

# POSI

## CERTIFICATE

# 质量管理体系认证证书

兹证明

宁波柯泰医疗器械有限公司

统一社会信用代码： 91330201799531493B

注册地址：浙江省宁波高新区创苑路98号1号楼16-1

经营地址：浙江省宁波高新区创苑路98号1号楼16-1（办公）；  
浙江省宁波高新区万特商务中心1号楼18-1（库房）

的质量管理体系适用于：

医疗器械的销售（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。

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。



  
总经理

证书编号：381230144R0S

首次发证日期：2023.07.03

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有效期：2026.07.02




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

产品明细：全硅胶导尿管，血袋，电刀笔，避孕套，气管切开插管，导尿管，血氧仪，不可吸收缝合线，水胶体敷料，无液血压表，无纺布片，纱布片，纱布绷带，纱布卷，弹性绷带，急救包，止血粘性敷料系列(创口贴、输液贴、自粘敷料贴)，敷料盘，脱脂棉球，眼垫，扩阴器，尿袋，脐带夹，口咽通气道，手术衣，肛管，手术刷，尿套，妇科包，妇检刷，鼻镜，冲洗器，无纺口罩，酒精纱布片，肛门袋，鼻咽通气道，压舌板，男用/女用拭子，电子血压表，电子体温计，红外线耳温枪，红外线额温枪，氧气面罩，雾化面罩，不重吸面罩，CPR面罩，鼻氧管，气管插管，PVC导尿管，喂食管，胃管，吸痰管，闭合式吸痰管，杨克连接管，加强型气管插管，喉罩，集痰器，注射器，胰岛素注射器，安全式注射器，静脉输液针，注射针，留置针，输液器，小儿吊瓶，输血器，三通阀，肝素帽，手术刀片，采血针，负压引流器，手术手套，可调面罩，超声波雾化器，气体压缩雾化器，听诊器，一次性医用包装袋，氧化锌胶带，无纺手术胶带，PE手术胶带，丝绸手术胶带，石膏绷带，PVC手套，冷热袋，防褥疮床垫，心电电极片，超声耦合剂，手术灯，手术台，病床，担架，PE手套，一次性床垫，无纺帽，鞋套，便盆，蒸汽灭菌器，尿杯，无菌检查手套，手术巾，棉签，纱布球，气管切开面罩，手动复苏器，手术包，电动吸痰器，T型引流管，彭罗氏管，腹部垫，胰岛素笔针，心电图机，妇检板，人体润滑剂，医用剃刀，真空采血管，离心机，一次性使用塑料镊子，一次性使用肛门镜，气管插管探条，麻醉呼吸回路，带吸痰管气管插管，可测二氧化碳鼻氧管，湿化杯，储雾罐，安全自毁注射器，止血带，药杯，识别带，酒精棉棒，一次性使用输液连接管，导管塞，小儿尿袋，灌肠袋，阴道给药器，运送介质拭子，麻醉面罩，复苏面罩，咬嘴式雾化器，氧气连接管，雾化器，三通阀带延长管，齿科针，一次性使用真空采血管，一次性使用脐带剪，静脉采血针，一次性使用麻醉咽喉镜，湿热交换器，呼吸过滤器，引流管，螺旋盖帽，螺旋帽，灌肠器，医用手指套，无汞体温计，一次性使用口腔器械包，载玻片，引流瓶，洗胃器，喂食袋，手术缝合线尼龙线，手术缝合线铬肠线，身高尺，麻醉呼吸回路，气垫，气垫，口垫，空气温度计，呼吸管路，盖玻片，缝合针，采血针，牙科垫，碘棒，酒精棉签，石蜡纱布片，粘性伤口敷料卷，无纺布胶带，PE胶带，洗鼻器适配器，洗鼻器，棉片，棉卷，热水袋，排卵测试条，早孕测试条，PBT 绷带，条形帽，乳胶导尿管，手术刀，T型连接管，防护面罩，利器盒，碘片，隔离衣，蒸汽指示胶带，吸奶器，诊断笔，检耳镜套装，ECG纸，叩诊锤，皮肤吻合器，急救毯，洗耳球，病历夹，折叠担架，载玻片，三球呼吸训练器，体重秤，头部固定器，拆钉器，颈围领，三角绷带，药盒，气管插管支架/固定器，牙科棉卷，连接管，剪刀，牙科铺单，宫颈匙，宫颈刮片，脐带管，无针接头，牙科盒，宫内节育器，压舌板，石膏衬垫，玻璃纤维绷带，玻璃纤维夹板，消毒包布/纸，吸唾管，尿不湿，牙科套装，输液港专用针，急救绷带，呼吸囊，蒸汽指示卡/带，EO指示卡/带，等离子卡/带，BD 测试包，蒸汽指示卡/带，平面消毒袋，平面消毒卷袋，立体消毒卷袋，腰子盘，呕吐袋，标本袋，针头盒，无纺/PU 辅料卷，皮肤记号笔，拆线刀，采血笔，轮椅，拐杖，助行器，尿壶，流量调节器，双向采血针，加热袋，离心管，吸头，废液收集装置，废液收集袋，持针器，消毒湿巾，消毒擦片，尿袋挂钩，超生探头套，冰袋，试管



  
 总经理

# POSI

## CERTIFICATE

This is to certify that the Quality Management System of

### **Ningbo Greetmed Medical Instruments Co., Ltd.**

Business License Number: 91330201799531493B

Registered Address: 16F-1, Building 1, No.98 Chuangyuan Road, Hi-Tech Zone,  
315042 Ningbo, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

Audit Address: 16F-1, Building 1, No.98 Chuangyuan Road, Hi-Tech Zone, 315042 Ningbo,  
Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA (office); 18-1, Wante Business Center,  
No.487 Yangmuqi Road, High-tech Zone, Ningbo City, Zhejiang Province, China (Warehouse)

applicable to

Sales of medical devices (see attachment for details)

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.

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](http://www.posicert.com)

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



A handwritten signature in black ink, appearing to read "Jie Chen".

General Manager

Certificate Registration No: 381230144R0S

Initial issue date: 2023.07.03

Issue date: 2023.07.03

Valid until: 2026.07.02



Shanghai POSI Certification Co., Ltd.

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



## Annex to Certificate No.: 381230144R0S

Product details: Electrosurgical Pencils, Condom, Tracheostomy Tubes, Urethral Catheters, Pulse Oximeter, Non-absorbable Surgery Suture, Sterile Hydrocolloid Dressings, Aneroid Sphygmomanometers, Non-woven Swab, Gauze Swab, Gauze bandage, Gauze Roll, Elastic Bandage, First-Aid-Kit, Sterile Hemostasis Adhesive Dressing Series (Sterile Wound Plaster, Liquid Transfusion Plaster and Adhesive Dressing), Dressing kits, Absorbent Cotton Balls, Eye Pad, Vaginal Speculum, Urine Bag, Umbilical Cord Clamp, Oropharyngeal Airway, Surgical Gowns, Rectal Tube, Surgical Brush, External Male Catheter, Gynecological Sets, Cervical Brushes, Nasal Speculas, Irrigation Syringes, Non-woven Face Masks, Alcohol Swabs, Disposable Colostomy Bags, Nasopharyngeal Airway, Wooden Tongue Depressors, Male/Female Swabs, Electronic Sphygmomanometers, Digital Thermometers, Infra-red Ear Thermometers, Infra-red Forehead Thermometers, Oxygen Masks, Aerosol Masks, Non-Rebreath Masks, CPR Masks, Nasal Oxygen Cannula, Tracheal Tubes, Nelaton Catheters, Feeding Tubes, Stomach Tubes, Suction Catheters, Closed suction catheter, Connecting Tubes with Yankauer Handle, Reinforced Endotracheal Tubes, Laryngeal mask, Mucus Extractor, Disposable Syringe sets, Insulin Syringe, Safety Syringes, Disposable Scalp vein sets, Hypodermic Needle, I.V. Cannula, Disposable Infusion sets, Infusion Set with Burette, Disposable Blood transfusion sets, Three-way Stopcocks, Heparin Caps, Disposable Surgical Blades, Sterile Blood Lancets, Wound Drainage Reservoir, Surgical Gloves, Venturi Masks, Ultrasonic Nebulizer, Compressor Nebulizer, Stethoscope, Single-use Medical Packaging for Sterilized Medical Devices, Zinc Oxide Adhesive Plaster, Non-woven Surgical Tape, PE Surgical Tape, Silk Surgical Tape, Plaster of Paris Bandage, PVC Gloves, Cold & Hot Pack, Bedsore prevention mattress, Disposable ECG Electrodes, Ultrasound Gel, Operation Lamps, Operating Tables, Hospital Bed, Stretcher, PE Gloves, Disposable Underpad, Non-woven Caps, Shoe Covers, Plastic Bedpan, Steam Sterilizers, Urine Container, Sterile Examination Gloves, Surgical Drapes, Cotton Tipped Applicators, Gauze Ball, Tracheostomy Mask, Manual Resuscitators, Surgical Set, Electric Suction Apparatus, T-Drainage Tube, Penrose Tube, Lap Sponges, Insulin Pen Needles, Electrocardiograph, Wooden Ayre Spatulas, Lubricating Jelly, Medical Prep Razors, Vacuum Blood Collection Tubes, Centrifuge, Disposable Plastic Forceps, Disposable Anoscope, Endotracheal Tube Introducers, Anesthetic Breathing Circuits, Endotracheal Tubes with Evacuation Lumen, O<sub>2</sub>+CO<sub>2</sub> Sampling Cannulas, Humidifier Jar, Mask Nebulizer Container, Auto-disable Syringe, Tourniquet, Medicine Cup, I.D. Bracelets, Alcohol Swabsticks, Disposable Infusion Connection Tube, Spigot, Urine Bag Infant, Enema Bag, Sterile Vaginal Applicator, Transportation Swabs with Medium, Anesthesia Mask, Resuscitation Mask, Nebulizers with Mouth-pieces, Oxygen Connection Tubings, Nebulizer Set, Three-way Stopcock and Extension Tube, Dental Needles, Disposable Vacuum Blood Collection System, Disposable Umbilical Cord Scissors, Blood-Collecting Needles, Disposable Anesthesia Laryngoscope, Heat & Moisture Exchanger Filters, Breathing System Filters, Drainage Tubes, Screw Cap, Combi Stopper, Enema Set, Medical Finger Cover, Mercury Free Clinical Thermometer, Oral Cavity Kits for Dental Examination, Microscope slides, Disposable closed drainage bottle, Stomach Pump, Disposable enteral feeding bag, Nylon monofilament, Chromic catgut, Altimeter device, Anesthesia Breathing tube, Air pad, Air cushion, Disposable bite block with tie, Air thermometer, Catheter mount, Microscope cover, Suture needle, Scoff clix tube, Dental bib, Povidone-Iodine Stick, Alcohol cotton stick, Parafin gauze, Adhesive Wound Dressing Roll, Non-woven Medical Tape, PE Medical Tape, Nasal Adaptor, Nasal Irrigator, Cotton pad, Cotton wool, Hot water bag, Ovulation test, Pregnancy test, Conforming bandage, Clip cap, Latex Foley Catheter, Surgical scalpel, Extension with T tube, Face Shield, Sharp Container, Povidone-Iodine Swab, Isolation gown, Autoclave indicator tape, Breast reliever, Penlight, Diagnostic otoscope set, ECG paper, Reflex hammer, Skin stapler, Emergency blanket, Ear syringe, Medical folder, Foldway stretcher, 3 balls Spirometer, Health scale, Head Immobilizer, Staple Remover, Cervical collar, Triangular Bandage, Medicine/pill box, endotracheal tube holder, Dental cotton roll, Suction connecting tube, Trauma shears, Dental drape, Cervical Small Curet, Cervical Spatula, Umbilical catheter, Needle free connector, Dental box, Spiral for Intrauterine Contraception, Tongue depressor, Orthopedic padding, Orthopedic Casting tape (Fiberglass), Fiberglass Splint, Wrapper for sterilization, Salive ejector, Diaper, Dental kit, Huber needle with extension tube, First-aid bandage, Breathing bag, Steam indicator strip/tape, Ethylene Oxide indicator strip/tape, Plasma indicator strip/tape, Bowie Dick test pack, Steam Indicator strip/tape, Self-sealing sterilization flat pouch, Self-sealing sterilization flat reels/roll, Self-sealing sterilization gusseted reels/roll, kidney dish /tray, Vomit bag, Specimen Bag, Needle counter, Adhesive dressing roll, Skin maker, Stitch Cutter blade, Lancing device, Wheelchair, Stick, Walker, Urine bottle, I.V flow regulator, Blood collection needle(set), Body warmer (heating bag), Centrifuge tube, Pipette tip, Suction liner system, Suction liner, Needle holder, Disinfecting Wipes, Alcohol free swabs, Urine bag hanger, Ultrasound probe cover, Ice bag, Test tube



*Joe Zhou*

General Manager

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