



# Certificate

No. Q5 095729 0010 Rev. 02

**Holder of Certificate:** **Ningbo Pinmed Instruments Co., Ltd.**  
Room (22-1)(22-2)  
No.455, East Zhongshan Road  
Yinzhou District  
315040 Ningbo  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design, Development, Production and Distribution of Medical Device**  
**(For detail information see page 3)**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 095729 0010 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5 095729 0010 Rev. 02)

**Report No.:** SH22104501  
**Valid from:** 2022-08-23  
**Valid until:** 2025-08-21

**Date,** 2022-08-23



Christoph Dicks  
Head of Certification/Notified Body



Product Service

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**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):** Ningbo Pinmed Instruments Co., Ltd.  
Room (22-1)(22-2), No.455, East Zhongshan Road, Yinzhou  
District, 315040 Ningbo, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

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For the product(s)/product category (ies):

**Design, Development, Production and Distribution of  
Pulse Oximeter, Patient Monitor, Foam Dressing, Hydrocolloid Dressing, Absorbent Dressing,  
Hydrogel Dressing, Urethral Catheters, All Silicone Foley Catheters, Tracheostomy Tubes,  
Electrosurgical Pencil, Non-absorbable Surgical Suture, Blood Bags, Foley catheter kit**

**Production and Distribution of**

**Electronic Sphygmomanometers, Digital Thermometers, Infra-red Ear Thermometers, Infra-red Forehead Thermometers, Oxygen Masks, Venturi Masks, Nebulizer Masks, Non-Rebreath Masks, Tracheostomy Masks, Nebulizers with Mouth -Pieces, CPR Masks, Anesthesia Mask, Resuscitation Mask, Nasal Oxygen Cannulas, Oxygen Connection Tubings, Nebulizer Set, Reinforced Endotracheal Tubes, Urethral Catheters, Tracheal Tubes, Nelaton Catheters, Connecting Tubes with Yankauer Handle, Laryngeal Mask, Suction Catheters, Feeding Tubes, Stomach Tubes, Manual Resuscitators, Anesthetic Breathing Circuits, Endotracheal Intubation Kit, Lap Sponge, Heat & Moisture Exchanger, Endobronchial Tubes, Intubating stylets, Ambulatory Blood Pressure Monitor, Pocket Fetal Doppler, Disposable infusion connection tube, Rectal Tubes, Oropharyngeal Airways, Nasopharyngeal Airways, External Male Catheter, Elastic Bandage, Non-adhesive Dressing (Wound Compress), Gauze Swabs, Gauze Bandages, Gauze Balls, Absorbent cotton, Cotton Tip Applicators, Non-woven sponge, Alcohol Swabsticks, Alcohol prep pad, Surgical gown, Isolation gown, Surgical set, Surgical drape, Sterile wound dressing, Absorbent cotton pads, Face mask, Disposable Anesthesia Laryngoscope, Aneroid Sphygmomanometers, Adult diapers, Underpad, Urostomy bags, Stethoscope, Operation table, Obstetric table, Operation lamp, X-ray film observation luminaire, Breathing System Filters, Infusion Sets, Disposable Blood Transfusion Set, Three-way Stopcocks, Three-way Stopcock and Extension Tube, I.V. Cannula, Disposable Hypodermic Needle, Scalp Vein Set, Disposable Syringes, Insulin Syringe, Infusion Set with Burette, Dental Needles, Heparin Caps, Safety Syringe, Safety Needle for Single Use, Auto-disable Syringe, Compressor Nebulizer, Surgical Gloves, Disposable Scalpel with Plastic Handle, Surgical Blade, Blood Lancet, Blood Collection Needle, Safety I.V. Catheter, Closed Suction Catheter, Continuous Positive Airway Pressure Mask, Vacuum Blood Collection System, Extractor Mucus, Drainage Tube, Wound Drainage Reservoir, Dental Oral Irrigator, Humidifier Bottle, Connecting Tube, Adult Urine Bag, Urine Bag Infant, Irrigation Syringe, Eye Pad, Gauze Roll, Cotton Ball, Tongue Depressor, Umbilical Cord Clamp, Dressing Kits, Urine Container, Medicine Cup, Male Swab, Female Swab, Mercury Free Clinical Thermometer, Peak Flow Meter, Spirometer, Leg Bag, Feeding Bag, Zinc Oxide Adhesive Plaster, Medical Tape, Paraffin Gauze Dressing, ECG Electrode, Nitrile Examination Gloves, Latex Examination Gloves, Ultrasound Gel, Medical Bandage, Endotracheal Tube Introducers, Endotracheal Tubes with Evacuation Lumen, O<sub>2</sub>+CO<sub>2</sub> Sampling Cannulas, Insulin Pen Needles, Disposable Umbilical Cord Scissors, Screw Cap, Combi Stopper, Enema Set, Penrose Tube, Vaginal Speculum, Disposable Plastic Forceps, Disposable Anoscope, Sterile Vaginal Applicator, Transportation Swabs with Medium, Surgical Brush, Gynecological Sets, Cervical Brushes, Nasal Speculas, Spigot, Disposable Colostomy Bags, Wooden Ayre Spatulas, I.D. Bracelets, Enema Bag, Sterile Hemostasis Adhesive Dressing Series (Sterile Wound Plaster, Liquid Transfusion Plaster and Adhesive Dressing), Cotton Roll, Tourniquet, Sterile Wound Dressings/Strip, First Aid Kit, Sport Tape (include Kinesiology Tape, Rigid Tape and Fix Tape), Walking Aids, Wheelchair, Bedsore Prevention Mattress, Percussion Hammer, Examination Light, Otoscope, Ophthalmoscope, Lancing Devices, Specimen Cups**