



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 17 05 43199 023

Manufacturer: Suzhou Hengxiang Import & Export Co., Ltd.

18F., 1638 Xi Huan Road
215004 Suzhou
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)

Eiffestraße 80
20537 Hamburg
GERMANY



Product Category(ies):

Laparotomy Sponges,
X-Ray Detectable Gauze Swabs,
Surgical Gloves, Acupuncture Needles,
Surgical Blades, Disposable Syringes,
Infusion Sets, Blood Transfusion Sets,
Scalp Vein Sets, Sterile Hypodermic
Needle for Single Use, Syringe for Insulin,
Auto-disable Syringe, Nasal Oxygen Cannula,
Oxygen Mask, Endotracheal Tube,
Wound Drainage Reservoir,
Latex Foley Catheter, Humidifier Bottle,
Series of Nebulizer with Mask,
Extracorporeal Circulation Conduct of Blood
Purification Apparatus, First Aid Kits,
Digital Thermometers, Blood Pressure Monitors,
Infrared Ear Thermometers,
Infrared Forehead Thermometers

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH17116EXT01

Valid from: 2017-06-14

Valid until: 2022-06-13

Date, 2017-06-13



Stefan Preis

TÜV SÜD Product Service GmbH is Notified Body with Identification no. 0123

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Facility(ies):

Suzhou Hengxiang Import & Export Co., Ltd.
18F., 1638 Xi Huan Road, 215004 Suzhou,
PEOPLE'S REPUBLIC OF CHINA

Suzhou Hengxiang Import & Export Co., Ltd.
11F., 888 Chenghu Road, 215168 Suzhou,
PEOPLE'S REPUBLIC OF CHINA





Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
**Anhui Tiakang Medical
Products Co., Ltd.**
No. 20 South Renhe Road
239300 Tianchang City, Anhui Province
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 and additional sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

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

Effective Date: 2020-11-20
Certificate Registration No.: SX 60104288 0001
An audit was performed. Report No.: 15043138 005
This Certificate is valid until: 2021-07-11

Certification Body



Date 2020-11-20

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

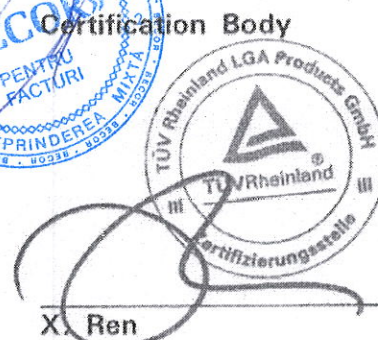
TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SX 60104288 0001
Report No.: 15043138 005

Organization: Anhui Tiankang Medical
Products Co., Ltd.
No. 20 South Renhe Road
239300 Tianchang City, Anhui Province
China

Scope: Products:

- Disposable Syringes
- Auto Disable Syringes
- Safety Syringes with Retractable Needles
- Disposable Infusion Sets
- Disposable Blood Transfusion Sets
- Scalp Vein Sets
- Disposable Blood Taking Needles
- Disposable Hypodermic Needles
- Disposable Dental Needles
- A.V.Fistula Needles
- Disposable IV Catheters
- Heparin Caps
- Extracorporeal Blood Circuits for Haemodialysers
- Circumcision Devices
- Disposable Insulin Syringes
- Intravenous Infusion Sets With Burette
- Single Use Oral Syringes
- Extension Lines



Date: 2020-11-20