

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

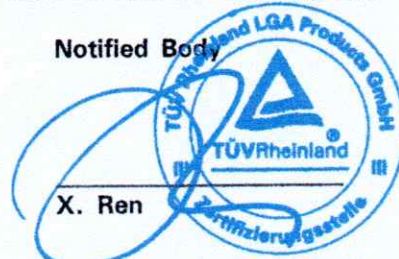
Expiry Date: 2022-08-22

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 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

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

Doc. 1/1, Rev.0

**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 Jiangsu
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

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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 Jiangsu
China

Scope:

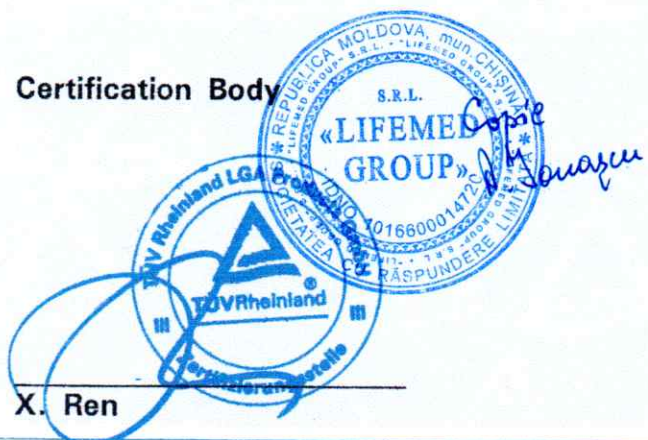
Design and Development, Manufacture and Distribution of
Non Absorbable Suture with or without Needles, Tracheostomy
Tubes, Urethral Catheters, All silicone Foley Catheters;

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;



Date: 2017-08-29

Certification Body



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

