

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
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

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

Doc. 2/2, Rev. 0

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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:

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

