



SHANXIAN RUNTE MEDICAL INSTRUMENTS CO., LTD  
单县润特医疗器械有限公司

Add: Nanduan Wenhua Road, Shanxian, Heze City, Shandong, China

Date: Nov. 25<sup>th</sup>, 2015

## EC Declaration of Conformity

**Manufacturer:**

Shanxian Runte Medical Instruments Co., Ltd

Add: Nanduan Wenhua Road, Shanxian, Heze City,  
Shandong, China

Tel: +86-530-4660062 Fax: +86-530-4660055

Http://www.suturescn.com

**whose single Authorized Representative:**

Prolinx GmbH

Address: Brehmstr.56, 40239, Duesseldorf,  
Germany

Fax: 0049 2131 4051968-9

We, the manufacturer, herewith declare that the products

**Disposable suture needles with Non-absorbable Threads**

**SIZE:** Needle length varies from 6 mm to 85 mm;

Thread diameter varies from 0.050 to 0.699 mm.

UMDNS-Code: 12-754

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

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

**CE 0197**

The product concerned has been manufactured under a quality management system according to Annex V of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assured via assessment of the quality management system by the Notified Body

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

Certificate No.: DD601063070001

Issue date: 2015.11.24

Expiry date: 2020.11.23





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following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Shanxian Runte Medical Instruments Co., Ltd

Address: Nanduan Wenhua Road, Shanxian, Heze City, Shandong, China



*Handwritten signature*

Shanxian Runte Medical Instruments Co., LTD.



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



**Registration No.:** DD 60106307 0001

**Report No.:** 15089783 001

**Manufacturer:**

Shanxian Runte Medical  
Instruments Co., Ltd.  
Nanduan Wenhua Road, Shanxian,  
274300 Heze City, Shandong  
China

**Products:**

- Disposable Suture Needles with Non-absorbable Threads
- Sterile Syringe for Single Use
- Sterile Infusion Sets for Single Use
- Disposable Lancets for Blood Specimen Collection

Replaces Approval, Registration No.: DD 60034791 0001

**Expiry Date:**

2020-11-23

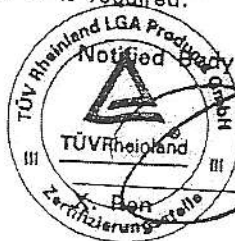
The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned 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:**

2015-11-24

**Date:**

2015-11-24



**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 0187.

