

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices
for the following scope:

Manufacture and Distribution of Medical Devices

(see attachment for products included)

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012
EN ISO 13485:2012/AC:2012**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-11-23
Certificate Registration No.: SX 60106308 0001
• An audit was performed. Report No.: 15089783 001
This Certificate is valid until: 2023-11-22



Date 20 20-1123



X. Ren

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**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



Date: 2020-11-23