EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60144914 0001

Report No.: 15069765 009

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 60140709 0001

Expiry Date: 2024-05-26

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: 2020-02-20

Date: 2020-02-20

Notified Body

Fuxiu Sheng

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

Digitally signed by Ionascu Andrei
Date: 2023.11.21 14:44:55 EET
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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60144914 0001
Report No.: 15069765 009

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

Products:

- Sterile Syringes for Single Use
- 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 Connecting Extension Tubes
- Disposable Infusion Enteral Giving Sets

Date: 2020-02-20

Notified Body

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Fuxiu Sheng

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