

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

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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.