

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Ningbo Greatcare Trading Co., Ltd.
Unit 93, Building 12, No. 818,
Qiming Road, Yinzhou
315105 Ningbo, Zhejiang
China

has established and applies a quality management system for medical devices
for the following scope:

(see attachment for scope included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-07-19
Certificate Registration No.: SX 60135839 0001
An audit was performed. Report No.: 15094479 008
This Certificate is valid until: 2022-07-18

Certification Body



Date 2019-05-16



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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60135839 0001
Report No.: 15094479 008

Organization: Ningbo Greatcare Trading Co., Ltd.
Unit 93, Building 12, No. 818,
Qiming Road, Yinzhou
315105 Ningbo, Zhejiang
China

Scope:

Design and Development, Manufacture and Distribution of Urethral Catheters, All Silicone Foley Catheters, Hemodialyzers, Gastrostomy Tubes, Tracheostomy Tubes; Manufacture and Distribution of Tracheal Tubes, Stomach Tubes, Nasal Oxygen Cannulas, Suction Connecting Tubes with and without Yankauer, Wound Drainage Systems with and without Trocar, Sterile Three-Way Stopcocks for Single Use, Sterile Infusion Sets for Single Use, Sterile Syringes for Single Use, Scalp Vein Sets for Single Use, Three Way Stopcocks and Extension Tubes, Irrigation Sets, Digital Thermometers, Injection Site Adapters, Lap Sponges, Nebulized Masks, Oxygen Masks, Non-rebreath Masks, Laryngeal Masks, Intubating Stylets, Blood Lancets, Surgical Blades, Disposable Scalpels With Plastic Handle, Silicone/SEBS/PVC Manual Resuscitators, Disposable Needles, C.P.R. Masks, Sterile Latex Surgical Gloves, I.V.Catheters, Nelaton Catheters, Air Cushion Masks, Tracheobronchial Tubes, Heat and Moisture Exchangers, Venture Masks, Latex Penrose Tubes, Breathing System Filters;

Certification Body



Date: 2019-05-16



Fuxiu Sheng

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60135839 0001
Report No.: 15094479 008

Organization: Ningbo Greatcare Trading Co., Ltd.
Unit 93, Building 12, No. 818,
Qiming Road, Yinzhou
315105 Ningbo, Zhejiang
China

Scope:

Manufacture and Distribution of Disposable Anesthesia Breathing Circuits, I.V.Flow Regulators for Single Use, Injection Caps and Valves, Disposable Sputum Collectors, Alcohol Swabs/Pads, Suction Catheters, Feeding Tubes, Urine Bags, Oropharyngeal Airways, Sterile Vaginal Speculums, Sterile Hemostasis Adhesive Dressing Devices, Feeding Sets, Disposable Umbilical Cord Clamps, Disposable Colostomy Bags, Urine Meters (W/WO Urine Sampling Blunt Canular), Urine Bags (with and without Gloves Pack), Paediatric Urine Collectors, Urinary Swabs, Endometrial Suction Curettes, Cervical Spatulas, Cervical Spoons, Cervical Brushes, Cervix Brush Plushes, Wooden Tongue Depressors, Male External Catheters, Nasopharyngeal Airway, Gauze Swabs, Non-woven Swabs, Absorbent Cottons, Disposable Dental Instruments Kits, Spigots, Irrigation Syringes, Aneroid Sphygmomanometers, Bile T-Tubes, Sterile Trocars for Single Use, Ureteral Stent Sets, Ureteral Stents, Guide Wire, Dilation Sets, Ureteral Access Sheaths, Disposable Rectal Tubes, Disposable I.D. Bracelets, Stethoscopes, Tourniquet

Certification Body



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Fuxiu Sheng