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

TÜVRheinla

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

DAKKS

Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

FuXiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany