[Product Name]

Generic name: Detection Kit for 2019-nCoV (PCR-Fluorescence)

[Package Specifications]

Large package, 24 tests/kit; Large package, 48 tests/kit; Large package, 96 tests/kit.

Single tube, 24 tests/kit; Single tube, 48 tests/kit; Single tube, 96 tests/kit.

[Intended Use]

This kit is used for the in vitro qualitative detection of 2019 novel coronavirus (2019-nCoV) ORF1ab and N gene in the throat swabs and sputum specimens of suspected COVID-19 patients, clustering cases and others needing diagnosis or differential diagnosis for 2019-nCoV.

For the definitions of "suspected cases" and "clustering cases", refer to the documents such as *Diagnosis and Treatment Scheme for Pneumonia Patients Infected by 2019-nCoV* and *Prevention and Control Scheme for Pneumonia Patients Infected by 2019-nCoV*.

This kit is only used for the auxiliary diagnosis of related cases during the pneumonia epidemic caused by the 2019-nCoV infection and emergency storage of in vitro diagnostic reagents for this epidemic, and it should not be used as regular in vitro diagnostic reagents for clinical diagnosis and comply with the relevant documents such as *Diagnosis and Treatment Scheme for Pneumonia Patients Infected by 2019-nCoV* and *Prevention* and *Control Scheme for Pneumonia Patients Infected by 2019-nCoV* in using this kit.

Detection of 2019-nCoV RNA shall meet the requirements of Laboratory Detection for 2019-nCoV Infected Pneumonia Technical Guideline and other documents, so as to carry out the regulations on biosafety.

The detection results of this kit are for clinical reference only and should not be used as the sole criteria for clinical diagnosis. It is recommended to conduct a comprehensive analysis on the condition in combination with the clinical manifestations of the patient and other laboratory tests.

[Test Principle]

This kit is based on one-step RT-PCR technique. In practice, 2019-nCoV ORF1ab and N genes are selected as amplification target regions. Specific primers and fluorescent probes are designed for the detection of 2019-nCoV RNA in the specimen. This kit also includes an endogenous internal standard detection system, which is used for monitoring over the processes of specimen collection, RNA extraction and PCR amplification, thereby reducing false negative results. In addition, this kit adds an anti-pollution component (uracil DNA glycosylase, which is UDG enzyme), whose mechanism of action is to selectively hydrolyze and break the uracil glycosidic bond in double-stranded or single-stranded DNA containing dU to form the DNA chains with missing bases, which would be further hydrolyzed and broken under alkaline media and high temperature, thus being eliminated.

[Main Components]

Component name		Specification	Quantity	Main constituents
PCR detection	2019-nCoV PCR reaction	459μL/ tube	1	Specific primers, probes, tris(hydroxymethyl)aminomethane-hydrochloric

reagents (Large package, 24 tests/kit)	solution A			acid buffer
	2019-nCoV PCR reaction solution B	102μL/ tube	1	Hot start Taq abzyme enzyme, Taq enzyme, C-MMLV enzyme, dNTPs, UDG enzyme, RNasin
PCR detection reagents (Large package, 48 tests/kit)	2019-nCoV PCR reaction solution A	918μL/ tube	1	Specific primers, probes, tris(hydroxymethyl)aminomethane-hydrochloric acid buffer
	2019-nCoV PCR reaction solution B	204μL/ tube	1	Hot start Taq abzyme enzyme, Taq enzyme, C-MMLV enzyme, dNTPs, UDG enzyme, RNasin
PCR detection reagents (Large package, 96 tests/kit)	2019-nCoV PCR reaction solution A	918μL/ tube	2	Specific primers, probes, tris(hydroxymethyl)aminomethane-hydrochloric acid buffer
	2019-nCoV PCR reaction solution B	204μL/ tube	2	Hot start Taq abzyme enzyme, Taq enzyme, C-MMLV enzyme, dNTPs, UDG enzyme, RNasin
PCR detection reagents (Single tube, 24 tests/kit)	2019-nCoV PCR reaction tube (Unlabeled tube)	1 test/tube	24	Specific primers, probes, tris(hydroxymethyl)aminomethane-hydrochloric acid buffer Hot start Taq abzyme enzyme, Taq enzyme, C-MMLV enzyme, dNTPs, UDG enzyme, RNasin
PCR detection reagents (Single tube, 48 tests/kit)	2019-nCoV PCR reaction tube (Unlabeled tube)	1 test/tube	48	Specific primers, probes, tris(hydroxymethyl)aminomethane-hydrochloric acid buffer Hot start Taq abzyme enzyme, Taq enzyme, C-MMLV enzyme, dNTPs, UDG enzyme, RNasin
PCR detection reagents (Single tube, 96 tests/kit)	2019-nCoV PCR reaction tube (Unlabeled tube)	1 test/tube	96	Specific primers, probes, tris(hydroxymethyl)aminomethane-hydrochloric acid buffer Hot start Taq abzyme enzyme, Taq enzyme, C-MMLV enzyme, dNTPs, UDG enzyme, RNasin

Quality Control (Large package, 24 tests/kit; Large package, 48 tests/kit; Single tube, 24 tests/kit; Single tube, 48 tests/kit)	2019-nCoV negative control	450μL/ tube	1	Pseudovirus containing 2019-nCoV internal standard fragments(RNase P gene), TE
	2019-nCoV positive control	450μL/ tube	1	Pseudovirus containing 2019-nCoV target fragments, pseudovirus containing 2019-nCoV internal standard fragments(RNase P gene), TE
Quality Control (Large package, 96 tests/kit; Single tube, 96 tests/kit)	2019-nCoV negative control	450μL/ tube	2	Pseudovirus containing 2019-nCoV internal standard fragments(RNase P gene), TE
	2019-nCoV positive control	450μL/ tube	2	Pseudovirus containing 2019-nCoV target fragments, pseudovirus containing 2019-nCoV internal standard fragments(RNase P gene), TE

Note: The above components in different batches of kits cannot be interchangeable.

Extraction reagents do not contain in this kit but necessary for detection: RNA extraction or purification reagents(YSXB No. 20170583 and YSXB No. 20200293 produced by Da An Gene Co., Ltd. of Sun Yat-sen University). YSXB No. 20200293 is not suitable for preservation solutions containing guanidine salts.

Preservation solutions do not contain in this kit but necessary for detection:

Throat swab: 1) Disposable virus sampling tube(YSXB No. 20190041) produced by Shenzhen Zijian Biological Technology Co., Ltd.; 2) Disposable virus sampling tube(YSXB No. 20180466 produced by Shenzhen Huachenyang Technology Co., Ltd.; 3) Specimen preservation solution(YSXB No. 20190369) produced by Shenzhen MRC Technology Co., Ltd.; 4) Specimen preservation solution(YSXB No. 20160299 containing guanidine salts) produced by Guangzhou BDS Biological Technology Co., Ltd.; 5) Virus sampling kit(JXZZ No. 20182400236) produced by Yocon Biology (Beijing) Co., Ltd.; 6) Saline, that is, 0.9% sodium chloride aqueous solution; 7) Phosphate buffer, that is, PBS buffer.

Sputum: 1) Nucleic Acid Extraction Reagent (HMXB No. 20200070) produced by Shanghai ZJ Bio-Tech Co., Ltd.; 2) Normal saline, that is, 0.9% sodium chloride aqueous solution; 3) Phosphate buffer, that is, PBS buffer; 4) Sputasol(GXB No. 20140121) produced by Thermo Fisher (Shanghai) Instrument Co., Ltd.; 5) Virus sampling

kit(JXZZ No. 20182400236) produced by Yocon Biology (Beijing) Co., Ltd.; 6) Saline containing 0.1mg/ml proteinase K.

Description of negative/positive control: The 2019-nCoV positive control is pseudovirus containing 2019-nCoV target fragments and 2019-nCoV internal standard fragments(RNase P gene), while the negative control is pseudovirus containing 2019-nCoV internal standard fragments(RNase P gene). During use, they should be involved in extraction and should be considered as infectious substance. They shall be handled and disposed in accordance with relevant regulations.

[Storage Conditions and Validity Date]

The kit is stored at -20±5℃, and the validity period is 6 months.

See the product label for the date of manufacture and validity of the kit.

[Applicable Instruments]

AGS4800, AGS8830-8, AGS8830-16, ABI 7500.

[Specimen Requirements]

1. Applicable specimen types: Throat swab and sputum.

2. Specimen collection (aseptic technique) The sampling process should in accordance with the *Guideline for Laboratory Detection Technology for 2019-nCoV Infected Pneumonia* issued by the National Health Commission of People's Republic of China.

2.1 Throat swab: Wipe the tonsil and posterior pharyngeal wall with two plastic rod swabs with polypropylene fiber heads or the swabs included in sampling liquid that specified in the instructions at the same time, and immerse the swab heads into the sampling tube containing 3mL sampling liquid, discard the swabs tail and tighten the cap.

2.2 Sputum: Collect the coughed sputum in the 50mL screw-cap test tube which containing 3mL sampling liquid.

It had been verified that the preservation solution containing guanidine salt (the specimen preservation solution(YSXB No. 20160299) produced by Guangzhou BDS Biological Technology Co., Ltd. and the nucleic acid extraction reagent(HMXB No. 20200070) produced by Shanghai ZJ Bio-tech Co., Ltd) can be used to inactivate the virus in the specimen. The specimen can also be inactivated by heating at 56℃ for 30 minutes, 56℃ for 2 hours or 60℃ for 30 minutes.

3. Specimen storage

The specimens for virus isolation and RNA detection should be tested as soon as possible. The specimens that can be detected within 24 hours can be stored at 4℃; those cannot be detected within 24 hours can be stored at -70℃ or below for 6 months (Tentative). If there are no -70℃ storage conditions, those to be tested specimens can be stored at -20℃ refrigerator for 10 days. The specimens freezing and thawing rounds should not exceed 5 rounds.

[Test Method]

1. Specimen processing and RNA extraction (specimen processing area)

1.1 Throat swab: Take 200μL of specimen and use RNA extraction or purification reagent(YSXB No. 20170583) for RNA extraction. For throat swab specimens without guanidine salts sampling solution, take 100μL of specimen and use RNA extraction or purification reagent(YSXB No. 20200293) for RNA extraction.

1.2 Sputum: Take 200μL of specimen and use RNA extraction or purification reagent(YSXB No. 20170583) produced by Da An Gene Co., Ltd. of Sun Yat-sen University for RNA extraction.

1.3 Both negative and positive control in this kit are involved in the extraction process.

2. PCR reagent preparation (reagent preparation area)

2.1 Large package reagent: Take out the 2019-nCoV PCR reaction solution A and 2019-nCoV PCR reaction solution B from the kit. After thawing at room temperature, oscillate to mix. Centrifuge at 8,000 rpm for a few seconds before use.

Take N PCR reaction tube (N = number of specimens to be tested + 2019-nCoV negative control + 2019-nCoV positive control). A single-reaction amplification system is prepared as follows:

2019-nCoV PCR reaction solution A	2019-nCoV PCR reaction solution B	Amplification system
17μL	3μL	20μL

After thoroughly mixing the components, centrifuge for a short time to make all the liquid on the tube wall fall to the bottom of the tube, and then aliquot 20μL of the amplification system into each PCR tube.

2.2 Single tube reagent: Use 2019-nCoV PCR reaction tube directly.

3. Sample Adding (specimen preparation area)

Add 5μL each of the processed 2019-nCoV negative control, the to be tested specimens RNA, and the 2019-nCoV positive control into the PCR reaction tubes, cover the tubes tightly.

3.1 Large package reagent: Transfer them to the amplification detection area after 15 seconds instant centrifugation.

3.2 Single tube reagent: Instant centrifuge for 15 seconds, oscillate to mix for 10 seconds, instant centrifuge for 15 seconds again, and then transfer them to the amplification detection area.

4. PCR amplification (amplification detection area)

4.1 Place the reaction tube in the specimen sink of the instrument.

4.2 Setting of ABI 7500 Instrument

4.2.1 Open the "Setup" window, set the negative control (NTC), positive control and unknown specimen (Unknown) in the corresponding order, and set the specimen name in the column of "Sample Name"; the probe detection modes are set as: Repoiter1: FAM, Quencher 1: NONE; Reporter2: VIC, Quencher2: NONE; Reporter3: Cy5, Quencher3: NONE; Passive Reference: NONE.

4.2.2 Open the "Instrument" window and set the cycle conditions as follows:

Stage	Reps	Target (℃)	Running Time	Data Collection
1	1	50	00：02：00	
2	1	95	00：02：00	
3	10	95	00：00：05	
		60	00：00：35	
4	32	95	00：00：05	
		60	00：00：35	√

After setting, save the file and run the program.

4.3 Setting of AGS4800 Instrument

4.3.1 Turn on the computer first, then turn on the power of the quantitative PCR instrument host, and finally start the AGS4800 software, select the corresponding layer (upper, middle, and lower).

4.3.2 Click the New button, edit the experiment name and file path in the experiment name, save and click OK to open a blank file.

4.3.3 Program parameter: in the program parameter page. The amplification parameters are as follows::

Program stage	Cycles	Target (℃)	Running Time	Read fluorescence
1	1	50	00：02：00	
2	1	95	00：02：00	
3	10	95	00：00：05	
		60	00：00：10	
4	32	95	00：00：05	
		60	00：00：10	√

4.3.4 Specimen parameters: Click on the specimen parameter page, and select the current program dye settings (channel 1 FAM, channel 2 VIC, channel 5 Cy5) in the shortcut key of the home menu, and select the specimen well in the 48-well table below, and select FAM, VIC, and Cy5 on the edge of the picture for dye type at right side and select the corresponding specimen type from the buttons below: negative control, unknown specimen, etc.

4.3.5 Start amplification: After confirming that the 48-well plate is properly placed in the host, click the start button to start the PCR cycle.

4.3.6 Monitoring process: Switching the program running page, which can display the actual situation of the PCR curve gradually increasing as the cycle increases. If the marker is FAM, VIC or Cy5, only the change of the corresponding probe will be displayed.

4.3.7 Save the result: After the program ends, it is automatically saved to the file path.

4.4 Setting of AGS8830-8 and AGS8830-16 Instrument

4.4.1 Turn on the AGS8830 instrument.

4.4.2 Click “custom” to set the program.

4.4.3 Program parameters: in the program parameter page. The amplification parameters are as follows:

Program stage	Cycles	Target (℃)	Running Time	Read fluorescence
1	1	50	00：02：00	
2	1	95	00：02：00	
3	10	95	00：00：05	
		60	00：00：10	
4	32	95	00：00：05	
		60	00：00：10	√

4.4.4 Dye parameters: click on the dye parameter page, select the current program dye settings (channel 1 FAM, channel 2 VIC, channel 4 Cy5), then select the specimen well, and select specimen type: negative control, positive control products, unknown specimens, etc.

4.4.5 Start amplification: After confirming that the PCR reaction tube is properly placed in the host, click the start button to start the PCR cycle.

4.4.6 Monitoring process: Switching the program running page,which can display the actual situation of the PCR curve gradually increasing as the cycle increases. If the marker is FAM, VIC or Cy5, only the change of the corresponding probe will be displayed.

4.4.7 Save the result: After the program ends, it is automatically saved to the file path.

5. Analysis of results (please refer to the instruction for use of each instrument for setting, taking ABI7500 Instrument as an example)

After reaction, the results would be saved automatically. Adjust the Start value, End value and Threshold value of Baseline according to the image after analysis (the user can adjust them according to the actual conditions, the Start value can be set at 3~15 and the End value at 5~20, adjust the Threshold value at the Log chart window, enabling the Threshold value line to be at the log phase, the amplification curve of the negative control to be straight or lower than the threshold line), click Analysis to obtain the analysis result automatically, and read the test result in the "Report" window.

6. Quality control

2019-nCoV negative control: no Ct value or obvious amplification curve for FAM and VIC detection channels, and Ct≤25 for Cy5 channel;

2019-nCoV positive control: Ct value ≤ 22 for FAM and VIC detection channel;

The above requirements must be met at the same time in the same experiment; otherwise, the experiment is invalid and needs to be carried out again.

Note: FAM channel is N gene; VIC channel is ORF1ab gene, Cy5 channel is internal standard gene.

7. Determination of results

FAM channel	VIC channel	Cy5 channel	Result judgment
Ct value＞30 or no Ct value	Ct value＞30 or no Ct value	Ct value≤30	Negative
Ct value≤30	Ct value≤30	Has or no amplification curve	Positive

Ct value≤30	Ct value＞30 or no Ct value	Has or no amplification curve	Retest: specimens of which internal standard Ct value＞30 or without amplification curve need to be re-sampled and tested; specimens of which internal standard Ct value ≤30 can be re-tested with the extracted RNA or re-tested from sampling.
Ct value＞30 or no Ct value	Ct value≤30	Has or no amplification curve	
Ct value＞30 or no Ct value	Ct value＞30 or no Ct value	Ct value ＞ 30 or no amplification curve	

The re-test results are interpreted as follows:

The retest result of FAM channel or VIC channel is positive (Ct value ≤ 30), Cy5 channel is positive (Ct value ≤ 30), the specimen can be judged to be positive for 2019-nCoV;

The retest result of FAM channel and VIC channel are both negative (Ct value> 30, or no Ct value), Cy5 channel is positive (Ct value ≤ 30), the specimen can be judged to be negative for 2019-nCoV;

The retest result of FAM channel, VIC and Cy5 channel retest are all negative (Ct value>30, or no Ct value), conduct re-testing from sampling process.

[Positive Judgment Value]

According to the clinical specimen test results, the positive judgment value of the target gene N and ORF1ab by this kit was determined by the ROC curve method as 30, and the positive judgment value of the internal standard gene RNaseP is 30.

[Interpretation of Test Results]

1. Negative and positive control should be tested in each test. Only when the control meet the quality control requirements can the test results be determined;

2. When the FAM and VIC detection channels are positive, the result of the Cy5 channel (internal standard channel) may be negative due to the competition of the system;

3. The report is recommended to be in the following format:

The format of negative results report is: negative for 2019-nCoV RNA ;

The format of positive result report is: positive for 2019-nCoV RNA.

[Limitations of Test Method]

1. Negative results can not rule out 2019-nCoV infection, and it is necessary to rule out factors that may produce false negatives, including: poor specimen quality; factors of technology itself, such as virus mutation, PCR inhibition, etc.

2. The specimen test results are related to the quality of specimen collection, processing, transportation and storage. Unreasonable specimen collection, transfer, storage and processing may lead to incorrect test results;

3. Cross contamination is not well controlled during specimen processing, and a false positive result may appear;

4. The genetic mutation of the virus during the epidemic period may also lead to false negative results;

5. The test results of this kit are for clinical reference only. The clinical diagnosis and treatment of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests and treatment response.

[Product Performance Indicators]

Product analysis performance evaluation results:

1. The analytical sensitivity of this kit is 500 copies/mL. Test the national sensitivity reference product S, which meets the requirements.

2. Cross-reaction: this kit has no cross-reactivity with other pathogens (such as influenza A virus (H1N1, H1N1(2009), H3N2, H5N1, H7N9), influenza B virus (B/Yamagata, B/Victoria), parainfluenza virus (type I, type II, type III), respiratory syncytial virus (type A, type B), and nasal infection) Rhinovirus C, adenovirus (type 1, type 2, type 3, type 4, type 5, type 7 and type 55), enterovirus (type A, type B, type C and type D), human metapneumovirus, Epstein-Barr virus, measles virus, human cytomegalovirus, rotavirus, norovirus, mumps virus, varicella-zoster virus and mycoplasma pneumoniae Streptococcus pneumoniae, Streptococcus pyogenes, Klebsiella pneumoniae, Mycobacterium tuberculosis, Aspergillus fumigatus, Nostoc albicans, Candida glabrata, Cryptococcus neoformans, coronavirus (NL63, OC43, HKU1 229E), SARS coronavirus and MERS coronavirus) and human genomic DNA .

3. Exogenous interfering substances: There is no interference on the detection results of the kit when therapeutic drugs for 2019-nCoV present in the specimen, such as phenylephrine (100μg/mL), oxymetazoline (100μg/mL), sodium chloride (0.9%), beclomethasone (100μg/mL), dexamethasone (100μg/mL), flunisone (100μg/mL), triamcinolone acetonide (100μg/mL) (100μg/mL), oseltamivir (100μg/mL), peramivir (100μg/mL), lopinavir (100μg/mL), mupirocin (100μg/mL), levofloxacin (100μg/mL), azithromycin (100μg/mL), tobramycin (100μg/mL), ritonavir (100μg/mL), meropenem (100μg/mL) and Abidor (100μg/mL) and ceftriaxone (100μg/mL).

4. Endogenous substances such as whole blood (10%) and mucus (20μg/mL) that may be present in sputum and throat swab specimens have no interference with the test results of the kit.

5. Precision: the coefficient of variation (CV) of intra-batch/inter-batch precision of strongly positive specimen, within-day/day-to-day precision, and precision between different operators are not more than 5%; the coefficient of variation of precision of detecting national reference material R is less than 5%..

6. Coincidence rate of positive reference materials: The coincidence rates of 5 enterprise positive reference materials is 100%. The national reference products P1-P7 are tested and meet the requirements.

7. Coincidence rate of negative reference materials: the coincidence rate of the 10 enterprise negative reference materials is 100%; the national reference materials N1-N22 were tested and the results are negative.

8. Clinical evaluation: Clinical trial including 604 specimens were completed in 3 clinical institutions. Compared with similar reagents on the market, the positive coincidence rate was 97.64%, the negative coincidence rate was 99.71%, and the total coincidence rate was 98.84%.

[Precautions]

1. This product is used for in vitro test only. Please read the Instruction carefully before experiment;

2. In order to avoid any potential biological hazards in the specimens, the test specimens should be regarded as infectious and avoid contact with human skin and mucosa; the specimens should be handled in a biosafety cabinet that prevents aerosol outflow. The test tubes and tips used in the specimen preparation area should be poured into a container containing disinfectant and sterilized with the medical wastes before discarding; specimen handling and processing must comply with relevant regulations: including the *General Biosafety Standard for Microbiological and Biomedical Laboratories* and *Regulations on the Administration of Medical Wastes* issued by the Ministry of Health;

3. Product processing: After PCR, the product is likely to cause pollution. All reaction tubes should be put into a biosafety garbage disposal bag or other container by the person who is no longer involved in the test that day, and then discarded after these reaction tubes are completely sealed;

4. Avoid RNase contamination during the whole process. Wear work clothes, disposable gloves and masks during the experiment. Complete the operation in a well-ventilated chemical hood or biosafety cabinet that is clean, disinfected and sterilized by ultraviolet light to prevent any harmful substances from entering the respiratory tract;

5. Use autoclaved disposable centrifuge tubes and tips or purchase DNase-free and RNase-free centrifuge tubes and tips;

6. Thaw PCR detection reagents completely before use, and use after centrifugation at 8000 rpm for several seconds, and avoid repeated freezing and thawing;

7. False positive result may appear if cross contamination is not well controlled during specimen processing;

8. The laboratory management shall be in strict accordance with the management practice of PCR gene amplification laboratory. The laboratory personnel must receive professional training. The experimental process shall be strictly divided into different areas (reagent preparation area, specimen preparation area, amplification test area). All consumables shall be sterilized for single use. Special instruments and equipment shall be used in each stage of test. No cross-utilization of the supplies of each area in each stage shall be allowed;

9. After the experiment, 10% hypochlorite or 75% alcohol should be used to disinfect the worktable and pipette, followed by exposing them in ultraviolet light for 20-30 minutes;

10. After the RNA extraction of specimen is completed, it is recommended to proceed to the next process immediately;

11. Quality control must be performed over each test.

12. When using nucleic acid extraction or purification reagents (YSXB No. 20200293), it is recommended to mix the specimen with nucleic acid extraction or purification reagents in 4:1 ratio for nucleic acid lysis and release according to its instruction for use. The specimen usage amount should be at least 50 μL.

13. A variety of factors may cause performance changes during the storage, transportation, and use of reagents, such as improper storage and transportation, non-standard specimen collection, specimen processing and testing. Please strictly follow the Instruction. Due to the characteristics of the specimen collection process such as sampling with swabs and the virus infection process itself, there may be false negative results caused by insufficient specimen collected. Therefore, the test results should be comprehensively judged in combination with other clinical diagnosis and treatment information and re-testing should be carried out if necessary.

[References]

1. Clinical management of severe acute respiratory infection when novel coronavirus (nCoV) infection is suspected — Interim guidance. 2020.

[Basic Information]

Name of registrant / manufacturer: Da An Gene Co., Ltd. of Sun Yat-sen University

Address: No.19, Xiangshan Road, Science Park, High & New Technology Development District, Guangzhou, Guangdong,P.R.China

Contact information:

Production address: No.19, Xiangshan Road, Science Park, High & New Technology Development District, Guangzhou, Guangdong, P.R.China; No. 6, Lizhishan Road, Science Park, High & New Technology Development District, Guangzhou, Guangdong, P.R.China

Production License number:

[Medical Device Registration Certificate No./Product Technical Requirements No.]

[Date of approval and amendment of the Instruction for Use]