

# POSI

## CERTIFICATE

### 质量管理体系认证证书

兹证明

浙江理能医疗器械有限公司

统一社会信用代码： 91330104MA28ULGX0H

注册地址：浙江省杭州市江干区环站东路777号东子国际B座6楼614室

经营地址：浙江省杭州市江干区环站东路777号东子国际B座6楼614室

的质量管理体系适用于：

- 一、二类医疗器械和医院实验室耗材的销售（仅限出口）  
（明细详见附件）

已经通过上海波西认证有限公司根据标准：

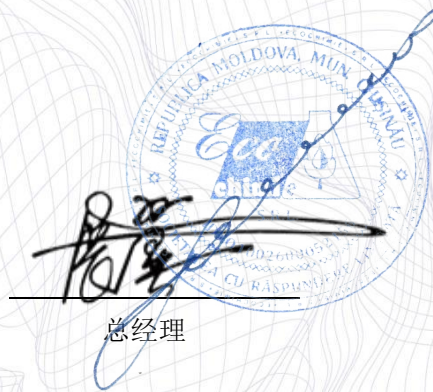
ISO13485:2016

审核和注册

本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POSI进行监督。

查询网站： [www.posicert.com](http://www.posicert.com)

该证书信息可在国家认证认可监督管理委员会官方网站<http://cx.cnca.cn>查询。



总经理

证书编号： 381210195R0S

首次发证日期： 2021.12.03

本次发证日期： 2021.12.03

有效期： 2024.12.02



上海波西认证有限公司

上海市浦东新区世纪大道1500号1301-C-7室 Email: [info@posicert.com](mailto:info@posicert.com)

# POSI

## CERTIFICATE

This is to certify that the Quality Management System of

### ZHEJIANG RENON MEDICAL INSTRUMENT CO.,LTD

Business License Number: 91330104MA28ULGX0H

Registered Address: NO.777 EAST HUANZHAN ROAD, XIZI BUILDING B-614,  
HANGZHOU CITY, ZHEJIANG PROVINCE, CHINA

Audit Address: NO.777 EAST HUANZHAN ROAD, XIZI BUILDING B-614,  
HANGZHOU CITY, ZHEJIANG PROVINCE, CHINA

applicable to

Sales of Class I and II medical devices and hospital laboratory  
consumables (for export only)

has been assessed and registered by POSI against the provisions of

**ISO13485:2016**

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

Please consult the website: [www.posicert.com](http://www.posicert.com)

The certificate information is also available on the CNCA official website: <http://cx.cnca.cn>.



General Manager

Certificate Registration No: 381210195R0S

Initial issue date: 2021.12.03

Issue date: 2021.12.03

Valid until: 2024.12.02



Shanghai POSI Certification Co., Ltd.

Room 1301-C-7, No.1500, Century Avenue, Pudong New Area, Shanghai ,China.Email:[info@posicert.com](mailto:info@posicert.com)





**销售产品明细：**

Pipette Tips, Pipette Tip Rack, Centrifuge Tube, Cryovial Tube, Test Tube, Test Tube Stopper, Plastic Rack, Plastic Box, Embedding Cassette, Pipette, Cuvette, Sharp Container, Petri Dish, Tissue Culture Plate, Cell Bottles, Waste Bin, Plastic Cool Box, Tourniquets, Sample Cup, Specimen Container, Inoculation Loop, Blood Collection Tube, Glass Slide, Glass Slide box, Cover Slide, Laboratory Glass Container, Serological Pipette, Pasteur Pipette, ESR Tube, Cotton Tip, Umbilical Cord Clamp, Swab Tube, Centrifuge, Forceps, Medicine Cup, Sample Bag, VTM Tube, Specimen Collection Swab, Wooden Applicator

移液器吸嘴，移液器吸嘴盒，离心管，冷冻管，试管，试管塞，塑料架，塑料盒，包埋盒，移液器，比色皿，利器盒，培养皿，培养板，细胞瓶，垃圾桶，塑料冷藏盒，止血带，样品杯，采样杯，取样环，采血管，载玻片，载玻片盒，盖玻片，实验室玻璃容器，血清移液管，巴氏吸管，ESR 管，棉签，脐带夹，采样管，离心机，镊子，药杯，样品袋，病毒采样运输管，采样拭子，木棒棉签

Gauze Swab, Cotton Wool, Bandage, Wound Plaster, Medical Tape, Face Mask, Head Cap, Shoe Cover, Surgical Gown, Isolation Gown, Lab Coat, Blood Lancet, I.D Bracelets, Foley Catheter, Yankauer Suction, Endotracheal Tube, Stomach Tube, Feeding Tube, Suction Tube, Infusion Set, Disposable Syringe, Disposable Needle, Vaginal Speculum, Nasal Oxygen Cannula, Oxygen Mask, Nebulizer Mask, Urine Bag, Surgical Glove, Surgical Suture, Ostomy bag, Non Woven Alcohol Swab, Disposable Apron, Surgical Blade

纱布片、药棉、绷带、创口贴、医用胶带、口罩、条帽、鞋套、手术衣、隔离衣、实验室外套、采血针、识别带、导尿管、杨考尔吸管、气管插管、胃管、喂食管、吸引管、输液器、一次性注射器、一次性针头、窥阴器、鼻氧套管、氧气面罩、雾化器面罩、尿袋、手术手套、手术缝合线、造口袋、酒精片、一次性围裙、手术刀片



General Manager

证书编号：381210195R0S

Shanghai POSI Certification Co., Ltd.

Room 1301-C-7, No.1500, Century Avenue, Pudong New Area, Shanghai ,China.Email:info@posicert.com

## 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, HAIMEN 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 racks & 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 charge, Microscope Slides, Glass Cover Microscope Slides, Blood Counting Chamber paper. SAMPLE CUP (German LABOR, German BCCL<sub>4</sub>, German BE, CUP TECO, CUP HITACHI, CUP BECKMAN, CUP STAGO), sample cup German Labor sample cup TECO, sample cup German, sample CUP German BECL<sub>4</sub>, 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 acid/Sodium citrate +gel Prp, ESR Tube Capillary, Blue, Capillary Red, Stainless steel blood box, Stainless steel LOOPS, Transfer Pipettes. Embedding CASSETTE, Inoculation Loops Plastic, ALCOHOL SWAB prep pad, Petri Dishes Glass. Centrifuge Tube Conical, 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. Polarimeter, 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, AntiCoagulant Tubes, Cylinder, Boiling flask, Tub, urine cups.

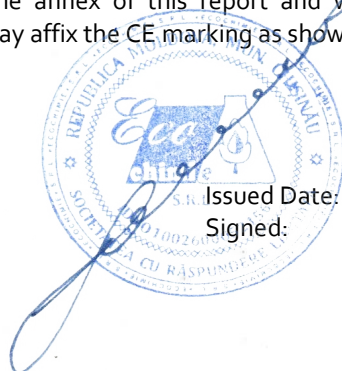
**Classification:** class 1

**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:

浙江理能医疗器械有限公司  
ZHEJIANG RENON MEDICAL INSTRUMENT CO.,LTD