

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**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:**

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



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**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

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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**



**Fuxiu Sheng**



TÜV Rheinland LGA Products GmbH  
TÜVRheinland  
Zertifizierungsstelle



# EC Certificate



## Production Quality Assurance MDD Annex V

Registration No.: DD 2063008-1

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

Products: Nasal Oxygen Cannulae, Suction Catheters, Stomach Tubes, Feeding Tubes, Suction Connecting Tubes with Yankauer, 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 Masks, Non-Rebreathing Masks, Aerosol Masks, Closed Suction Catheters, 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, Wound Drainage System with and without Trocars, Needle Free Connectors, Digital Thermometers, Humidifier Jar (Bubble Humidifier Jar), Enteral Feeding Sets (Bag);  
Aspects of manufacture concerned with securing and maintaining sterile conditions: Sterile Hemostasis Adhesive Dressing Series (Sterile Wound Plaster, Liquid Transfusion Plaster and Adhesive Dressing), Disposable

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Report No.: 15092074 009

Effective date: 2020-11-18

Expiry date: 2024-05-26

Issue date: 2020-11-18

  
  
Jason Pan  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

# EC Certificate



## Production Quality Assurance MDD Annex V

Registration No.: DD 2063008-1

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

Medical Brushes, Disposable Vaginal Speculums, Disposable Gynecological Sets, Disposable Dressing Kits, Disposable Colostomy Bags, Disposable Umbilical Cord Clamps, Disposable Urine Drainage Bags, Sterile Wooden Tongue Depressors, Non Woven Surgical Drapes, Non Woven Surgical Gowns, X-ray Detectable Gauze Swabs (Sponges), Gauze Balls and Lap Sponges in Sterilization Packing, Gauze Swabs (Sponges), Gauze Balls Gauze Bandages and Non Woven Wound Care Products, Medical Elastic Bandages, First Aid Kits and Its Related Products, Disposable Nasal Speculums, Disposable Ear Checkers, Disposable Oral Cavity Kits and Implements, Sterile Urine Meters;  
Aspects of manufacture concerned with conformity of products with metrological requirements: Sphygmomanometers, Mercury-free Clinical Thermometers

Replaces Approval, Registration No.: DD 60142274 0001

Report No.: 15092074 009  
Effective date: 2020-11-18  
Expiry date: 2024-05-26  
Issue date: 2020-11-18

A blue ink signature of Jason Pan is written over a circular seal. The seal contains the text 'TÜV Rheinland LGA Products GmbH' and 'Zertifiziert nach EN ISO 13485'. Below the signature, the text 'Jason Pan' and 'TÜV Rheinland LGA Products GmbH' is printed, followed by the address 'Tillystraße 2 · 90431 Nürnberg · Germany'.

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



# 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



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com http://www.tuv.com/safety