



**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 Jiangsu  
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



**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**

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**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**

