



TÜVRheinland®

**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60121146 0001

**Report No.:** 16801042 007

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

**Products:**

- Non Absorbable Suture with or without Needles
- Tracheostomy Tubes
- Urethral Catheters
- All Silicone Foley Catheters

Replaces Approval, Registration No.: HD 60077582 0001

**Expiry Date:** 2022-08-22

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2017-08-29

**Date:** 2017-08-29

Notified Body



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

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**  
**Directive 93/42/EEC Annex V**  
**Production Quality Assurance**  
**Medical Devices**

**Registration No.:** DD 60121147 0001

**Report No.:** 16801042 007

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

**Products:** Medical Devices  
  
(see attachment for products included)  
  
Replaces Approval, Registration No.: DD 60077583 0001

**Expiry Date:** 2022-08-22

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.

**Effective Date:** 2017-08-29

**Date:** 2017-08-29

Notified Body



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

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



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

**Attachment to  
Certificate**

**Registration No.:** DD 60121147 0001  
**Report No.:** 16801042 007

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

**Products:**

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;

Aspects of manufacture concerned with securing and  
maintaining sterile conditions:

Disposable Medical Brushes, Disposable Umbilical Cord  
Clamps, Disposable I.D.Bracelets, Disposable Colostomy  
Bags, Disposable Gynecological sets, Disposable  
Endometrial Suction Cannulas, 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

**Notified Body**

**Date:** 2017-08-29

**X. Ren**



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

Doc. 1/2, Rev.0

**Attachment to  
Certificate**

**Registration No.:** SX 60121149 0001  
**Report No.:** 16801042 007

**Organization:** Changzhou Operson Imp And Exp  
Co., Ltd.  
#7008, #12083~12085 Modern City  
217 Huangshan Road, Changzhou  
213022 Jiangu  
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: 2017-08-29**

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

Doc. 2/2, Rev.0

**Attachment to  
Certificate**

**Registration No.:** SX 60121149 0001  
**Report No.:** 16801042 007

**Organization:** Changzhou Operson Imp And Exp  
Co., Ltd.  
#7008, #12083~12085 Modern City  
217 Huangshan Road, Changzhou  
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: 2017-08-29**



**X. Ren**