EC Certificate

Production Quality Assurance
MDD Annex V

Digitally signed by Iarovoi Petru
Date: 2022.01.14 16:07:17 EET
Reason: MoldSign Signature
Location: Moldova

Registration No.: DD 2159866-1

Manufacturer: Shandong Lee Med Technology Co., Ltd.
No. 10, Sanying Road, Technology Industrial Park,
Zhangdian District, Zibo, 255000 Shandong,
P. R. China

Products:
- Disposable Infusion Sets;
- Disposable Blood Transfusion Sets;
- Disposable Burette Infusion Sets;
- Disposable Infusion Sets for Pump;
- Disposable Lightproof Infusion sets;
- Extension Sets;
- Three Way Stopcocks;

For the following medical devices the scope covers the aspects of manufacture concerned with securing and maintaining sterile conditions:
- Transfer devices;
- Infusion Connectors and Caps;
- Medical Face Masks

Replaces Approval, Registration No.: DD 60127441 0001

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.

Report No.: 50118652 006

Effective date: 2020-12-21

Expiry date: 2023-04-16

Issue date: 2020-12-21

TÜV Rheinland LGA Products GmbH

Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2159866-1

Organization: Shandong Lee Med Technology Co., Ltd.
No. 10, Sanying Road, Technology Industrial Park,
Zhangdian District, Zibo, 255000 Shandong,
P.R. China

Scope: Manufacture and Distribution of Disposable Infusion Sets, Disposable Blood Transfusion Sets, Disposable Burette Infusion Sets, Disposable Infusion Sets for Pump, Disposable Lightproof Infusion Sets, Extension Sets,Transfer Devices, Three Way Stopcocks, Infusion Connectors and Caps, 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.: 190130981 110
Effective date: 2021-04-17
Expiry date: 2024-04-16
Issue date: 2021-04-14

TÜV Rheinland LGA Products GmbH

Jing Zhang
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Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Business Stream Products
Certification Department

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Shandong Lee Med Technology Co., Ltd.
No. 10, Sanying Road, Technology Industrial Park,
Zhangdian District, Zibo, 255000 Shandong,
P.R. China

Contact

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Date April 15, 2021

Application for: QMS
Certificate No. : SX 2159866-1
Requirement : EN ISO 13485:2016

Dear Madam or Sir,

Enclosed please find the new certificate No. SX 2159866-1replacing the previous certificate.

With effective date of the new certificate, the previous certificate becomes invalid.

Best regards,

Jing Zhang
Certification body

TÜV Rheinland
LGA Products GmbH

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Germany

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