



安徽江南医疗器械股份有限公司

Anhui JN Medical Device Co., Ltd.

Address: Caicun Town Jing County Xuancheng City, Anhui, China
TEL: +86 563 5456 998 FAX: +86 563 5456618 email: 13905632616@163.com

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY DECLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: /
Name and address of the manufacturer: /
Nom et adresse du fabricant: /
Nome e indirizzo del fabbricante:

Anhui JN Medical Device Co., Ltd.
Caicun Town, Jing County, Xuancheng City, 242525 Anhui, China

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che
das Medizinprodukt / der Klasse
the medical device / of class
le dispositif médical / de la classe
il dispositivo medico / di classe

Disposable syringe 1ml luer lock / Ila

European Authorized Representative:
Prolinx GmbH
Brehmstr. 56
40239 Duesseldorf
Germany

nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive 93/42/EEC /
selon l'annexe IX de la directive 93/42/CEE / secondo l'allegato IX della direttiva 93/42/CEE
den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale
Gesetze entspricht.

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it.

remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE et de ses transpositions en droit
national qui le concernent.

soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano.
The manufacturer is exclusively responsible for the declaration of conformity.

Konformitätsbewertungsverfahren: /
Conformity assessment procedure: /
Procédure d'évaluation de la conformité: /
Procedura di valutazione della conformità:

Directive 93/42/EEC Annex VII
in connection with Annex V

Registrier-Nr.: /
Registration No.: /
N° d'enregistrement: /
Numero di registrazione:

DD 60140171 0001

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197

2020-6-1

Ort, Datum / Place, date /
Lieu, date / Luogo, data



General Manager:

Signature and Function / Name and function /
Firma e funzione / Nome e funzione



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev.0

**Attachment to
Certificate**

Registration No.: DD 60140171 0001
Report No.: 15062350 009

Manufacturer: Anhui JN Medical Device Co., Ltd.
Caicun Town, Jing County
Xuancheng City
242525 Anhui
China

Products:

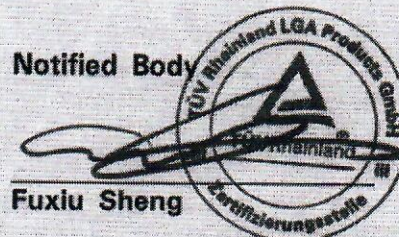
Infusion Sets for Single Use, Scalp Vein Sets
for Single Use, Transfusion Sets for Single Use,
Sterile Hypodermic Syringes for Single Use,
Sterile Hypodermic Needles for Single Use, Infusion
Sets with Precision Filters for Single Use, Disposable
Insulin Syringes;

Aspects of manufacture concerned with securing and
maintaining sterile conditions:

Irrigation Syringes, Disposable Transfer Sets

Date: 2019-06-19

Notified Body





Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Anhui JN Medical Device Co., Ltd.
Caicun Town, Jing County
Xuancheng City
242525 Anhui
China

has established and applies a quality management system for medical devices
for the following scope:

Manufacture and Distribution of Medical Devices

(see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-06-19
Certificate Registration No.: SX 60140170 0001
An audit was performed. Report No.: 15062350 009
This Certificate is valid until: 2021-10-18

Certification Body



Date 2019-06-19



Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev.0

**Attachment to
Certificate**

Registration No.: SX 60140170 0001
Report No.: 15062350 009

Organization:

Anhui JN Medical Device Co., Ltd.
Caicun Town, Jing County
Xuancheng City
242525 Anhui
China

Scope:

Products:

- Infusion Sets for Single Use
- Scalp Vein Sets for Single Use
- Transfusion Sets for Single Use
- Sterile Hypodermic Syringes for Single Use
- Sterile Hypodermic Needles for Single Use
- Infusion Sets with Precision Filters for Single Use
- Irrigation Syringes
- Disposable Transfer Sets
- Disposable Insulin Syringes

Certification Body

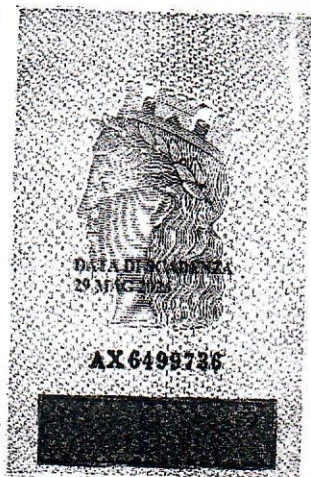


Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2019-06-19



Fuxiu Sheng



Cognome SACCA
Nome LUIGI
nato il 29-05-1973
(atto n. 51495 P. 4 S. A16)
e ROMA
Cittadinanza ITALIANA
Residenza ROMA
Via VIA TRIVULZIO D'ARCA
Stato civile CONIUGATO
Professione non presente in elenco
CONNOTATI E CONTRASSEGNI SALIENTI
Statura 1,75
Capelli neri
Occhi castani
Segni particolari

