

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to
Registration No.: SX 60106308 0001
Report No.: 15089783 001

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

Scope: 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
- Absorbable Surgical Sutures with or without Needle

Certification Body

**DAKkS**
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02
Date: 2019-11-24


TÜVRheinland
K. Ren

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



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- Disposable Suture Needles with Non-absorbable Threads
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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.