

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'.

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



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Registration No.: DD 2063008-1

Manufacturer: Boen Healthcare Co., Ltd.
Unit 602, International Center, No. 535, Shenxu Road,
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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.

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Jason Pan
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Tillystraße 2 · 90431 Nürnberg · Germany

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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
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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:
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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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

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Unit 602, International Center
No. 535, Shenxu Road
215021 Suzhou, Jiangsu
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Connectors, Disposable Nasal Speculums, Disposable Ear
Checkers, Enteral Feeding Sets (Bag), Disposable Oral Cavity
Kits and Implements, Mercury-free Clinical Thermometers,
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