

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 2101842-1

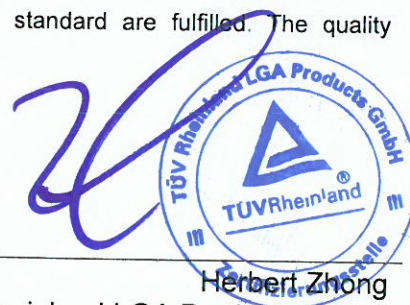
Organization: Nubenco (Shanghai) Company Co. Ltd.
Room 3021, Building 2, No. 1559
ZuCongzhi Road, Pilot Free Trade Zone,
201203 Shanghai
P.R. China

Scope: Design and Development, Manufacture and Distribution of Sterile Foley Catheters, Tracheostomy Tubes, Condoms;
Manufacture and Distribution of Sterile Syringes for Single Use, Sterile Hypodermic Needles, Sterile Infusion Sets for Single Use, Sterile Infusion Sets with Burette, Sterile Blood Transfusion Sets for Single Use, Scalp Vein Sets for Single Use, I. V. Catheters, Extension Tubes, Stopcocks, Fistula Needles, Sterile Stomach Tubes, Sterile Feeding Tubes, Sterile Rectal Tubes, Urine Bags, Sterile Nelaton Catheters, Sterile Suction Catheters, Connecting Tubes with Yankauer Handle, Wound Drainage Systems, Laryngeal Mask Devices, Oropharyngeal Airways, Face Masks with Air Cushion, Tracheal Tubes, Endotracheal Tubes with Evacuation Lumen, Endobronchial Blocker Tubes, Disposable Breathing Systems, Disposable Breathing Circuits, HMEF (heat and moisture exchanger filters), Tracheostomy Masks, Oxygen Masks, Nasal Oxygen Cannula, Bubble Humidifiers, Nebulizers, Multi-vent Masks, Non-rebreath Masks, Surgical Gloves, Disposable Surgical Blades, Sterile Scalpel with Plastic Handle, Lap Sponges, Sterile Non-woven Swabs, Sterile Gauze Swabs, Sterile Gauze Swabs with X-ray detectable, Sterile Gauze Balls with X-ray detectable, Adhesive Wound Dressings, Transparent Island Dressings, Transparent Semi-permeable Dressings, Surgical Films, Umbilical Clamps,

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 244404082-200
Effective date: 2022-08-25
Expiry date: 2025-02-19
Issue date: 2022-08-25



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Insulin Pen needles, Auto-disable Syringes, Sterile Burette, Disposable Injection Adapters, End Cap, Injection Cap (Heparin), Silicone Male External Catheters, Silicone Drainage Tubes (flat, round, various shapes), Nasopharyngeal Airways, Non-woven Caps, Non-woven Overshoes, Aprons, Surgical Face Masks, Examination Gloves, Alcohol Prep Pads, Non-woven Sterile Surgical Drapes and Fields, Sterilization Paper Rolls, Sterilization Pouches Heat and Self-sealed, Surgical Tapes, Sterilization Wraps Non-woven Crepes, Sterilization Bowie-dickie Test, Absorbent Cotton, Applicator Cotton, Hospital Gauze, Non-sterile Gauze Swabs, Paraffin Gauze Dressing, Gauze Bandages, Surgical Adhesive Tapes, Elastic Bandages, Plaster of Paris, Fiberglass Bandages, Cast Padding, Surgical Bandages (Stockinette, Elastic Tubular Net Bandage), Vaginal Speculum, Wood Tongue Depressors, Thermometers, Electrodes, Medical X-ray Film, Microscope Slide, Microscope Cover, ID Bracelets, Non-woven Non-sterile Diapers, Colostomy Bags, Safety Syringes and Needles, Circumcision Trays

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