





**Product Service** 

## **Certificate**

No. Q5 095166 0012 Rev. 02

Holder of Certificate: NINGBO TRUSTLAB

**INSTRUMENTS CO., LTD** 

18-7, No.1 Building, Wante Business Centre

Hi-tech zone 315042 Ningbo

PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:** 



Scope of Certificate: Design and Development, Production and

Distribution of Medical Devices (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 095166 0012 Rev. 02

Report No.: SH22104401

 Valid from:
 2022-07-21

 Valid until:
 2025-07-20

2022-07-15

Christoph Dicks

Head of Certification/Notified Body

Date,



## **Certificate**

No. Q5 095166 0012 Rev. 02

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 TRUSTLAB INSTRUMENTS CO., LTD

18-7, No.1 Building, Wante Business Centre, Hi-tech zone, 315042

Ningbo, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate





## Certificate

No. Q5 095166 0012 Rev. 02

Design and Development, Production and Distribution of Urethral Catheters, All Silicone Foley Catheters, Tracheostomy Tubes, Sterile Hydrocolloid Dressings.

Production and Distribution of Oxygen Masks, Venturi Masks, Nebulizer Masks, Non-Rebreath Masks, Tracheostomy Masks, Nebulizers with Mouth-pieces, CPR Masks, Anesthesia Mask, Resuscitation Mask, Nasal Oxygen Cannula, Oxygen Connection Tubings, Nebulizer Set, Reinforced Endotracheal Tubes, Urethral Catheters, Tracheal Tubes, Nelaton Catheters, Connecting Tubes with Yankauer Handle, Laryngeal Masks, Suction Catheters, Feeding Tubes, Stomach Tubes, Manual Resuscitators, Anesthetic Breathing Circuits, Disposable Infusion Sets, Disposable Syringes, Three-way Stopcocks, Heparin Caps, Dental Needles, Scalp Vein Set, I.V. Cannula, Hypodermic Needle, Infusion Set with Burette, Disposable Blood Transfusion Set, Three Way Stopcock and Extension Tube, Insulin Syringe, Wound Drainage Reservoir, Surgical Gloves, Disposable Surgical Blade, Blood-Collecting Needles, Disposable Vacuum Blood Collection System, Disposable Umbilical Cord Scissors, Rectal Tubes, Oropharyngeal Airways, Nasopharyngeal Airways, External Male Catheter, Irrigation Syringes, Elastic Bandage, Gauze Swabs, Gauze Bandages, Gauze Balls, Lap Sponges, Absorbent Cotton, Cotton Tip Applicators, Non-woven Sponge, Alcohol Swabsticks, Alcohol Prep Pad, Umbilical Cord Clamp, Urine Bag, Wooden Tongue Depressors, Surgical Gowns, Isolation Gowns, Nonwoven Face Masks, Cervical Brushes, Disposable Plastic Forceps, Disposable Vaginal Speculum, Male Swab, Female Swab, Transportation Swabs with Medium, Disposable Anoscope, Sterile Vaginal Applicator, Sterile Urine Containers, Aneroid Sphygmomanometers, Spirometer, Electrode Code, Ultrasound Gel, Zinc Oxide Adhesive Plaster, PE Tape, Silk Tape, Non-woven Tape, Self-adhesive Bandage, Medicine Cup, Wooden Ayre Spatulas, Disposable Infusion Connection Tube, Gauze Roll, Eye Pad, Sterile Examination Gloves, Breathing System Filters, Heat & Moisture Exchanger Filters, Drainage Tubes, Humidifier Bottle, Mask Nebulizer Container, Auto-disable Syringe, Oxygen Concentrator, Electric Suction Apparatus, First-Aid-Kit, Sterile Hemostasis Adhesive Dressing Series(Sterile Wound Plaster, Liquid Transfusion Plaster and Adhesive Dressing), Absorbent Cotton Balls, Dressing Kits, Surgical Brush, Surgical Drapes, Surgical Set, Gynecological Sets, Disposable Colostomy Bags, Urine Bag Infant, Enema Bag, I.D. Bracelets, Spigot, Disposable Anesthesia Laryngoscope, Nasal Speculas, Mercury Free Clinical Thermometer, Mucus Extractor, Closed Suction Catheter, T-Drainage Tube. Penrose Tube. Endotracheal Tube Introducers. Endotracheal Tubes with Evacuation Lumen, O2+CO2 Sampling Cannulas, Safety Syringes, Sterile Blood Lancets, Insulin Pen Needles, Screw Cap, Combi Stopper, Enema Set, Lubricating Jelly, Non-woven Balls, Electronic Sphygmomanometers, Digital Thermometers, Infra-red Ear Thermometers, Infra-red Forehead Thermometers.