

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

Registration No.: DD 60142089 0001

Report No.: 15096003 006

Manufacturer: Anhui Tiankang Medical
Technology Co., Ltd.
No. 228 Weiyi Road
Economic Development Zone
Tianchang City
239300 Anhui
China

Products: Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: DD 60131061 0001

Expiry Date: 2024-05-27

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: 2019-08-26

Date: 2019-08-26

Notified Body



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**

Registration No.: DD 60142089 0001
Report No.: 15096003 006

Manufacturer: Anhui Tiakang Medical
Technology Co., Ltd.
No. 228 Weiyi Road
Economic Development Zone
Tianchang City
239300 Anhui
China

Products:

- Disposable Syringes
- Auto Disable Syringes
- Safety Syringes with Retractable Needles
- Disposable Infusion Sets
- Disposable Blood Transfusion Sets
- Scalp Vein Sets
- Disposable Blood Lancets
- Disposable Hypodermic Needles
- Disposable Dental Needles
- A.V.Fistual Needles
- Disposable IV Catheters
- Heparin Caps
- Extracorporeal Blood Circuits for Haemodialysers
- Disposable Insulin Syringes
- Intravenous Infusion Sets With Burette
- Extension Tubes
- Safety Insulin Syringes with Retractable Needles
- Disposable Safety Needles

Date: 2019-08-26

Notified Body



Fuxiu Sheng

**TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg**

**Attachment to
Certificate**

Registration No.: DD 60142089 0001
Report No.: 15096003 006

Manufacturer: Anhui Tiankang Medical
Technology Co., Ltd.
No. 228 Weiyi Road
Economic Development Zone
Tianchang City
239300 Anhui
China

Aspects of manufacture concerned with securing and
maintaining sterile conditions:

- Single Use Oral Syringes
- Disposable Three-way Stopcock

Site included:

South of Tiankang Road and West of Jingsi Road,
Xicheng District, 239300 Tianchang City,
Anhui Province, China

Date: 2019-08-26

Notified Body



Fuxiu Sheng

Business Stream Products
Certification Department



Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Anhui Tiankang Medical
Technology Co., Ltd.
No. 228 Weiyi Road
Economic Development Zone
Tianchang City
239300 ANHUI
CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date August 26, 2019

Application for : QMS Produktion, Anhang V MDD
Certificate No. : DD 60142089 Sheet 0001
Device : Only for QM-System audit
Test requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

Enclosed please find the new certificate No. DD 60142089 0001 replacing the previous certificate.

With effective date of the new certificate, the previous certificate (number see new certificate) becomes invalid.

Kind regards

Certification body

Fuxiu Sheng

A blue ink handwritten signature of Fuxiu Sheng, consisting of several loops and a long horizontal stroke.

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

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