Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2158884-1

Organization: Hunan Luzhou Huikang
Development Co., Ltd.
Xiangshang Industrial Park, Guanxia County,
Suining,
422601 Hunan
P.R. China

Scope: Manufacture and Distribution of Sterile Infusion Sets for Single Use(with Needle), Sterile Syringes for Single Use (with needle), Sterile Automatic Liquid Stop Infusion Sets for Single Use(with Needle), Sterile Infusion Sets with Precise Filter for Single Use, Sterile Retractable Auto-disable Syringes for Single Use, Sterile Hypodermic Needles for Single Use, Sterile Scalp Vein Sets for Single Use, Vaginal Speculum for Single Use, Medical face masks, Protective clothings for medical use

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.: 15093045 012

Effective date: 2020-07-21

Expiry date: 2022-08-28

Issue date: 2020-07-21

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

TÜV Rheinland LGA Products GmbH
Zertifizierstelle

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

EC Certificate

TÜVRheinland®

Production Quality Assurance
MDD Annex V

Registration No.: DD 2158884-1

Manufacturer: Hunan Luzhou Huikang
Development Co., Ltd.
Xiangshang Industrial Park, Guanxia County,
Suining,
422601 Hunan
P.R. China

Products: Sterile Infusion Sets for Single Use(with Needle), Sterile Syringes for Single Use (with Needle), Sterile Automatic Liquid Stop Infusion Sets for Single Use(with Needle), Sterile Infusion Sets with Precise Filter for Single Use, Sterile Retractable Auto-disable Syringes for Single Use, Sterile Hypodermic Needles for Single Use, Sterile Scalp Vein Sets for Single Use; Aspects of manufacture concerned with securing and maintaining sterile conditions of Vaginal Speculum for Single Use, Medical face masks, Protective clothings for medical use

Replaces Approval, Registration No.: DD 60122221 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.: 15093045 012

Effective date: 2020-07-21

Expiry date: 2021-06-03

Issue date: 2020-07-21

TÜV Rheinland LGA Products GmbH
Zertifizierstelle

Fuxiu Sheng
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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.