

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Boen Healthcare Co., Ltd.
Unit 602, International Center
No. 535, Shenxu Road
215021 Suzhou, Jiangsu
China

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

Manufacture and Distribution of Medical Devices
(see attachment for products 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: 2019-08-07
Certificate Registration No.: SX 60138020 0001
An audit was performed. Report No.: 15092074 004
This Certificate is valid until: 2022-02-27

Certification Body



Date 2019-08-07



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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60138020 0001
Report No.: 15092074 004

Organization: Boen Healthcare Co., Ltd.
Unit 602, International Center
No. 535, Shenxu Road
215021 Suzhou, Jiangsu
China

Scope:

Products:

Gauze Swabs (Sponges), Gauze Balls Gauze Bandages and Non Woven Wound Care Products, Medical Elastic Bandages, First Aid Kits and Its Related Products, Tracheostomy Tubes, Laryngeal Mask Devices, Disposable Air Cushion Face Masks, Disposable Breathing Circuits, Oropharyngeal Airways, Venturi Masks, Self-destruction Safety Syringes, Blood Collecting Needles, Foley Catheters, Disposable Acupuncture Needles, Three-way Stopcocks (with Extension Tube), Nelaton Catheters, Insulin Needles for Single Use, Humidifier Jar (Bubble Humidifier Jar), Wound Drainage System with and without Trocars, Sterile Urine Meters, Needle Free Connectors, Disposable Nasal Speculums, Disposable Ear Checkers, Enteral Feeding Sets (Bag), Disposable Oral Cavity Kits and Implements, Mercury-free Clinical Thermometers, Digital Thermometers

Certification Body



Date: 2019-08-07



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/2, Rev. 0

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Certificate**

Registration No.: SX 60138020 0001
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Organization: Boen Healthcare Co., Ltd.
Unit 602, International Center
No. 535, Shenxu Road
215021 Suzhou, Jiangsu
China

Scope:

Products:

Sterile Hemostasis Adhesive Dressing Series (Sterile Wound Plaster, Liquid Transfusion Plaster and Adhesive Dressing), Sphygmomanometers, Disposable Medical Brushes, Disposable Vaginal Speculums, Disposable Gynecological Sets, Disposable Dressing Kits, Disposable Colostomy Bags, Disposable Umbilical Cord Clamps, Nasal Oxygen Cannulae, Suction Catheters, Stomach Tubes, Feeding Tubes, Suction Connecting Tubes with Yankauer, Disposable Urine Drainage Bags, Sterile Wooden Tongue Depressors, Sterile Latex Surgical Gloves, Disposable Surgical Blades & Scalpels With Plastic Handle, Sterile Blood Lancets, Disposable Syringes, Disposable Infusion Sets, Disposable Transfusion Sets, Intravenous Needles for Single Use, Sterile Hypodermic Needles for Single Use, Disposable Tracheal Tubes (Standard & Reinforced), Disposable Oxygen Mask, Non-Rebreathing Masks, Aerosol Masks, Closed Suction Catheters, Non Woven Surgical Drapes, Non Woven Surgical Gowns, X-ray Detectable Gauze Swabs (Sponges), Gauze Balls and Lap Sponges in sterilization Packing

Certification Body



Date: 2019-08-07


Fuxiu Sheng

