

**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:** 2025-11-23

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:** 2021-11-24

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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.