

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60107350 0001

Report No.: 15089065 001

COPY

Manufacturer: Jiangxi Sanxin Medtec Co., Ltd.
No.999 Fushan Road,
XiaoLan Economic Development Zone
330200 Nanchang, Jiangxi
China

Products: Medical Devices
(see attachment for products and sites included)
Replaces Approval, Registration No.: HD 60097955 0001

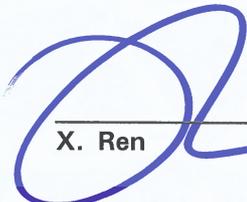
Expiry Date: 2021-01-13

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2016-01-14

Date: 2016-01-12

Notified Body


X. Ren


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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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Manufacturer: Jiangxi Sanxin Medtec Co., Ltd.
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XiaoLan Economic Development Zone
330200 Nanchang, Jiangxi
China

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Products:

- Hollow Fiber Haemodialysis Dialysers for Single Use
- Disposable Oxygen Masks
- Disposable Nasal Oxygen Cannulas
- Auto Stop Fluid Precise Filter Infusion Sets for Single Use with Needles
- Accessories Tubing for HDF
- Sterile Infusion Sets for Single Use (Spike, Drip Chamber, Filter, Tube, Flow Regulator, Protective Cap, Injection Site, Adaptor)
- Sterile Syringes for Single Use
- Sterile Hypodermic Needles
- Sterile Intravenous Needles
- Sterile Suction Catheters
- Sterile Feeding Tubes
- Sterile Stomach Evacuators
- Sterile Rectal Tubes
- Sterile Urinary Catheters
- Sterile Safety Syringes for Single Use
- Burette Type Infusion Sets for Single Use
- Sterile Hemodialysis Blood Circuits for Single Use (A.V. Fistula Needle Sets, Adaptor, Drip Chamber, Transducer, Injection Site)

Notified Body

Date: 2016-01-12

X. Ren



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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Manufacturer: Jiangxi Sanxin Medtec Co., Ltd.
No.999 Fushan Road,
XiaoLan Economic Development Zone
330200 Nanchang, Jiangxi
China

Products:

- Sterile Transfusion Sets for Single Use (Spike, Drip Chamber, Filter, Tube, Flow Regulator, Protective Cap, Injection Site, Adaptor)
- Extension Lines (Spike, Adaptor, Injection Site, Protective Cap, Flow Regulator, Three-way Stopcock)
- I.V. Catheters
- Auto-disable Syringes
- Sterile Insulin Syringes for Single Use
- Blood Collection Sets
- Bottle-type Infusion Sets with Needle for Single Use
- Bag Type Infusion Sets with Needles for Single Use
- Sterile Auto-Disable Syringes for Fixed Dose Immunization
- Infusion Sets with Precision Filters for Single Use with Needles
- Hemodialysis Concentrates
- Heparin Caps for Infusion
- Light-resistant Infusion Sets for Single Use with Needles
- I.V. Catheter Infusion Sets for Single Use
- Sharp Injury Prevention I.V. Infusion Needles for Single Use
- Precise Filter Infusion Sets for Single Use with Needles

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Manufacturer: Jiangxi Sanxin Medtec Co., Ltd.
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330200 Nanchang, Jiangxi
China

Products:

- Retractable Auto-disable Vaccine Syringes with Needles for Single Use
- Positive Pressure I.V. Catheters

Aspects of manufacture concerned with securing and maintaining sterile conditions:

- Vaginal Dilators
- Medical Gauzes
- Adhesive Dressings
- Cotton Swabs
- Urine Drainage Bags for Single Use
- Sterile Needles for Drug Dissolution for Single Use
- Sterile Dispenser Syringes with Needles for Single Use
- Dialysis Kits for Single Use
- Negative Pressure Drainage Devices

Date: 2016-01-12

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Manufacturer: Jiangxi Sanxin Medtec Co., Ltd.
No.999 Fushan Road,
XiaoLan Economic Development Zone
330200 Nanchang, Jiangxi
China

Sites included:

Sanjiang Road, Nanchang, Jiangxi 330204, China

Manufacture of a.m. products except
Hollow Fiber Haemodialysis Dialysers for Single Use,
Accessories Tubing for HDF

No.999 Fushan Road, XiaoLan Economic Development Zone,
Nanchang, Jiangxi 330200, China

Design and Development, Manufacture of a.m. products

Date: 2016-01-12

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