

# LS-1100 Dry Fluorescence Immunoassay Analyzer User Manual

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Operation Document



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# Chapter 1 Introduction

## 1.1 Intended Use

The basic principle of LS-1100 Dry Fluorescence Immunoassay Analyzer is to transform the fluorescent signal into a digital signal and calculate the concentration by the data processing system, which offers the advantages of high accuracy, strong stability and fast results. LS-1100 Dry Fluorescence Immunoassay Analyzer should be used only with in vitro diagnostic tests manufactured by Lansion Biotechnology Co.,Ltd. as per package insert provided with specific test kits used. For professional use and use at Point of Care. Please read this User Manual carefully before operation.

## 1.2 Scope of Application

LS-1100 Dry Fluorescence Immunoassay Analyzer works with in vitro diagnostic tests manufactured by Lansion Biotechnology Co.,Ltd. Its for in vitro diagnosis professionals and Point of Care use. It may be used in central laboratories of medical institutions, outpatient or emergency departments, clinical departments or medical services (such as community health centers), or medical center, etc. It can also be used in research laboratories. This product is used in conjunction with the fluorescent immunoassay reagent labeled with fluorescent microspheres produced by Lansion Biotechnology Co.,Ltd for in vitro quantitative detection of analytes in human samples.

## 1.3 Product and Model Type

Product name: LS-1100 Dry Fluorescence Immunoassay Analyzer

REF: L5-1100

Software Name: Dry Fluorescence Imunoassay Analyzer

Model: LS-1100

## Chapter 2 Components and Structure

### 2.1 Standard Equipment List

Packing List

No.	Description of Goods	Qty'	Remarks
1	Analyzer	1 unit	LS-1100
2	Power Adapter	1 pc	AC 100~240V 50/60Hz to DC 15V 4.0A
3	Certificate of Inspection	1 pc	
4	Power Line	1 pc	
5	Packing List	1 pc	
6	User Manual	1 pc	
7	QC Card	1 set	
8	Typing Paper	1 pc	

On receiving the box, please check the contents with this list and ensure that nothing is missing.

Note: If some parts are missing or damaged, please contact with us or our local sales representatives.

### 2.2 Fluorescence Immunoassay Analyzer

#### 2.2.1 External View





## 2.3 Technical Specification

Principle	Fluorescence Immunoassay
Measurement	Quantitative
Operating Conditions	<p>a) Temperature: 10°C~30°C;</p> <p>b) Relative humidity: 20%~70%, without condensate;</p> <p>c) Air pressure: 86.0kPa~106.0kPa;</p> <p>d) Other instructions: The workplace should try to avoid dust. Maintain good ventilation and avoid the strong electromagnetic field interference source.</p> <p>Make sure that the instrument is used under good grounding conditions.</p> <p>Do not place the instrument in a position where it is difficult to disconnect the device.</p>
Connecting Ways	RS232、RJ45、USB and Bluetooth
Dimensions (L×W×H)	225mm×152mm×105mm
Weight	1.5kg
Storage Conditions	<p>a) Temperature: -40°C~55°C;</p> <p>b) Relative humidity: ≤93%, without condensate;</p> <p>c) Air pressure: 50.0kPa~106.0kPa;</p> <p>d) Other instructions: Non-corrosive gas and well-ventilated place.</p> <p>The packaged analyzer shall be transported according to the conditions stipulated in the contract.</p> <p>Hoisting and transporting should be handled with care.</p> <p>To ensure the integrity of the master carton, pay attention to waterproof and moisture.</p>
Performance	Accuracy: the relative deviation of the certified reference material shall not exceed ± 15%.

	<p>Repeatability: The fluorescence intensity ratio (T/C) of T line/C line of three different QC cards shall be tested, and the coefficient of variation (CV) shall be <math>\leq 5\%</math>.</p> <p>Linearity: After testing the fluorescence intensity ratio of the T line/C line of three different QC cards, the linear correlation coefficient (r) not less than 0.990 .</p> <p>Stability: Test the fluorescence intensity ratio (T/C) of the T line/C line of three different QC cards, and the relative deviation between the measurement results at the 4th and 8th hours after the startup in stable state and the measurement results at the beginning of stable state should not exceed <math>\pm 5\%</math>.</p> <p>Note: These performance indicators will be tested when the finished product is manufactured, and can only be delivered after qualified.</p>
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## Chapter 3 Installation

### 3.1 Checklist upon opening the box

#### 3.1.1 Check before opening the box:

Before opening the box, check the packaging is in good condition and box was not damaged during transportation.

#### 3.1.2 Check after opening the box:

- ① Open the box carefully, check the contents according to 2.1 Standard Equipment List to ensure it is complete.
- ② Examine the analyzer power adapter to see whether it is in good condition. If any defects are found, please contact the manufacturer or your local distributor.

Note: Please keep the analyzers original box and packing materials for any future shipping/reference purpose.

### 3.2 Environmental Requirement

According to 2.3 Operating Conditions

Do not place the instrument close to the wall or in front of other obstacles, which will make it impossible to switch the instrument on and off normally. If the instrument fails and cannot be used according to the following steps, please disconnect the power supply of the instrument and contact the After-sales Department of Lansionbio.

### 3.3 Placement

 <p>Attention</p>	<p>a) Avoid direct sunlight or near heat source and wind regime. The bearing weight of the installed table must be over 40Kg.</p> <p>b) Not used in a strong magnetic and wet field.</p> <p>c) The instrument should be installed in the laboratory where the temperature and humidity meet the technical requirements.</p> <p>d) The instrument should avoid excessive dust erosion.</p> <p>e) The staff for installation and operation of the instrument must be trained professionally.</p> <p>f) Do not place the device in a position where it is difficult to operate the disconnect device.</p> <p>g) Correctly use the power adapter configured in this instrument, connect the power line and attach the power plug.</p> <p>h) Do not connect the power line first when installing the instrument to prevent accidental booting.</p> <p>i) If encountering the resistance when installing the components, please find out the cause, and avoid violence to prevent damage to</p>
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	<p>the instrument.</p> <p>j) Ensure that the space for instrument installation is large enough, and the back and left and right sides of the instrument should be at least 20cm from the wall, which is convenient for future operation LS-1100 and maintenance.</p> <p>k) Please do not use other power adapters to replace the originally equipped power adapter, so as to ensure the suitable power supply socket.</p>
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### 3.4 Analyzer Installation

Carefully unpack the analyzer and check the appearance. If there is any transport damage, please make a statement immediately. Check the analyzer and confirm the packing list to ensure the complete configuration. If you find that the configuration is not complete, please contact with our After-sales Department or the agent in your area.

Place the mainframe of the dry fluorescence immunoassay analyzer on the platform. Connect the power adapter and normally open the machine.

Note:

- a) Ensure the table is clean and tidy. The samples should be measured and containers are properly put aside and the samples are numbered.
- b) Ensure the instrument is connected to the correct power supply.
- c) Ensure the used test kits are not placed in the sampling parts.
- d) Confirm the good quality of the test kits and samples, no deterioration and the enough quantity.
- e) Confirm the QR card matched with the test kits.
- f) Safety and safety protection, safety signs and instructions in pre-operation and use.
- g) Please confirm the stability of the instrument installation to prevent the instrument slipping to hurt people.
- h) The operator needs to wear gloves in the operation.
- i) This instrument is only matched with the fluorescence immunoassay kit produced.
- j) The anti-dust of installation and use environment, indoor temperature 10~30°C, supposed to be equipped with air conditioner.
- k) All spare parts except printing paper and consumables must be provided by our company. Otherwise, our company won't be responsible for any problem.
- l) Power Supply: AC 100~240V、50~60Hz 、60VA.

- m) If the instrument is shut down for reasons such as blackout, please turn on the machine after 30 seconds.
- n) If there is something wrong with the instrument, please contact us in time. Without permission, anyone who is not authorized as professional maintenance staff by our company can't check and disassemble any parts of the instrument. Otherwise, our company won't be responsible for any problem.
- o) In the case of standardized operation and reasonable maintenance, the service life of the instrument is 5 years (no more than 8 hours per day).

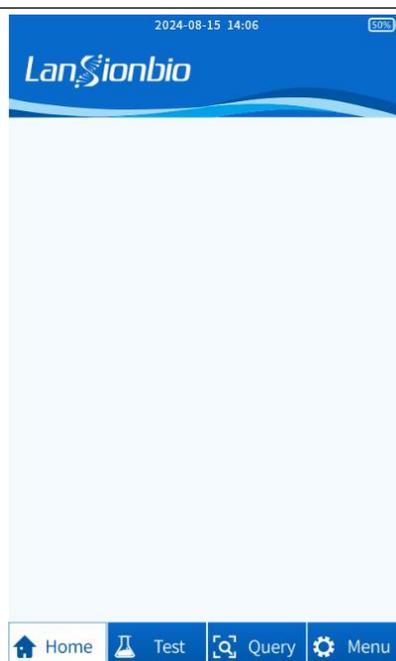
## Chapter 4 Directions for Use

### 4.1 Operation

#### 4.1.1 Software Module and Function

This product can be divided into 6 modules according to its functions and applications (see P1):

Test	This function can be used for sample tests (one-step tests), patient information input and so on.
Query	This function can search historical data and print selected records. Users can search through time, item, sample No. And date.
Item Management	This function is used to import the project data into the ID card. The data can be used as important reference data for this batch of reagents, and the project data can not be detected without the introduction of the project data.
Device QC	This function can control the quality and ensure the stability of the instruments.
System Setting	This function is used for the basic maintenance and setting of the instrument.
On/Off	This function can realize the one-switch turning on or off the instrument.



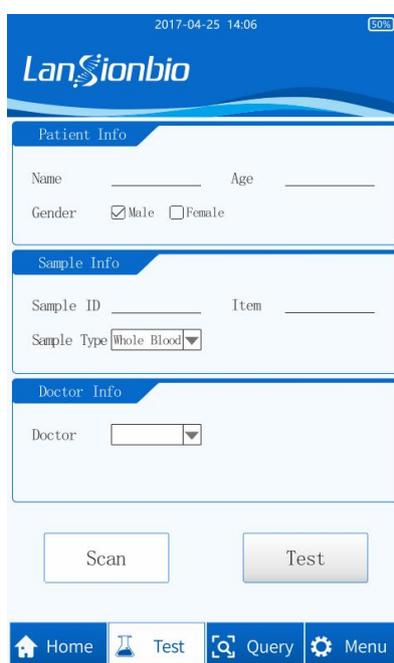
P1- Homepage

### 4.1.2 On/Off

This function is realized by the 'Start' on the interface. Long pressing for 2 seconds to turn on and long-pressing for 2 seconds to turn off.

### 4.1.3 Test

- a) When the initialization is completed, click the 'Test' on the homepage to enter the measure page (see P2).
- b) After entering the sample detection page, you can input the relevant information of the sample. And then insert the strip to be checked and click on the test button of the sample detection page to start the detection.
- c) After test results pop out, the user can click the print button on the test result page to print the result.



P2-Test

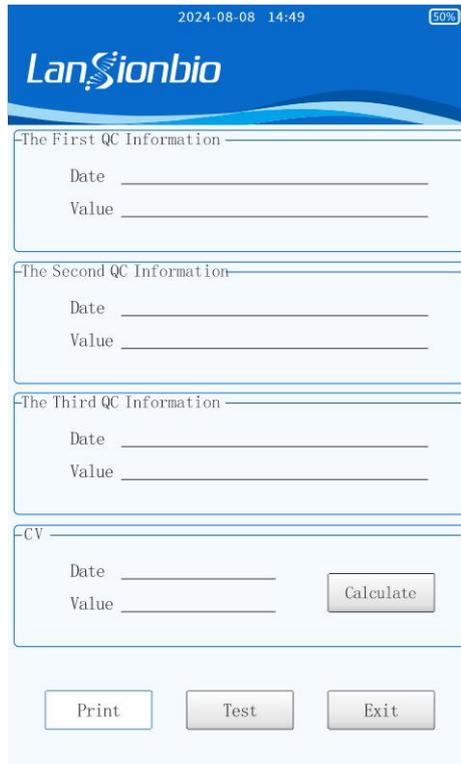
### 4.1.4 Query

- a) On the homepage, click the 'Query' button and enter into the resulting search (see P3).
- b) On this page, users can manually enter one or more of the conditions to search for the corresponding detection record. Click on the "Print" button on the search page to print out the current record you need.



#### 4.1.6 Device QC

- a) On the homepage, click on the 'Device QC' button and enter the Q.C. page (see P5).
- b) After inserting the QC Card, click the 'Test' button to go on the quality control. After quality control ends, it pops out the T/C Value. Retest the same card for 3 time and the coefficient of variation (CV) shall be  $\leq 5\%$ . And if the CV is  $>5\%$ , please contact with the manufacturer.



The screenshot shows the 'P5-Device QC' software interface. At the top, there is a blue header with the 'Lansionbio' logo on the left, the date and time '2024-08-08 14:49' in the center, and a battery status icon showing 50% on the right. Below the header, the interface is divided into four main sections for data entry:

- The First QC Information:** Contains two input fields labeled 'Date' and 'Value'.
- The Second QC Information:** Contains two input fields labeled 'Date' and 'Value'.
- The Third QC Information:** Contains two input fields labeled 'Date' and 'Value'.
- CV:** Contains two input fields labeled 'Date' and 'Value', and a 'Calculate' button to the right.

At the bottom of the interface, there are three buttons: 'Print', 'Test', and 'Exit'.

P5-Device QC

### 4.1.7 Setting

a) After the completion of turn-on self initialization, click on the 'Setting' button and enter the system setting page (see P6).



P6-System Setting

b) Click on the 'User Info' button to enter the user information setting page. On this page, users can manually enter the user information. Click on the 'Confirm' button to save the setting.

c) Click on the 'Print Setting' button to enter the print setting page. In this page, users can choose print contents and whether to print the test results automatically. Click on 'Confirm' button to save the setting.

d) Click on the 'Date & Time' button to enter the time setting page. On this page, users can manually enter the time. Click on the 'Confirm' button to save the setting.

e) Click on the 'Language' button to enter the language setting page. On this page, users can manually and select the language. Click on the 'Confirm' button to save the setting.

f) Click on the 'About Device' button to enter the device information page. On this page, users can check the version information and serial number of the device;

g) Click on the 'LIS' button to enter the LIS setting page. On this page, users can select the LIS connecting methods. Click on the 'Confirm' button to save the setting.

h) Click on the 'Debugging Mode' button and need to enter the password to enter the engineer commissioning page (see P7). This page is only for supplier engineers to maintain the device, not open to the users.



P7-Password

## 4.2 Network security

### 4.2.1 Operating environment

Processor: STM429

External memory: FLASH

Internal memory: SDRAM

Internal sweep: MJ-2000

External sweep: MJ-2000

Power supply: 15V power supply

Screen: 7" LCD

### 4.2.2 Software environment

Editing environment: KEIL V5.02

Writing language: C

Debugging tool: J-LINK

Download tool: J-LINK

### 4.2.3 Data interfaces

The LS-1100 instrument has Bluetooth (optional), USB, network and RS232 serial ports; the Bluetooth transmission uses the standard 4.0 protocol and is only used to connect to an external printer; the USB is only used for software maintenance and upgrading; the network and RS232 serial ports are used for the LIS to upload test data.

### 4.2.4 User access control

User identification methods

- a) Bluetooth user type is normal user, only used for wireless connection to an external printer of a customized model.
- b) USB user type is normal user, only used for software maintenance and upgrade.
- c) RS232 and network port user types are normal users and can be used to upload LIS. User types and permissions.

The system carries out user access control by assigning different access rights, which are divided into engineer and normal users.

Engineer's permission: access to the engineer's debugging interface can be made through the access password.

Ordinary user rights: The user type is distinguished by the access password, and ordinary users do not have the right to enter the engineer debugging interface.

#### **4.2.5 Security software updates**

Lansionbio's customer service team will monitor and record feedback on the released product and assess whether there are any problems with the software. When a software issue is judged to require a change to the released product, Lansionbio will follow the design change process by the design development control procedures and the software development life cycle procedures.

The product does not support partial updates to system software or clinical applications. Before the updated software arrives on-site, all changes are rigorously tested to ensure that the system meets safety, reliability and performance standards. Software updates are carried out by authorized Lansionbio field service engineers. This is the only way to update the product software.

Software security is regularly assessed internally, security vulnerabilities are monitored and impact assessments are carried out. If an unacceptable risk is identified that poses a threat to the safety and effectiveness of the product, the company will implement a software update.

## Chapter 5 Daily Maintenance and Cleaning

### 5.1 Maintenance

Use a medical alcohol cotton ball (75%) to clean and wipe around the location of the test port of the instrument.

The surface should be cleaned in the above manner after each use.

 <p>Attention</p>	<p>Shutdown is necessary before maintenance, please refer to the section on operating procedures, methods and precautions for shutdown.</p>
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### 5.2 Calibration

The device shall be calibrated on a regular basis of using a QC card (recommended once for three month) to ensure the device's measurement results accurate.

Method: in the Device QC interface, use the same QC card to test 10 times, and the repeatability  $\leq 5\%$  is qualified.

### 5.3 Maintenance Procedure

#### 5.3.1 Monitor Maintenance

Due to temperature , power supply voltage changes or other factors , the monitor may not display, or the handwriting shown is too light or to dark.The person concerned should be requested to maintain the service.

#### 5.3.2 Other Maintenance

After the analyzer has been used for 6 months, please contact a professional engineer for equipment maintenance.

### 5.4 Precautions

 <p>Biohazard</p>	<p>The reagents and specimens used in the instrument may be corrosive or contagious. Please pay attention to the self-protection when operating the instrument and waste centralized processing.</p>
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	Warning	Before operating the instrument, please check the instructions first and strictly operate it by its steps.
	Attention	The instrument has many dynamic parts in the working process, and the dynamic parts should not be touched by hand to avoid injury.
	Beware of electric shock	There is the danger of high temperature and high voltage when the instrument is working. To avoid personal safety hazards, please pay attention to the mark on the instrument when using the instrument.

- a) The dry fluorescence immunoassay analyzer is only suitable for the in-vitro analysis of human blood or urine samples, no other specific use.
- b) Only the test strip mentioned in this manual can be adopted, otherwise the obtained results might be unreliable.
- c) Read this manual carefully before operating and keep it properly for future use.
- d) If the instrument gives off an unusual smell or smoke, cut off the power and contact with service engineers immediately, otherwise it would result in a fire, electric shock or personal injury.
- e) If any liquid enters in the interior of the instrument, cut off the power and contact with service engineers immediately, otherwise it would result in a fire, electric shock or personal injury.
- f) Take proper safeguard measures according to health and safety standards in local country, including wearing protective goggles, surgery gloves and laboratory coat (even more).
- g) The operator or charge person of the instrument shall be trained upon attention matters and operation guidance of the instrument by the after-sale engineer, and the instrument only can be operated after the training.
- h) In the case of standardized operation and reasonable maintenance, the service life of the instrument is 5 years (no more than 8 hours per day).

## 5.5 Maintenance and repair when out of use for a long time

Firstly remove the reagent card and clean the device refer to the daily cleaning procedures , and then lubricated maintenance , with a dust cover for the device, stored in a dry and shady place

## Chapter 6 Service, Repair and Disposal

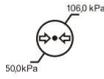
Error code	Code definition	Error Type	Recovery method
100	System initialization error	Unrecoverable error	Restart the analyzer. If problems are not solved, please contact Lansionbio's technical support team.
101	AD initialization error	Unrecoverable error	Restart the analyzer. If problems are not solved, please contact Lansionbio's technical support team.
102	Scanner error	Unrecoverable error	Restart the analyzer. If problems are not solved, please contact Lansionbios technical support team.
103	Motor error	Unrecoverable error	Restart the analyzer. If problems are not solved, please contact Lansionbio's technical support team.
104	Optocoupler error	Unrecoverable error	Restart the analyzer. If problems are not solved, please contact Lansionbio's technical support team.
105	Temperature sensor error	Unrecoverable error	Restart the analyzer. If problems are not solved, please contact Lansionbio's technical support team.
106	Limit switch error	Unrecoverable error	Restart the analyzer. If problems are not solved, please contact Lansionbio's technical support team.
107	Scan time out (Sample code error)	Recoverable error	Rescan the code. If problems are not solved, please contact Lansionbio's technical support team.
108	No parameter on item (not read corresponding item parameter during the test)	Recoverable error	Enter the item management interface to add the corresponding item and batch to re-test. If problems are not solved, please contact Lansionbio's technical support team.
109	Read the wrong item parameter or unscanned (wrong or unscanned Itemcode)	Recoverable error	Check the code with no issue and scan the code again. If problems are not solved, please contact Lansionbio's technical support team.

200	Reagent strip not inserted into the detection position	Recoverable error	Insert the reagent strip into the detection position to re-test. If problems are not solved, please contact Lansonbios technical support team.
201	Abnormal reagent strip (cannot detect C line)	Recoverable error	Confirm whether the sample is added to the reagent strip and re-test. If problems are not solved, please contact Lansionbio's technical support team.
202	Overdue reagent strip	Recoverable error	Confirm whether the date setting of the analyzer is wrong, and replace a batch of undue reagent strip to re-test after confirmation. If problems are not solved, please contact Lansionbio's technical support team.
203	The currently measured reagent is not a QC reagent strip.	Recoverable error	Take the QC reagent strip to re-test. If problems are not solved, please contact Lansionbio's technical support team.

### Alarm analysis and handling methods

If the above phenomenon occurs and the customer cannot handle it by himself, please contact our company in time. If the above involves problems with instrument components, the company's after-sales engineers will need to determine and provide replacement parts.

## Chapter 7 Manufacturer Information

Symbols	Description
	Attention
	Biological risks
	Beware of electric shocks
	Electronic equipment waste
	This side up
	Fragile, please handle with care
	Keep dry
	Store between -40~55°C
	Packaging: Humidity limits
	Packaging: Atmospheric pressure

	<p>Consult instructions for use</p>
	<p>Manufacturer</p>
	<p>EU Authorized Representative</p>
	<p>CE mark</p>
	<p>For in vitro diagnostic use only</p>
	<p>Serial Number</p>
	<p>Use by date</p>



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Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Email: info@lotusnl.com

Revision Date: March 21, 2025

Release Version: V1

Version Number: V06

## Warranty Card

User Information	Product Repair Maintenance Record	Receipt																																																
Product Name   _____	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 25%;">Data</th> <th style="width: 25%;">Service Type</th> <th style="width: 25%;">Service Item</th> <th style="width: 25%;">Engineer</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table>	Data	Service Type	Service Item	Engineer																																													Product Name   _____
Data		Service Type	Service Item	Engineer																																														
Product Model   _____	Serial Number   _____																																																	
Serial Number   _____	ProductModel   _____ Delivery Date   _____																																																	
Delivery Date   _____	Consumer Department   _____																																																	
Consumer Department   _____	Contact Address   _____																																																	
Contact Address   _____	Contact Person   _____																																																	
Contact Person   _____	Contact Number   _____																																																	
Contact Number   _____	Delivery Department   _____ Consumer Department   _____ <small>(sign and stamp) (sign and stamp)</small>																																																	
Delivery Representative   _____																																																		
Delivery Department   _____																																																		

This is a return receipt. For the convenience of after-sales service, please submit this to the delivery representative to return to our company for registration, or mail it directly to our company.

User Acceptance:

Product Integrity:

Complete       Defective

Product Performance:

Normal       Abnormal

User Evaluation:

Product Satisfaction Evaluation:

Satisfied       Generalized       Dissatisfied

Evaluation of service personnel's attitude:

Satisfied       Generalized       Dissatisfied

User Comments:

- (1) This card, which is the warranty certificate, needs to be shown for product maintenance. The warranty date will be subject to manufacture date if the card is lost.
- (2) Our commitment: the delivery department will repair free of charge if product quality problems occur within 12 months from the date of delivery.

Add : No.6 Qiande Road, Science Park, Jiangning District, 210000 Nanjing, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA

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