# 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:** 2023-11-23

**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:** 2018-11-24

**Date:** 2018-11-24

TÜV Rheinland LGA Products GmbH Notified Body TÜVRheinland Zertifizierungsstelle

X. Ren

**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.**

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