



CE 1434

# COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) - Saliva

## Self-testing



Anhui Deepblue Medical Technology Co.,Ltd.  
Website:[www.dbluemedical.com](http://www.dbluemedical.com)  
Address:4th Floor D-1# Zone, Pearl Industrial Park 106  
Innovation Avenue,High-Tech Development Zone 230088 Hefei,  
Anhui, China



German Version:

1pc/box, 500pcs/carton

Carton size: 59.5\*49.5\*35cm, G.W. 14.5 KG



5pcs / box      200boxes /carton --1000Tests/carton Box

size : 130\*70\*52mm

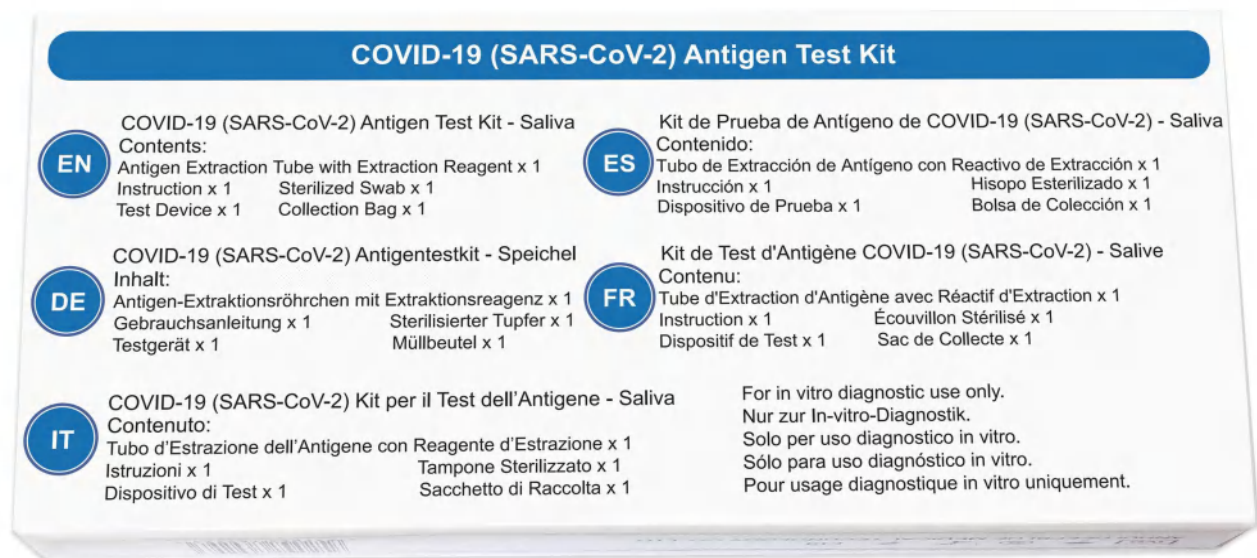
Carton size:55\*54\*37cm,G.W.16.5kg



25 pcs / box 50 boxes /carton --1250 Tests /carton Box

size :260\*120\*70mm

Carton size: 62\*54\*38cm, G.W. 18.5 kg



Multi language version:1 pc/box,500pcs/carton

Box size:144\*65\*19mm

Carton size: 59.5\*49.5\*35cm, G.W. 18 kg



Scan QR code for Multi language IFU

Multi language box and Instruction For Use. Smooth circulation and distribution in multinational markets. Scan QR code and access to multi language IFUs, convenient and efficient.



CE 1434



Operation Video

## COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) - Saliva

For Self-testing / Zum Selbsttest / Per Auto-test / Para Autoevaluación / Pour Auto-test

**For private use** - Please refer to the instructions for use for details.

**Für den privaten Gebrauch** - Einzelheiten entnehmen Sie bitte der Gebrauchsanweisung.

**Per uso privato** - Per dettagli, si prega di fare riferimento alle istruzioni per l'uso.

**Para uso privado** - Consulte las instrucciones de uso para más detalles.

**Pour un usage privé** - Veuillez vous référer au mode d'emploi pour plus de détails.

For in vitro diagnostic use only.

Nur zur In-vitro-Diagnostik.

Solo per uso diagnostico in vitro.

Sólo para uso diagnóstico in vitro.

Pour usage diagnostique in vitro uniquement.



REF :SL030101SST-1

ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.

## COVID-19 (SARS-CoV-2) Antigen Test Kit

EN

COVID-19 (SARS-CoV-2) Antigen Test Kit - Saliva

Contents:

Antigen Extraction Tube with Extraction Reagent x 1

Instruction x 1 Sterilized Swab x 1

Test Device x 1 Collection Bag x 1

COVID-19 (SARS-CoV-2) Antigen Test Kit - Speichel

Inhalt:

Antigen-Extraktionsröhrchen mit Extraktionsreagenz x 1

Gebrauchsanleitung x 1 Sterilisierte Tupfer x 1

Testgerät x 1 Müllbeutel x 1

COVID-19 (SARS-CoV-2) Kit per il Test dell'Antigene - Saliva

Contenuto:

Tubo d'Estrazione dell'Antigene con Reagente d'Estrazione x 1

Istruzioni x 1 Tampone Sterilizzato x 1

Dispositivo di Test x 1 Sacchetto di Raccolta x 1

ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.

4th Floor,D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue, High-Tech Development Zone, 230088 Hefei, Anhui, China



Luxus Lebenswelt GmbH  
Kochstr. 1, 47877, Willich, Germany

ES

Kit de Prueba de Antígeno de COVID-19 (SARS-CoV-2) - Saliva

Contenido:

Tubo de Extracción de Antígeno con Reactivo de Extracción x 1

Instrucción x 1 Hisopo Esterilizado x 1

Dispositivo de Prueba x 1 Bolsa de Colección x 1

Kit de Test d'Antigène COVID-19 (SARS-CoV-2) - Salive

Contenu:

Tube d'Extraction d'Antigène avec Réactif d'Extraction x 1

Instruction x 1 Écouvillon Stérilisé x 1

Dispositif de Test x 1 Sac de Collecte x 1

LOT

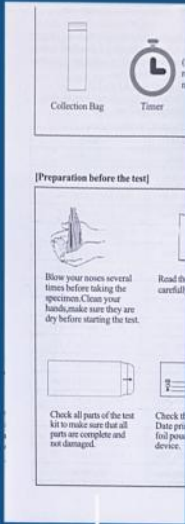


6 952062 769507 >

## Multi language soft package

One test in one soft bag, 25 pcs per ziplock bag, 1000 pcs per carton, carton size: 62\*54\*45cm, G.W. 20 kg

Box



IFU



Test device



Antigen Extraction Tube



Saliva swab



Collection bag

## Your kit contains the following materials

Box\*1

IFU\*1

Saliva swab\*1

Test device\*1

Collection bag\*1

Antigen Extraction Tube\*1



## Your kit contains the following materials

Bag\*1

IFU\*1

Saliva swab\*1

Test device\*1

Collection bag\*1

Antigen Extraction Tube\*1

Multi language soft package

Soft package with minimum size and weight, suitable for supermarket or Pharmacy to hang it on the shelf.



CE 1434

# COVID-19 (SARS-CoV-2) Antigen test kit (Colloidal Gold) - Saliva (Self-Testing)



Specification	1 pcs/box 5 pcs/box 25 pcs/box
Specimen	Human Saliva
Storage	4~30°C

## PERFORMANCE

**SENSITIVITY: 98.7% (95% CI: 92.33% - 99.07%)**

**SPECIFICITY: >99.9% (95% CI: 98.17% - 100%)**



## PRODUCT ADVANTAGES

- ◆ Sterilized aluminum foil sealing pre-filled buffer solution, minimum leaking risk, easier operation.
- ◆ UK CTDA Approved. Passed Germany PEI evaluation.
- ◆ Easy sampling, more suitable for students and children.
- ◆ No need instrument, get results within **15 minutes**.
- ◆ Identify acute or early infection.
- ◆ No reduction in sensitivity test against **the Alpha, Beta, Delta, Gamma, Lambda, Omicron variant and so on.**

## UK GOVERNMENT VALIDATED

The UK Government Public Health England, joint PHE Porton Down and University of Oxford was independently evaluated over 140 lateral flow devices that have been referred by the Department of Health and Social Care (DHSC). **Only a few can passed the phase 3A trials, and our DEEPBLUE even have passed phase 3B.** That means our test has very high accuracy at multiple viral loads and able to detect the asymptomatic patients and the new different variants.

## EASY TO USE

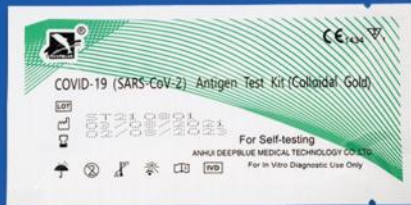
Using a saliva swab to collect the specimen in mouth, just like a lollipop.



Scan the following QR code to watch the demonstration video on YouTube.



# Your kit contains the following materials



Test device

Antigen Extraction Tube

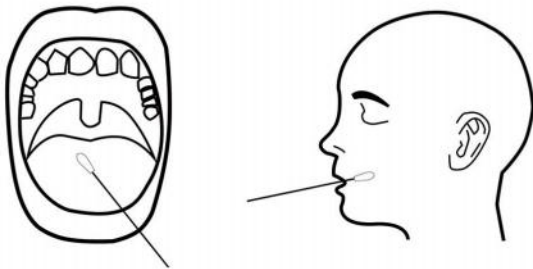
IFU

Saliva swab

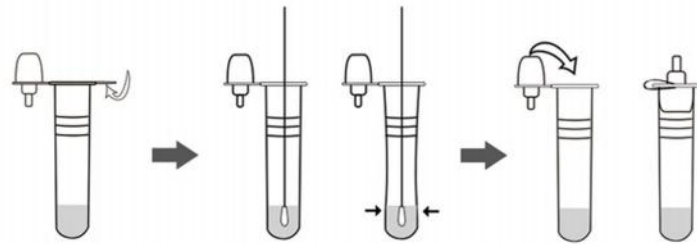
Waste bag

## TEST PROCEDURE

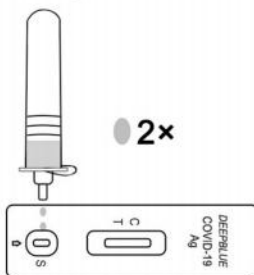
### 1. Specimen Collection



### 2. Specimen Preparation

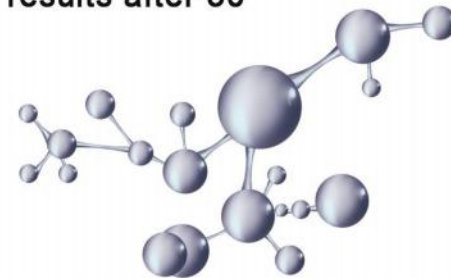
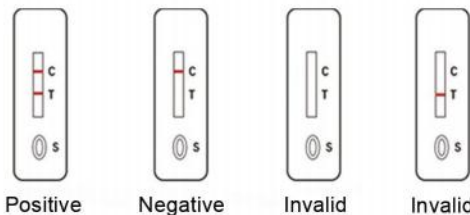


### 3. Testing



Hold the extraction tube vertically and add two drops of the test specimens into the specimen well (s). Start the timer. Interpret the results at 15 minutes, and the results after 30 minutes are no longer valid.

### 4. Interpretation of test results



ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.

【Address】 4th, Floor, D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue, High-Tech Development Zone, Hefei 230088, Anhui, China

【Website】 [www.dbluemedical.com](http://www.dbluemedical.com) 【Contact】 0551-65326797



# CERTIFICATE

**EC Certificate No. 1434-IVDD-057/2022**

**EC Design-examination  
Directive 98/79/EC concerning  
*in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies  
that manufactured by:

**Anhui Deepblue Medical Technology Co., Ltd.  
4th Floor, D-1#Zone, Pearl Industrial Park, 106  
Innovation Avenue, High-Tech Development Zone,  
230088 Hefei, Anhui, China**

*in vitro* diagnostic medical devices  
for self-testing

**COVID-19 (SARS-CoV-2) Antigen Test Kit  
(Colloidal Gold) – Saliva**

*The list of medical devices covered by this certificate is provided in the annex 1*

in terms of design documentation, comply with requirements  
of Annex III (Section 6) to Directive 98/79/EC (as amended)  
implemented into Polish law,  
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 30.03.2022 to 27.05.2025

The date of issue of the Certificate: 30.03.2022

The date of the first issue of the Certificate: 10.11.2021



Issued under the Contract No. MD-113/2021  
Application No: 230/2021  
Certificate bears the qualified signature.  
Warsaw, 30/03/2022  
Module A1

**Aleksandra** Digitally signed  
**Kostrzewa** by Aleksandra  
Kostrzewa  
**President**



# ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

**No 1434-IVDD-057/2022**

*List of medical devices covered by the certificate:*

**DEEPBLUE, ShenLanTest, Highbluetest, NewBluetest,  
Quicklyblue**

REF:

SL030101SST-1,  
SL030101SST-2,  
SL030101SST-3,  
SL030101SST-4,  
SL030101SST-5,  
SL030101SST-6,  
SL030101SST-7,  
SL030101SST-8,  
SL030101SST-9,  
SL030101SST-10,  
SL030101SST-11,  
SL030101SST-12,  
SL030101SST-13,

SL030101SST-14,  
SL030101SST-15,  
SL030101SST-16,  
SL030101SST-17,  
SL030101SST-18,  
SL030101SST-19,  
SL030101SST-20,  
SL030101SST-21,  
SL030101SST-22,  
SL030101SST-23,  
SL030101SST-24,  
SL030101SST-25



Issued under the Contract No. MD-113/2021  
Application No: 230/2021  
Certificate bears the qualified signature.  
Warsaw, 30/03/2022

Aleksandra Kostrzewa  
Digitally signed  
by Aleksandra  
Kostrzewa  
President



Zhang chao  
Lotus Global Co Ltd  
4th Floor,D-1# Zone,  
Pearl Industrial Park,  
106 Innovation Avenue,High-Tech Development Zone,  
230088 Hefei, Anhui,  
China.

01 December 2022

Dear Stakeholder,

**Re: Notification of result – CTDA desktop review – COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) - Saliva**

Thank you for your application for approval of a coronavirus test under the requirements that came into force on 28 July 2021 via The Medical Devices (Coronavirus Test Device Approvals) (Amendment) Regulations 2021.

I can confirm the desktop review for your product has now been completed. I can inform you that based on the information and evidence provided your application has been successful.

Your product details will be published on the register of products that have been approved under regulation 38A(5) of the Medical Devices Regulations 2002: COVID-19 test validation approved products - GOV.UK ([www.gov.uk](http://www.gov.uk)). The details published on the register will include the name and address of the registered place of business of the applicant and manufacturer; the country in which the manufacturer is established; and if there is one, the name and address of a UK Responsible Person or Authorised Representative of the manufacturer.

The approval is valid for a period of 5 years from the date of this letter.

The MHRA, in its capacity as an enforcing authority for medical device legislation in the UK, is in copy to this letter.

Yours sincerely

CTDA Team



www.dbluemedical.com

## DECLARATION OF CONFORMITY

**MANUFACTURER:** ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.  
4<sup>th</sup> Floor,D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue,  
High-Tech Development Zone , 230088 Hefei, Anhui, People's  
Republic of China

**EUROPEAN REPRESENTATIVE:** Luxus Lebenswelt GmbH  
Kochstr. 1, 47877, Willich, Germany

**PRODUCT:** COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) -Saliva

**Models:** SEE ATTACHMENT

**REF:** SEE ATTACHMENT

**CLASSIFICATION:** SELF-TESTING

**EDMA CODE:** 15 70 90 90 00

**CONFORMITY ASSESSMENT ROUTE:** Following the procedure relating to the EC Declaration of Conformity set out in Annex III Article 6 of Directive 98/79/EC.

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

**STANDARDS APPLIED:** EN ISO 13485:2016  
EN ISO 18113-1:2011, EN ISO 18113-4:2011, EN 13612:  
2002/AC:2002, EN ISO 23640:2015, EN 13641: 2002, EN ISO  
15223-1: 2016, EN 13975:2003, EN 13532:2002, EN ISO  
14971:2012.

**NOTIFIED BODY:** Polish Center for Testing and Certification  
469 Puławska Street,02-844 Warsaw,Poland

**(EN) CERTIFICATE(S):** 1434-IVDD-057/2022

**START OF CE-MARKING:** 2021-11-10

**PLACE, DATE OF ISSUE:** HEFEI, 2022-03-30

**SIGNATURE:** CHEN FENGLING *Chen Fengling*  
**GENERAL MANAGER**



EC Declaration of Conformity

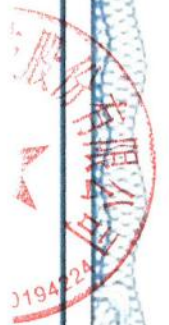
DOC-COVID-19 Ag(N/0)



www.dbluemedical.com

## DECLARATION OF CONFORMITY ATTACHMENT

Specification	REF
1 piece per box	SL030101SST-1
2 pieces per box	SL030101SST-2
3 pieces per box	SL030101SST-3
4 pieces per box	SL030101SST-4
5 pieces per box	SL030101SST-5
6 pieces per box	SL030101SST-6
7 pieces per box	SL030101SST-7
8 pieces per box	SL030101SST-8
9 pieces per box	SL030101SST-9
10 pieces per box	SL030101SST-10
11 pieces per box	SL030101SST-11
12 pieces per box	SL030101SST-12
13 pieces per box	SL030101SST-13
14 pieces per box	SL030101SST-14
15 pieces per box	SL030101SST-15
16 pieces per box	SL030101SST-16
17 pieces per box	SL030101SST-17
18 pieces per box	SL030101SST-18
19 pieces per box	SL030101SST-19
20 pieces per box	SL030101SST-20
21 pieces per box	SL030101SST-21
22 pieces per box	SL030101SST-22
23 pieces per box	SL030101SST-23
24 pieces per box	SL030101SST-24
25 pieces per box	SL030101SST-25





Product Service

# Certificate

No. Q5 003706 0001 Rev. 01

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

**Facility(ies):** ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.  
4th Floor, D-1# Zone, Pearl Industrial Park, 106 Innovation  
Avenue, High-Tech Development Zone, 230088 Hefei, Anhui,  
PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate



# Certificate

No. Q5 003706 0001 Rev. 01

**Holder of Certificate:** **ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.**

4th Floor, D-1# Zone  
Pearl Industrial Park  
106 Innovation Avenue, High-Tech Development Zone  
230088 Hefei, Anhui  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents by Colloidal Gold and Enzyme Chemical Reaction Method, Medical Ultrasonic Couplant, Acetowhite Solution, Epithelial Tissue Staining Solution, Rapid Test for Vaginitis(Polyamines) and Cell Preservation Solution**

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 003706 0001 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5 003706 0001 Rev. 01)

**Report No.:** SH21130301

**Valid from:** 2021-06-22

**Valid until:** 2024-06-21

**Date,** 2021-06-16



Christoph Dicks  
Head of Certification/Notified Body

# Antigen-Tests auf SARS-CoV-2 zur Eigenanwendung

die Gegenstand des Anspruchs nach §1 Satz 1 Coronavirus-Testverordnung (TestV) sind („Selbsttests“)

▶ Allgemeine Hinweise

Q ANHUI DEEPBLUE MEDICAL Los Aktionen

☑ Nach 'ANHUI DEEPBLUE MEDICAL' suchen

Test-ID	Name des Tests	Evaluierung PEI	Omikron-Erkennung entsprechend der Bridging-Prüfung des PEI	Hersteller		Europäischer Bevollmächtigter		Probennahme..
				Name ↑	Land	Name	Land	
AT1190/21	COVID-19 (SARS-CoV-2) Antigenstestkit (kolloidales Gold)	Ja	Ja	ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.	CN	Luxus Lebenswelt GmbH	DE	nasal
AT1288/21	COVID-19 (SARS-CoV-2) Antigenstestkit (kolloidales Gold) - Speichel	Ja	Ja	ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.	CN	Luxus Lebenswelt GmbH	DE	Speichel

## Germany BfArM Self Test List

# Antigen-Tests auf SARS-CoV-2

die Gegenstand des Anspruchs nach §1 Satz 1 Coronavirus-Testverordnung (TestV) sind („Selbsttests“)

▶ Allgemeine Hinweise

Q ANHUI DEEPBLUE MEDICAL Los Aktionen

☑ Nach 'ANHUI DEEPBLUE MEDICAL' suchen

Test-ID	Name des Tests	Evaluierung PEI	Omikron-Erkennung entsprechend der Bridging-Prüfung des PEI	Hersteller	
				Name ↑	Land
AT1190/21	COVID-19 (SARS-CoV-2) Antigenstestkit (kolloidales Gold)	Ja	Ja	ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.	CN
AT1288/21	COVID-19 (SARS-CoV-2) Antigenstestkit (kolloidales Gold) - Speichel	Ja	Ja	ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.	CN

Passed the PEI & Omicron evaluation

# ISO9001 certification



## QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate No. 00121Q310783R0M/3400

We hereby certify that

**ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO., LTD.**

Unified Social Credit Code: 913401005501903714

4th Floor, D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue, High-Tech Development Zone, Hefei City,  
AnHui Province, P.R.China

by reason of its  
**Quality Management System**

has been awarded this certificate for compliance with the standard

**GB/T 19001-2016 / ISO 9001:2015**

The Quality Management System Applies in the following area:

Colloidal Gold and Enzymatic Chemical Reaction Method in Vitro Diagnostic Reagents, Medical  
Ultrasound Coupling Agent, Epithelial Tissue Staining Solution, Vaginitis Rapid detection Kit  
(Polyamine Method), Cell Preservation Solution, Virus Sampling Tube, Medical Ice Cap and Wound  
Dressing within the Scope of Qualification's Development and Production

**Certified since: November 11, 2021 Valid from: November 11, 2021 Valid until: November 10, 2024**

After a surveillance cycle, the certificate is valid only when used together with an Acceptance Notice of Surveillance Audit issued by CQC.  
Please access [www.cqc.com.cn](http://www.cqc.com.cn) for checking validity of the certificate.

This certificate and its relevant information can query in the website of Certification and Accreditation Administration of the People's  
Republic of China ( [www.cnca.gov.cn](http://www.cnca.gov.cn)).



谢肇煦  
Signed by: Xie ZhaoXu



**CHINA QUALITY CERTIFICATION CENTRE**

Section 9, No.188, Nansihuan(the South Fourth Ring Road) Xilu(West Road), Beijing 100070,China

<http://www.cqc.com.cn>

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2021年版