

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）
（详见附件）

已经通过上海波西认证有限公司根据标准：

GB/T 42061-2022/ISO 13485:2016

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。

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。

查询网站： 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。



证书编号： 381210195R1S

首次发证日期： 2021.12.03

本次发证日期： 2024.11.27

有效期： 2027.12.02



上海波西认证有限公司

中国（上海）自由贸易试验区世纪大道1500号1402A室 Email: info@posicert.com

证书381210195R1S附件:

一、实验室耗材: 移液器吸嘴, 移液器吸嘴盒, 移液器, 血清移液管, 巴氏吸管, 离心管, 冷冻管, 样品杯, 采样杯, 采样管, 样品袋, 采样拭子, 取样环, 试管, 试管塞, 比色皿, ESR管, 采血管, 塑料架, 塑料盒, 载玻片, 载玻片盒, 盖玻片, 培养皿, 培养板, 细胞瓶, 实验室玻璃容器, 塑料冷藏盒, 包埋盒, 病毒采样运输管, 介质拭子, 肝素帽, 真空采尿管, 毛细采血管, 血球计数板, 病理切片刀片, 石蜡

二、医用耗材: 镊子, 药杯, 棉签, 木棒棉签, 纱布片, 药棉, 绷带, 创口贴, 医用胶带, 识别带, 脐带夹, 手术刀片, 造口袋, 酒精片, 采血针, 手术缝合线, 止血带, 窥阴器, 石膏绷带, 纱布卷, 敷贴, 洗手刷, 妇科刷, 灌洗器, 耦合剂, 消毒袋, 头皮针, 吸唾管, 针灸

三、麻醉、呼吸: 杨考尔吸管, 气管插管, 鼻氧套管, 氧气面罩, 雾化器面罩, 三通阀延长管, 三通阀, 呼吸回路延长管, 过滤器, 氧袋面罩, 口咽通气道, 呼吸回路, 麻醉面罩, 喉罩, 气管切开插管, 吸痰管

四、导管、引流: 负压引流器, 吸引管, 导尿管, PVC导尿管, 胃管, 喂食管, 肛门管, 引流管, 中心静脉导管, 喂食袋, 尿袋

五、输血、输液及注射: 输血器, 输液器, 一次性注射器, 一次性针头

六、医用防护用品: 手术衣, 隔离衣, 实验室外套, 一次性围裙, 手术手套, 口罩, 条帽, 鞋套, 手术单, 牙科垫, 尿垫, 尿不湿

七、医疗设备: 热水袋, 电刀笔, 复苏球, 利器盒, 垃圾桶

八、医用有源设备: 离心机, 显微镜, 培养箱, 干燥箱, 搅拌器, 水浴锅, 混匀器, 漩涡混匀器

九、监测、测量设备: 电极片, 温度计, 血压计



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 Class II medical devices
 and hospital laboratory consumables (export only)
 (See attachment for details)

has been assessed and registered by POSI against the provisions of

GB/T 42061-2022/ISO 13485:2016

This registration is subject to the company maintaining a Quality Management System,
 to the above standard, which will be monitored by POSI.

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

Please consult the website: www.posicert.com

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



Certificate Registration No: 381210195R1S

Initial issue date: 2021.12.03

Issue date: 2024.11.27

Valid until: 2027.12.02

Shanghai POSI Certification Co., Ltd.

Room 1402A, No.1500, Century Avenue, China (Shanghai) Pilot Free Trade Zone. Email: info@posicert.com





Certificate No.381210195R1S Attachment:

- 1.Laboratory Consumable: Pipette Tips, Pipette Tip Rack, Pipette, Serological Pipette, Pasteur Pipette, Centrifuge Tube, Cryovial Tube, Sample Cup, Specimen Cup, Specimen Collection Swab, Sample Bag, Inoculation Loop, Test Tube, Test Tube Stopper, Cuvette, ESR Pipette, Blood Collection Tube, Plastic Rack, Plastic Box, Glass Slide, Glass Slide Box, Cover Glass, Petri Dish, Culture Plate, Culture Bottle, Laboratory Glassware Container, Plastic Cool Box, Embedding Cassette, VTM Tube, Transport Swab With Medium, Heparin Cap, Vacuum Urine Tube, Capillary Tube, Counting Chamber, Microtome Blade, Paraffin Wax
- 2.Medical Consumable: Forceps, Medicine Cup, Cotton Tip, Wooden Applicator, Gauze Swab, Cotton Wool, Bandage, Wound Plaster, Medical Tape, I.D Bracelets, Umbilical Cord Clamp, Surgical Blade, Ostomy Bag, Non Woven Alcohol Pad, Blood Lancet, Surgical Suture, Tourniquets, Vaginal Speculum, Pop Bandage, Gauze Roll, Wound Dressing, Surgical Brush, Cervical Brush, Irrigation Syringe, Ultrasound Gel, Sterilization Pouch, Scalp Vein Set, Saliva, Acupuncture
3. Anesthesia And Respiratory Consumables: Yankauer Suction, Endotracheal Tube, Nasal Cannula, Oxygen Mask, Nebulizer Mask, Extension Set, Three Way Stopcock, Catheter Mount, Filter, Non-Rebreathing Oxygen Mask, Airway,Breathing Circuit, Anesthesia Mask, Laryngeal Mask Airway, Tracheostomy Tube, Suction Tube
4. Catheters And Drainage Consumables: Wound Drainage System, Suction Tube, Foley Catheter, Nelaton Catheter, Stomach Tube, Feeding Tube, Rectal Tube, Thoracic Tube, Central Venous Catheter, Enteral Feeding Bag, Urine Bag
5. Blood Transfusion, Infusion And Injection Consumables: Blood Transfusion Set, Infusion Set, Disposable Syringe, Disposable Needle
6. Medical Protective Equipment: Surgical Gown, Isolation Gown, Lab Coat, Disposable Apron, Surgical Glove, Face Mask, Head Cap, Shoe Cover, Surgical Drapes, Dental Bib, Underpad, Diaper
7. Medical Devices: Hot Water Bag, Electrosurgical Pencil, Resuscitator, Sharp Container, Waste Bin
8. Medical Active Devices: Centrifuge, Microscope, Oven, Incubator, Stirrer, Water Bath, Shaker, Vortex Mixer
9. Monitoring And Measuring Equipment: Ecg Electrodes, Thermometer, Blood Pressure Machine



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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 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 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.

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

Issued Date: 2020-5-24

Signed:

