

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 0197.