



This is to certify that the Quality Management System of

## Nantong Renon Laboratory Equipment Co., Ltd.

Unified Social Credit Code : 91320684687160886X

Operation Address : No.128, Xiaohai Road, Sanhe Town, Haimen City, Nantong City, Jiangsu Province, China

Registered Address : No.128, Xiaohai Road, Sanhe Town, Haimen City, Jiangsu Province, China

applicable to

Production and Sale of Laboratory Plastic Consumables(Pipette Tips, Centrifuge Tube, Cryovial Tube, Test Tube, Tube Stopper, Plastic Rack, Plastic Box, Embedding Cassette, Pipette, Cuvette, Sharp Container, Petri Dish, Tissue Culture Plate, Cell Bottles, Recycling Bins, Plastic Tourniquets, Sample Cup, Specimen Container, Loop Sample Needle, Blood Collection Tube)(Exports to the United States and the European Union); Sales of Glass Slide, Cover Slide, Laboratory Glass Container, Serological Pipette, Transfer Pipette, ESR Tube, Non-sterile Cotton Tip, Umbilical Cord Clamp, Non-sterile Swab tube(Exports to the United States and the European Union)

has been assessed and registered by NQA against the provisions of

### ISO 13485: 2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website ([www.cnca.gov.cn](http://www.cnca.gov.cn))

SNQA's website : [www.snqa.com.cn](http://www.snqa.com.cn)

Managing Director

Certificate Number

**46815**

Date:

22 August 2019

Valid Until:

22 August 2022

EAC Code:

14/29



015



The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.

NQA is a trading name of NQA Certification Limited, Registration No 09351758. Registered Office: Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, UK.

This certificate is the property of NQA and must be returned on request.



### EC DECLARATION OF CONFORMITY

We hereby declare that the following specified product materials complies with the related European Directives 98/79/EC

**Name Manufacturing Factory:** NANTONG RENON LABORATORY EQUIPMENT CO.,LTD

**ADDRESS:** NO.128 XIAOHAI ROAD, SANHE TOWN, HAIMEI CITY, JIANGSU PROVINCE, CHINA

**Product description :** All products disposable items of laboratory plasticware & glassware including

Annex:, pipettes - all models variable and fixed volume - autoclavable and semi autoclavable. Blue pipette Tips (Eppendorf , Gilson ), yellow pipette Tips (Eppendorf , Gilson ), Gilson white pipette Tips . pipette tip (YELLOW ,WHITE ,BLUE ) , pipette tips rack s& boxes ,. filter tips box . Test Tubes glass, Test Tubes PS PP , Test Tubes CONICAL PP PS, test tubes WS, swab in tube swab in tube soft Plastic , Test Tube Rack Multi ,Test Tube Rack White, Micro centrifuge, Centrifuge Tubes 1.5ml, 2ml, 0.2ml, 0.5ml, Centrifuge Tubes conical bottom (10ML,15ML,50ML),Cryo-Tubes , Glass Microscopic Slides Adhesion Positive chargem Microscope Slides . Glass Cover Microscope Slides . Blood Counting Chamber paper . SAMPLE CUP (German LABOR , German BCCL4 . German BE. CUP TECO, CUP HITACHI, CUP BECKMAN, CUP STAGO), sample cup German Labor sample cup TECO, sample cup German, sample CUP German BECL4 . sample cup Hitachi, sample cup BECKMAN CX, sample cup CA6000 CUP CA530 CUP sample cup stago , cup Cuvette Mindray , Cuvette CUP Plastic , ESR System pipette+ tube ESR fast detector , Blood vacuum tubes Collection acd/Sodium citrate +gel Prp , ESR Tube Capillary ,Blue, Capillary Red, Stainless steel blood box , Stainless steel LP LOOPS Transfer Pipettes Embedding CASSETTE , Inoculation Loops Plastic ALCOHOL SWAB prep pad ,Petri Dishes Glass . Centrifuge Tube Conical M automatic pipette variable , Fixed pipette , CUP VISIBLE SPECTROPHOTOMETER. Autoclave .Centrifuge Machines Digital , Centrifuge Machines(800 , 801 , 802 ) , Microscopic Machines , Glass test tube, Slide Mailer ,Slide box , , ESR Pipette Multifunction , Metal rack, Glass pipette , Elisa plate , gloves & plaster ,specimen containers cup containers , GLASS Petri dishes, freezing tubes, plastic loops , Pasteur pipettes, cardboard slides trays, cardboard slides mailers , Tourniquet, Plastic rods ,medical equipment, tongues depressor, face mask , , Filter papers, Beakers, Flasks, Reagent bottle, blood lancet , spectrophotometer cup, ID bracelet, Balance ,Photometer Disposable needle, Water bath ,PH paper , , Ice Cap, Plaster and Band aid, Culture Plate, Measuring Cup, Cylinder Slide Storage Box ,Storage Box ,Freezing Box , Band aid Staining Jar, Freezing Tube, Pipette Variable fixed, Pipette aspirator ,Stop watch ,Thermometer, Sticks , Micro titration Plate , Wooden plastic Rods , Filter ,Shaker , Universal Rack , Disc Polari meter , Culture Plate, Transport Tube, Rack For Falcon Tube , Stopper test tube , Wooden Stick , Timer, Reagent Bottle ,Tongue depressor Washing Bottle Mixer Magnetic Stirring ,Culture Bottle, Capillary Tube Pipe capillarity, Balance, PCR Tube, PCR Plate PCR Storage box ,Photometer, Bakers , Ant Coagulant Tubes, Cylinder, Boiling flask, Tub, urine cups

**Classification :** class 1

**Conformity route :** The above mentioned product sample has been tested for CE marketing according to the related European Annex II&III of the 98/79/EC In Vitro Diagnostic Medical Devices Directive

**General applicable directives:** In-vitro Diagnostics Directive: COUNCIL DIRECTIVE 98/79/EC of In-vitro Diagnostics Directive (IVD 98/79/EC).

**Standard(s)** used for showing compliance with the essential requirements in the specified directive(s)

**Standard(s)** : The technical documentation of the listed devices is in conformity with the requirements. The test report is the annex of this report and we suggested they could be used together manufacturer may affix the CE marking as shown below to product.

Issued Date: 2020-5-24

Signed:



南通理能实验器材有限公司  
NANTONG RENON LABORATORY EQUIPMENT CO., LTD

Authorized Signature(s)





南通理能实验器材有限公司  
NANTONG RENON LABORATORY EQUIPMENT CO., LTD

Date of issue: January 1st, 2016

To whom it may concern

Our. ref. Nr. 2016-MD-Eco/03

Object: **distribution letter for tenders**

The company

**NANTONG RENON LABORATORY EQUIPMENT CO.,LTD**

**NO.128 XIAOHAI ROAD, SANHE TOWN, HAIMEN CITY, JIANGSU PROVINCE, CHINA**

**TEL:86(513)82233576**

declares that this letter acknowledges that

**"ECOCHIMIE" S.R.L.**

**5/1, I. Cuza-Voda Blvd., MD2060, Chisinau**

**Republic of Moldova**

**Tel.: +/373/22 523432**

**Fax: +/373/30 523422**

**E-mail: import@ecochimie.md**

is our authorized distributor for the complete NANTONG RENON LABORATORY EQUIPMENT CO.,LTD product line.

This company is able to provide competitive and professional sales information, to take parts in tenders and after-sales service of NANTONG RENON LABORATORY EQUIPMENT CO.,LTD products to their customers in his area and to participate in tenders on behalf of NANTONG RENON LABORATORY EQUIPMENT CO.,LTD

President

NANTONG RENON LABORATORY EQUIPMENT CO.,LTD

Signature and seal

南通理能实验器材有限公司  
NANTONG RENON LABORATORY EQUIPMENT CO.,LTD

Authorized Signature (S)



地址: 江苏省海门市三和镇小海路128号

ADDRESS: NO.128, XIAOHAI ROAD SANHE TOWN, HAIMEN CITY, JIANGSU PROVINCE, CHINA

TEL: 86(513)82233576

FAX: 86(513)82305748

E-mail: renonlab@yahoo.com.cn





## CE Compliance Report

Applicant: NANTONG RENON LABORATORY EQUIPMENT CO., LTD  
Address: NO128, XIAOHAI ROAD, SANHE TOWN, HAIMEN CITY, JIANGSU PROVINCE, CHINA  
Product: Pipette Tips, Centrifuge Tube, Cryotube, Reagent Bottle, Test Tube, Test Tube Stopper, Plastic Rack, Plastic Box, Embedding Cassettes, Transfer Pipette, Urine Cup, Stool Cup, Sample Cup, Colorimetric Cup, Cuvette, Petri Dish, Cell Culture Plate, Cell Culture Bottle, Loops, Swab Pads, Slides , Cover Glass, Pipette, Blood Collection Tube, Capillary Tube, Sample Swab Tube, Tweezers, Brush, ESR Tube, ESR Rack, Plastic Speculum, Centrifuge, Plastic Clamp, Glassware, Plastic Needle Sampling, Sample Box, Sample Bag, Tighten Belt, Centrifugal Rack, Slide Staining Rack, Slide Staining Jar, Slide Mailer  
Type: See Annex of details  
Product Classification: Other

**The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex II & III of the 98/79/EC In Vitro Diagnostic Medical Devices Directive.**

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met. This report is not a certificate of conformity.

No. **02747**

Initial Issue Date: **24 July 2017**

*Tony Chen*

General Manager (Signature)

This report is the property of NQA and should be returned to NQA upon request.







## Annex to Report (No. 02747 )

### NANTONG RENON LABORATORY EQUIPMENT CO., LTD

Product Name	Type
Pipette Tips	10ul, 100ul, 200ul, 300ul, 500ul, 1ml, 5ml, 10ml
Centrifuge Tube	0.2ml, 0.5ml, 1ml, 1.5ml, 2ml, 5ml, 7ml, 10ml, 15ml, 50ml, 100ml
Cryotube	0.5ml, 1.0ml, 1.5ml, 1.8ml, 2ml, 4ml, 5ml, 7ml, 10ml
Reagent Bottle	1ml, 2ml, 5ml, 10ml, 20ml, 50ml, 100ml, 500ml
Test Tube	PS test tube, PP test tube, Glass test tube, Screw test tube 12*60, 12*75, 13*75, 12*100, 13*100, 15*100, 16*100, 18*100, 18*150
Test Tube Stopper	Φ12mm, 13mm, 15mm, 16mm
Plastic Rack	Test tube rack, pipette rack, centrifuge tube rack
Plastic Box	TIPS BOX, CENTRIFUGE TUBE BOX, CRYO BOX
Embedding Cassettes	Square hole, Stripe hole, Round hole
Transfer Pipette	0.5ML, 1ML, 2ML, 3ML, 5ML, 10ML
Urine Cup	5ml, 10ml, 15ml, 20ml, 25ml, 30ml, 40ml, 50ml, 60ml, 80ml, 90ml, 100ml, 120ml, 150ml
Stool Cup	5ml, 10ml, 15ml, 20ml, 25ml, 30ml, 40ml, 50ml, 60ml, 80ml, 90ml, 100ml, 120ml, 150ml
Sample Cup	SPB1~SPB17
Colorimetric Cup	SPA1~SPA27
Cuvette	CV1~CV13

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## Annex to Report (No. 02747 )

### NANTONG RENON LABORATORY EQUIPMENT CO., LTD

Product Name	Type
Petri Dish	Φ30MM, 60MM, 90MM, 100MM, 120MM, 150MM
Cell Culture Plate	6 holes, 12holes, 24holes, 48holes, 96 holes V bottom, U bottom, Flat bottom
Cell Culture Bottle	25ml, 50ml, 250ml, 600ml
Capillary Tube	Blue type, Red type, EDTA type
Loops	1ul, 10ul, 1ul/10ul double use
Swab Pads	50*50MM, 60*60MM, 43*43MM, 50*50MM
Slides	7101, 7102, 7105, 7107, 7109
Cover Glass	18*18mm, 20*20mm, 22*22mm, 22*32mm, 24*24mm, 24*32mm, 24*50mm, 22*60mm, 24*60mm
Pipette	Adjustable, fixed
Blood Collection Tube	Vacuum blood tube, Non vacuum blood tube
Sample Swab Tube	12*160mm, RED TYPE , BLUE TYPE
Tweezers	Ge-33, GE-34, GE-35
Brush	17 TYPE, 18 TYPE, 19 TYPE
ESR Tube	GLASS ESR TUBE, PLASTIC ESR TUBE
ESR Rack	Plastic, steel
Plastic Speculum	A TYPE, B TYPE, C TYPE

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### NANTONG RENON LABORATORY EQUIPMENT CO., LTD

Product Name	Type
Centrifuge	0.5ml, 1.5ml, 15ml, 50ml, 800, 801, 802
Plastic Clamp	GE-31, GE -32
Glassware	Beaker, flask, measuring cylinder, measuring cup, Volumetric flask, reagent bottle, funnel, core filter device, dedicator, alcohol lamp, watch glass, petri dish
Plastic Needle Sampling	7, 7-1, 8, 9, 10, 11, 12, 13
Sample Box	PLASTIC SAMPLE BOX, PAPER SAMPLE BOX
Sample Bag	Large, Small
Tighten Belt	A, B, C
Centrifuge Tube Rack	90holes, 60holes, 40holes, 50holes
Slide Staining Rack	24hole, 30hole, 60hole
Slide Staining Jar	5hole, 9hole, 10hole, 30hole, 60hole
Slide Mailer	1HOLE, 2HOLE, 3HOLE, 5HOLE, 10HOLE, 12 HOLE, 20HOLE, 30HOLE, 50HOLE, 100HOLE

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兹证明

## 南通理能实验器材有限公司

统一社会信用代码: 91320684687160886X

经营地址: 江苏省南通市海门市三和镇小海路 128 号

注册地址: 海门市三和镇小海路 128 号

的质量管理体系适用于

实验室塑料耗材(吸头、离心管、冷冻管、试管、试管塞、塑料架、塑料盒、包埋盒、吸管、比色皿、利器盒、培养皿、培养板、细胞瓶、回收桶、塑料止血带、样本杯、取样杯、取样环、采血管)的生产和销售(出口至美国和欧盟); 载玻片、盖玻片、实验室玻璃容器、移液管、移液器、血沉管、非灭菌棉签、脐带夹、非灭菌拭子的销售(出口至美国和欧盟)

已经 NQA 根据标准

**ISO 13485: 2016**

审核和注册

注册要求组织必须按照上述标准保持其质量管理体系, 并由 NQA 进行监督。

获证组织必须定期接受监督审核并经审核合格, 此证书方继续有效。

本证书信息可在国家认证认可监督管理委员会官方网站 ([www.cnca.gov.cn](http://www.cnca.gov.cn)) 上查询

SNQA 查询网站: [www.snqa.com.cn](http://www.snqa.com.cn)

Managing Director



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