

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Changzhou Operson Imp And Exp  
Co., Ltd.**  
**#7008, #12083~12085 Modern City**  
**217 Huangshan Road, Changzhou**  
**213022 Jiangsu**  
**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: 2019-02-28  
Certificate Registration No.: SX 60135406 0001  
An audit was performed. Report No.: 16801042 008  
This Certificate is valid until: 2020-08-22

Certification Body



Date 2019-02-28



**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 60135406 0001  
**Report No.:** 16801042 008

**Organization:** Changzhou Operson Imp And Exp  
Co., Ltd.  
#7008, #12083~12085 Modern City  
217 Huangshan Road, Changzhou  
213022 Jiangsu  
China

**Scope:**

Design and Development, Manufacture and Distribution of  
Non Absorbable Suture with or without Needles, Tracheostomy  
Tubes, Urethral Catheters, All Silicone Foley Catheters;

Manufacture and Distribution of Disposable Amniotic Membrane  
Perforators, Disposable Medical Suction-connecting Tubes,  
Disposable Gynecologic samplers, Sterile Surgical Blades,  
Sterile Blood lancets, Connecting Tubes with Yankauer  
Handle, Reinforced Endotracheal Tubes, Nelaton Catheters,  
Suction Catheters, Feeding Tubes, Stomach Tubes, Oxygen  
Masks, Nasal Oxygen Cannulae, Medical Nebulizers, Laryngeal  
Mask Airways, Tracheal Tubes, Alcohol Pads, Disposable  
Medical Brushes, Disposable Umbilical Cord Clamps,  
Disposable I.D.Bracelets, Disposable Colostomy Bags,  
Disposable Gynecological sets, Disposable Endometrial  
Suction Cannulas;

**Certification Body**



**Date:** 2019-02-28



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

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**213022 Jiangsu**  
**China**

**Scope:**

Manufacture and Distribution of Disposable  
Oral Cavity Kits and Implements, Disposable Vaginal  
Speculums, Disposable Nasal Speculums, Disposable  
Ear Checker, Plastic Forceps, Disposable Dressing Kits,  
First Aid Kits, Fast Dressing Bandages, Bandages,  
Oropharyngeal Airways, Rectal Tubes, Urinary Drainage Bags,  
Sterile Wound Plaster/Strips, Sterile Dressings Adhesive,  
Gauze sponges, Gauze rolls, Single-use medical package  
for medical devices

**Certification Body**



**Date:** 2019-02-28

