	W55102-CU3, W55103-CU3, W55104-CU3, W55105-CU3, W55106-CU3, W55107-CU3, W55108-CU3, W55109-CU3, W55110-CU3, W55111-CU3, W55112-CU3, W55113-CU3, W55114-CU3, W55115-CU3, W55116-CU3, W55117-CU3, W55118-CU3
40	One Step Multi-Drug Urine Test (+Adulteration+Alcohol) T-cup	W55102-CU2, W55103-CU2, W55104-CU2, W55105-CU2, W55106-CU2, W55107-CU2, W55108-CU2, W55109-CU2, W55110-CU2, W55111-CU2, W55112-CU2, W55113-CU2, W55114-CU2, W55115-CU2, W55116-CU2, W55117-CU2, W55118-CU2
41	One Step Multi-Drug Urine Test Panel	W2002-P, W2003-P, W2004-P, W2005-P, W2006-P, W2007-P, W2008-P, W2009-P, W2010-P, W2011-P, W2012-P, W2013-P, W2014-P, W2015-P, W2016-P
42	One Step Opiate Urine Test	W16-S, W16-C
43	One Step Oxycodone Urine Test	W21-S, W21-C
44	One Step Phencyclidine Urine Test	W17-S, W17-C
45	One Step Propoxyphene Urine Test	W57-S, W57-C
46	One Step Synthetic Cannabis (K2) Urine Test	W089-S, W089-C, W089-P
47	One Step Tramadol Urine Test	W086-S, W086-C, W086-P
48	One Step Tricyclic Antidepressant Urine Test	W18-S, W18-C
49	Finecare™ FIA Meter	FS-112
50	Finecare™ FIA Meter III Plus	FS-205
51	Finecare™ Multi-channel FIA Meter	FS-201
52	Finecare™ AFP Rapid Quantitative Test	W208
53	Finecare™ AFP Control	W815

54	Finecare™ BNP Rapid Quantitative Test	W222
55	Finecare™ CEA Control	W820
56	Finecare™ CEA Rapid Quantitative Test	W226
57	Finecare™ CK-MB Control	W810
58	Finecare™ CK-MB Rapid Quantitative Test	W205
59	Finecare™ CRP Control	W806
60	Finecare™ CRP/PCT Rapid Quantitative Test	W218
61	Finecare™ cTn I/NT-proBNP Rapid Quantitative Test	W223
62	Finecare™ cTnI/CK-MB/Myo Multi-Control	W817
63	Finecare™ cTnI/CK-MB/Myo Rapid Quantitative Test	W216
64	Finecare™ Cys C Rapid Quantitative Test	W219
65	Finecare™ D-Dimer Control	W812
66	Finecare™ D-Dimer Rapid Quantitative Test	W211
67	Finecare™ FSH Rapid Quantitative Test	W245
68	Finecare™ HbA1c Rapid Quantitative Test	W207
69	Finecare™ H-FABP Rapid Quantitative Test	W217
70	Finecare™ CRP Rapid Quantitative Test	W201, W201P0008
71	Finecare™ LH Rapid Quantitative Test	W244
72	Finecare™ MAU Control	W813
73	Finecare™ One Step MAU Rapid Quantitative Test	W206
74	Finecare™ Myo Control	W809
75	Finecare™ Myo Rapid Quantitative Test	W204
76	Finecare™ NGAL Rapid Quantitative Test	W228
77	Finecare™ NT-proBNP Control	W807
78	Finecare™ NT-proBNP Rapid Quantitative Test	W202
79	Finecare™ One Step CK-MB Rapid Quantitative Test	W236
80	Finecare™ One Step cTn I Rapid Quantitative Test	W237
81	Finecare™ One Step cTn I/CK-MB/Myo Rapid Quantitative Test	W238
82	Finecare™ One Step Myo Rapid Quantitative Test	W235
83	Finecare™ One Step NT-proBNP Rapid Quantitative Test	W234
84	Finecare™ PCT Control	W805
85	Finecare™ PCT Rapid Test	W210
86	Finecare™ Progesterone Rapid Quantitative Test	W233
87	Finecare™ SAA Rapid Quantitative Test	W221, W221P0004
88	Finecare™ T3 Rapid Quantitative Test	W231
89	Finecare™ T4 Rapid Quantitative Test	W232
90	Finecare™ cTnI Control	W808
91	Finecare™ cTn I Rapid Quantitative Test	W203
92	Finecare™ TSH Rapid Quantitative Test	W220
93	Finecare™ β-hCG Rapid Quantitative Test	W225
94	Finecare™ β2-MG Rapid Quantitative Test	W229
95	Finecare™ β-hCG control	W819
96	Finecare™ One Step D-Dimer Rapid Quantitative Test	W227
97	Finecare™ One Step PCT Rapid Quantitative Test	W224

98	One Step Fecal Occult Blood (FOB) Test	W30-S, W30-C, W030P0031 W030P0032
99	Handheld Colloidal Gold Test Analyzer	IP-101
100	Invitech One Step hCG Urine Pregnancy Test	INV-FHC-101, INV-FHC-102
101	Invitech One Step hCG Urine pregnancy test(10mIU)	INV-FHC-U101, INV-FHC-U102
102	One Step hCG Urine Test	W1-C4P (10mIU), W1-C5P (10mIU), W1-C6P (10mIU), W1-CIP (10mIU), W1- CP, W1-CP (10mIU), W1-MIIP (10mIU), W1-MP (10mIU), W1-SP, W1-SP (10mIU)
103	One Step hCG Urine/Serum Test	W1-C3P, W1-S3P, W001P0721, W001P0720
104	One Step H. Pylori Feces Test	W028-C, W028-S, W028P0026, W028P0027
105	One Step H.Pylori Serum/Plasma Test	W38-C, W038P0043, W38-S, W038P0042
106	One Step Influenza A Test	W72-S, W72-C
107	One Step Influenza A&B Test	W71-C, W059P0010, W059P0011, W059P0012
108	One Step Influenza B Test	W73-S, W73-C
109	One Step Ovulation Urine Test	W2-SP, W2-CP, W2-CIP, W2-M4P, W2- M5P, W2-M6P, W2-M7P, W2-MP, W2- MIIP, W2-MIIP
110	One Step Malaria HRP2 (P.f) Test	W37-S, W37-C, W037P0039, W037P0040
111	One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C, W056-S, W056P0025, W056P0026
112	One Step Malaria HRP2/pLDH (P.f/Pan) Test	W62-C, W054P0016, W054P0017
113	Activated Clotting Time Reagent Kit (Clotting)	W483
114	Activated Partial Thromboplasting Time Reagent Kit (Clotting)	W481
115	Fibrinogen Reagent Kit (Clotting)	W482
116	Prothrombin Time Reagent Kit (Clotting)	W480
117	Thrombin Time Reagent Kit (Clotting)	W484
118	One Step Gonorrhea Swab test	W36-C, W036P0010
119	One Step Syphilis Serum / Plasma Test	W34-S, W34-C
120	One Step Syphilis Whole Blood / Serum / Plasma Test	W34-S4P, W34-C4P, W034P0070, W034P0071
121	One Step Strep A Swab Test	W39-S, W39-C, W039P0002, W039P0003

122	Wondfo® Blood Gas Analyzer Test Card	W459-C7P4-E, W461-C7P4-E, W465-C7P4-E, W466-C7P4-E
123	Wondfo® Blood Gas Analyzer Control	W847-L, W847-M, W847-H, W848, W849-L, W849-H
124	Wondfo® Blood Gas Analyzer Reagent Pack	W451-Z0P4-G, W451-Z0P4-I
125	Finecare™ hsCRP Rapid Quantitative Test	W240
126	Finecare™ Fincubator	IC-101
127	Finecare™ Vitamin D Rapid Quantitative Test	W241P0002, W241P0003
128	Wondfo® Coagulation Control	W863
129	Wondfo® Prothrombin Time PT/INR Reagent Kit (Clotting)	W486
130	Finecare™ FIA Meter II Plus SE	FS-114
131	Wondfo® Chemcare UREA Test Strip (Dry Biochemical Method)	W412-S2P6-E W412-S2P6-I
132	Wondfo® Chemcare ALT Test Strip (Dry Biochemical Method)	W416-S2P6-E W416-S2P6-I
133	Wondfo® Chemcare UA Test Strip (Dry Biochemical Method)	W413-S2P6-E W413-S2P6-I
134	SURESTEP™ URINE TEST DRUG SCREEN CARD Synthetic Cannabinoids (K2)	AWDK2-114-CE
135	One Step Synthetic Cannabis (K2) Urine Test	W185-P1EP-40N1 (25T) W185-P1FH-40N1 (40T)
136	One Step Multi-Drug Oral Fluid T-Cube	W602-CU6, W603-CU6, W604-CU6, W605-CU6, W606-CU6, W607-CU6, W608-CU6, W609-CU6, W610-CU6
137	Wondfo® Chemcare™ Dry Chemistry Analyzer	DC-101, DC-202
138	Wondfo® Chemcare CREA Test Strip (Dry Biochemical Method)	W418-S8P6-E, W418-S8P6-I
139	Wondfo® Chemcare HB Test Strip (Dry Biochemical Method)	W415-S7P6-E, W415-S7P6-I
140	Wondfo® Chemcare LPS Test Strip (Dry Biochemical Method)	W424-S8P6-E, W424-S8P6-I
141	Wondfo® Chemcare α-AMY Test Strip (Dry Biochemical Method)	W411-S3P6-E, W411-S3P6-I
142	Finecare™ fT3 Rapid Quantitative Test	W200
143	Finecare™ fT4 Rapid Quantitative Test	W259
144	Finecare™ 2019-nCoV IgM/IgG Test	W278
145	Finecare™ AMH Rapid Quantitative Test	W257P0001
146	Finecare™ Estradiol (E2) Rapid Quantitative Test	W247-C4P1-E
147	Finecare™ Prolactin Rapid Quantitative Test	W246P0001
148	Finecare™ Testosterone Rapid Quantitative Test	W248-C4P1-E
149	Finecare™ HbA1c Control	W873P0001

150	Finecare™ Vitamin D Control	W867-Z0P1-AG
151	Finecare™ 2019-nCoV Antigen Test	W286 W286P0002, W286P0003
152	Chemcare™ ALB Test Strip (Dry Biochemical Method)	W414-S8P6-E, W414-S8P6-I
153	Chemcare™ CK Test Strip (Dry Biochemical Method)	W422-S8P6-E, W422-S8P6-I
154	Chemcare™ CK-MB Test Strip (Dry Biochemical Method)	W423-S8P6-E, W423-S8P6-I
155	Chemcare™ GLU Test Strip (Dry Biochemical Method)	W425-S8P6-E, W425-S8P6-I
156	Chemcare™ ALC Test Strip (Dry Biochemical Method)	W421-S8P6-E, W421-S8P6-I
157	Chemcare™ AST Test Strip (Dry Biochemical Method)	W420-S8P6-E, W420-S8P6-I
158	Chemcare™ CHE Test Strip (Dry Biochemical Method)	W417-S8P6-E, W417-S8P6-I
159	Chemcare™ α-HBDH Test Strip (Dry Biochemical Method)	W426-S8P6-E, W426-S8P6-I
160	Chemcare™ LDH Test Strip (Dry Biochemical Method)	W419-S8P6-E, W419-S8P6-I
161	Finecare™ Ferritin Rapid Quantitative Test	W269P0001
162	Finecare™ iFOB Rapid Quantitative Test	W279P0001
163	ACCUDOCTOR Multi Drug Urine Test Panel/ Test Multi Drogas en Orina/ Test antidroga multiplo nelle Urine/ Multi Drogentest im Urin	W2005-P
164	ACCUDOCTOR Cocaine Urine Test Strip/ Test de Cocaína a tiras en Orina/ Test Cocaina su Striscia nelle Urine/ Kokain Teststreifen im Urin	W10-S
165	2019-nCoV Antigen Control	W888P0001
166	2019-nCoV Neutralizing Antibody Detection Kit (Chemiluminescence Immunoassay)	WA37P0001, WA37P0003
167	2019-nCoV RBD Antibody Detection Kit (Chemiluminescence Immunoassay)	WA38P0001, WA38P0003
168	Influenza/2019-nCoV Antigen Combo Test	W630P0002, W630P0003, W630P0004, W630P0005, W630P0006, W630P0007, W630P0008, W630P0009, W630P0010, W630P0011
169	U-Card Dx™ 2019-nCoV/Flu Test	WG01P0001, WG01P0002
170	NeuCheck™ 2019-nCoV Neutralizing Antibody Detection ELISA Kit	WA50P0001
171	Substrate Solution for Automatic Immunoassay System	A004P0002, A004P0003, A004P0004, A004P0005
172	Cleaning Fluid	A007P0002, A007P0003, A007P0004, A007P0005, A007P0006, A007P0007
173	Finecare™ PCT Rapid Quantitative Test	W210P0004
174	Finecare™ IL-6 Rapid Quantitative Test	W251P0001
175	Finecare™ One Step cTnT Rapid Quantitative Test	W254P0001

176	SURESTEP™ ORAL FLUID TEST DRUG SCREEN CUBE	OFCUBE-5WP, OFCUBE-6POL, OFCUBE-9REH, OFCUBE-10REH
177	2019-nCoV Real-Time RT-PCR Assay	WE06P0001, WE06P0002, WE06P0003, WE06P0004
178	Finecare™ FIA Meter Plus	FS-113
179	Finecare™ Cortisol Rapid Quantitative Test	W250
180	Finecare™ Dengue NS1 Ag Test	W282P0001
181	Finecare™ Cortisol Control	W896P0001
182	Finecare™ FSH/LH/PRL/Prog Multi-Control	W895P0001
183	Finecare™ ASO Rapid Quantitative Test	W297P0001
184	Finecare™ Total IgE Rapid Quantitative Test	W298P0001
185	U-Card Dx™ 2019-nCoV Test	WG02P0001, WG02P0002
186	Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)	W196P0010

For Wondfo Registration Use

b. IVD products for self-testing with CE Certificate

No.	Name Device	Catalogue number Device
1	One Step FSH Urine Test	W52-S, W52-C, W52-M
2	One Step hCG Urine Test	W001-C1HJ(20mIU)1, W001- M1HJ(20mIU)1, W001- MII1HJ(20mIU)1, W001- S1HJ(20mIU)1, W1-C, W1-C (10mIU), W1-C (20mIU), W1-C4, W1-C4 (10mIU), W1-C4 (20mIU), W1-C5, W1-C5 (10mIU), W1-C5 (20mIU), W1-CI, W1-CI (10mIU), W1-CI (20mIU), W1-M, W1-M (10mIU), W1-M (20mIU), W1-M10, W1-M10 (10mIU), W1-M10 (20mIU), W1-M11, W1-M11 (10mIU), W1-M11 (20mIU), W1-M12 (10mIU), W1-M12 (20mIU), W1-M13 (10mIU), W1- M13 (20mIU), W1-M14 (10mIU), W1-M14 (20mIU), W1-M15 (10mIU), W1-M15 (20mIU), W1- M16 (10mIU), W1-M16 (20mIU), W1-M19, W1-M19 (10mIU), W1- M19 (20mIU), W1-M4, W1-M4 (10mIU), W1- M4 (20mIU), W1-M5, W1-M5 (10mIU), W1- M5 (20mIU), W1-M6, W1-M6 (10mIU), W1- M6 (20mIU), W1-M7, W1-M7 (10mIU), W1- M7 (20mIU), W1-M8, W1-M8 (10mIU), W1- M8 (20mIU), W1-M9, W1-M9 (10mIU), W1- M9 (20mIU), W1-MI, W1-MI (10mIU), W1- MI (20mIU), W1-MII, W1-MII (10mIU), W1- MII (20mIU), W1-MIII, W1-MIII (10mIU), W1- MIII (20mIU), W1-S, W1-S (10mIU), W1-S (20mIU)
3	Analysis - Self Testing Pregnancy Test	00061437200000, 00061438200000
4	Apoteket Graviditetstest	207268, 207269
5	Clarity One Step Pregnancy Test	W1-M
6	Dr.Marcus Test Rapido di Gravidanza	02083800000000
7	Dr.Marcus Test Rapido do Gravidanza	03083800000000
8	nordtest Pregnancy test: One Step hCG Urine Test	W1-C (10mIU)

9	Optimac Schwangerschaftsfrühtest	W1-M(20mIU)
10	PiC Solution Personal Test (1 test)	2023010100000
11	PiC Solution Personal Test (2 test)	2023011100000
12	Teste de gravidez Continente	W1-MIII (20mIU)
13	Teste de gravidez Wells	W1-MIII
14	zwangerschapstest verdeeld door Kruidvat	W1-C
15	One Step Ovulation Urine Test	W2-C, W2-C4, W2-C5, W2-CI, W2-M, W2-M-1, W2-M4, W2-M5, W2-M6, W2-M7, W2-M8, W2-M9, W2-M10, W2-M11, W2-M19 W2-MII, W2-MIII, W2-S, W002-MII1HJ1, W002-S1HJ1
16	Apoteket Ägglossningstest	207270
17	Suretest test d'ovulation	2344085
18	SD SpermTest	1830103
19	Sperm Concentration Test	W121-S, W121-C
20	One Step Strep A Swab Test	W39-SH, W39-CH, W039P0001
21	One Step Influenza A Test	W72-SH, W72-CH
22	One Step Influenza A&B Test	W71-SH, W71-CH
23	One Step Influenza B Test	W73-SH, W73-CH
24	One Step Fecal Occult Blood (FOB) Test	W030-S (50ng/ml), W030-C (50ng/ml)
25	Natural Cycles Ägglossningstest	W2-S
26	Nesira Test de ovulación/Teste de ovulação	W2-M
27	MAKE SURE EGGLØSNINGSTEST STAV	W2-M (25 mIU/ml)
28	MAKE SURE EGGLØSNINGSTEST STRIMMEL	W2-S (25 mIU/ml)
29	MAKE SURE GRAVIDITETSTEST STAV	W001-M1H2-A W001-M1H2-C
30	MAKE SURE GRAVIDITETSTEST TIDLIG STRIMMEL	W1-S (10 mIU/ml)
31	MAKE SURE GRAVIDITETSTEST STRIMMEL	W1-S (25 mIU/ml)
32	Natural Cycles Graviditetstest	W1-S
33	Nesira Test de embarazo/Teste de gravidez	W1-MIII
34	Farma test TEST DE EMBARAZO	W1-M
35	GRAN CRUZ TEST DE EMBARAZO	W1-MIII
36	ia interapothek TEST DE EMBARAZO	W1-M
37	APOTEK SJÄLVTEST GRAVIDITET	W1-M4/1 W1-M4/2
38	APOTEK SJÄLVTEST ÄGGLOSSNING	W2-M4
39	Dr. Marcus TEST DI GRAVIDANZA	02083900000000
40	ALBERT HEIJN ZWANGERSCHAPSTEST	W1-M
41	Babyplan® Early Pregnancy Test Strip	W1-S (10mIU/ml), W1-S/1 (10mIU)
42	Babyplan® Pregnancy Test Midstream	W1-MII
43	Babyplan® Pregnancy Test Strip	W1-S, W1-S/1

44	Babyplan® Early Pregnancy Test Midstream	W1-M14
45	Valmed Graviditetstest Stav-Urintest	W1-M4
46	Valmed Graviditetstest Strimmel-urintest	W1-S
47	Matas medicare GRAVIDITETSTEST	W1-M4
48	Pregcheck Pregnancy test	W1-M
49	Pregcheck Pregnancy test strips	W1-S
50	Apteekkarin Pregnancy test	W1-M-1, W1-M-2
51	APOTEKSGRUPPENS GRAVIDITETSTEST 2 testremsor	W1-S
52	APOTEKSGRUPPENS GRAVIDITETSTEST 2 teststickor	W1-M
53	Suretest TEST DE GROSSESSE	2344083, 2344084
54	BARZA® TEST DE SARCINĂ CLASIC-BANDĂ	W1-S (20mIU/ml)
55	BARZA® TEST DE SARCINĂ CLASIC-CASETĂ	W1-C1
56	BARZA® TEST DE SARCINĂ CLASIC-STILOU	W1-M4
57	BARZA® TEST DE SARCINĂ ULTRASENSIBIL-BANDĂ	W1-S (10mIU/ml)
58	BARZA® TEST DE SARCINĂ ULTRASENSIBIL-CASETĂ	W1-C
59	BARZA® TEST DE SARCINĂ ULTRASENSIBIL-STILOU	W1-M
60	ETOS Early zwangerschapstest	W1-MII
61	DA Regular Zwangerschapstest Single pack	W1-M-1
62	DA Regular Zwangerschapstest DUO pack	W1-M-2
63	DA EARLY Zwangerschapstest DUO pack	W1-MII
64	Surecheck® CASSETTE pregnancy test	W1-C4
65	Surecheck® STREAMER PREGNANCY TEST	W1-M11
66	Folium Pregnancy Test	W1-C, W1-M4-1, W1-M4-2
67	Maria strip	W1-S
68	Maria plus	W1-C
69	Maria Express	W1-M
70	UNIFAMILY® Wondfo Test di gravidanza	W1-MIII
71	Easy@Home® Pregnancy Test	EZW1-S, EZW1-M
72	Premom® Pregnancy Test	PM1-M3
73	Preview® Pregnancy Test	W1-S, W1-MIII
74	Babyplan® Ovulation Test Midstream	W2-MII
75	Babyplan® Ovulation Test Strip	W2-S, W2-S/1
76	Valmed Ägglossningstest Stav-urinprov	W2-M4
77	Valmed Ägglossningstest Strimmel-Urintest	W2-S
78	matas medicare ÆGLØSNINGSTEST	W2-M4
79	Pregcheck Ovulation Test Strips	W2-S
80	Apteekkarin OVULAATIOTESTIG	W2-M
81	BARZA® TEST DE OVULATIE	W2-S
82	ETOS Ovulatietest	W2-MII
83	DA OVULATIE TEST	W2-MII

84	OVIEW® OVULATION TEST	W2-S
85	Folium Ovulation Test	W2-S
86	Maria baby strip	W2-S
87	Maria before baby	W2-M
88	Easy@Home® Ovulation Test	EZW2-S, EZW2-M
89	Premom® Ovulation Test	PM2-M3
90	Preview® Ovulation Test	W2-S
91	SCREEN CHECK TEST Influenza A&B	W71-CH
92	SCREEN CHECK TEST A Streptococcus	W39-CH
93	Teste de Gravidez FARMAbaby	W1-M4
94	Dr. Original Zwangerschapstest	W1-C-1, W1-C-2, W1-C-6
95	Dr. Original Vroege Zwangerschapstest	W1-MII
96	UNIFAMILY® Wondfo Test di gravidanza	W1-MII
97	Valmed Graviditetstest Stav	W1-M4/1
98	Etos Zwangerschapstest	W1-M-1, W1-M-2
99	Fertil Graviditetstest	W1-M4
100	Apotek Hjärtat Graviditetstest	APH01, APH02
101	Apotek Hjärtat Ägglossningstest	APH07
102	Verity Pregnancy Test / Τεστ Εγκυμοσύνης Verity Pregnancy Test	W1-M
103	Conceive Plus One Step HCG Urine Pregnancy	W1-M6 (10mIU)
104	Conceive Plus Male Fertility Test	W121-C
105	Trekpleister zwangerschapstest	W1-C
106	Pregnatest Pregnancy Test/Test de grossesse / اختبار الحمل	W1-M4
107	Pregnatest One Step HCG Urine Test	W1-CI
108	Pregnatest Ovulation Test/Test D'ovulation / فحص الإباضة	W2-M
109	PAN-MATE Pregnancy Test	W1-CI
110	SANICO TEST AUTODIAGNOSTICO DI GRAVIDANZA / HOME PREGNANCY TEST	MQ007
111	APOTEK SJÄLVTEST ÄGGLOSSNING	786303
112	Preview Pregnancy Test/ Test de Grossesse/ Schwangerschaftstest	P1-M6, P1-S(10mIU)
113	Preview One Step FSH Urine Test	P52-M
114	Woditop Pregnancy Test	WT1-S(10mIU)
115	Woditop Ovulation Test	WT2-S
116	Valmed Graviditetstest Stav	W1-MII/1 W1-MII/2
117	Valmed Graviditetstest Strimmel	W1-S
118	Valmed Ægløsningstest Stav	W2-MII
119	Valmed Ægløsningstest Strimmel	W2-S
120	Domowe Laboratorium (Home Laboratory) Test na grypę Influenza	DLN-FLU-1
121	GS Mamatest Comfort Těhotenský test	W1-M4

122	Accudoctor Pregnancy Test hCG / Test de Embarazo hCG / Test di Gravidanza hCG / Schwangerschaftstest hCG / Test de Grossesse hCG	W1-S(10mIU)
123	Accudoctor Ovulation Test LH / Test de Ovulación LH / Test di Ovulazione LH / Test d'ovulation LH / Ovulationstest LH	W2-S

c. IVD products in list B with CE certificate

No.	Name Device	Catalogue number Device
1	Finecare™ Prostate Specific Antigen Control	W814-L, W814-M, W814-H
2	Finecare™ PSA Rapid Quantitative Test	W209
3	Finecare™ FPSA (Free Prostate Specific Antigen) Rapid Quantitative Test	W230
4	One Step Prostatic Specific Antigen (PSA) serum/plasma Test	W31-S, W31-C
5	One Step Prostatic Specific Antigen (PSA) whole blood / serum / plasma Test	W31-S4P, W31-C4P
6	One Step Chlamydia Swab / Urine Test	W35-C
7	Diagnostic Kit for Human IgM Antibody of Chlamydia Pneumoniae (Immunochromatographic Assay)	W135-C

d. IVD products in list A with CE certificate

No.	Name Device	Catalogue number Device
1	Wondfo One Step HIV 1/2 Whole Blood/Serum/Plasma Test	W752-4G3-E, W752-C4G3-F

Issue date of first version: 13 March 2018

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This version supersedes the former version of the list of Devices covered by the Authorized Representative Agreement.

For approval,

For: Guangzhou Wondfo Biotech Co. Ltd.
No. 8 Lizhishan Road, Science City
Huangpu District, 510663 Guangzhou,
PR China

Date: 2024.2.14

SIGNATURE



Mia Jiang
RA Director

For Qarad BV
Pas 257
2440 Geel
Belgium
Social Siege: Cipalstraat 3, 2440 Geel,
Belgium

Date: 27 February 2024

SIGNATURE

Kirsten Van Garsse
Director AR Operations