

Certificate



**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2095027-1

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

Scope: **Sterile
Infusion Sets for Single Use, Sterile Transfusion Sets for Single Use, Sterile
Scalp Vein Type Needles for Single Use, Sterile Hypodermic Needles for
Single Use, Sterile Insulin Syringes for Single Use, Disposable Irrigating
and Feeding Syringes, Disposable Medical Three-way Stopcocks,
Disposable Infusion Enteral Giving Sets, Disposable Connecting Extension
Tubes, Medical Face Masks**

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 15069765 011

Effective date: 2020-09-09

Expiry date: 2023-07-06

Issue date: 2020-09-09



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Date September 11, 2020

Application for: QMS
Certificate No. : SX 2095027-1
Requirement : EN ISO 13485:2016

Dear Madame or Sir,

Enclosed please find the new certificate No. SX 2095027-1
replacing the previous certificate.

Best regards,



Fuxiu Sheng
Certification body