

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: 2018-11-23
Certificate Registration No.: SX 60106308 0001
* An audit was performed. Report No.: 15089783 001
This Certificate is valid until: 2021-11-22



Date 2018-11-23



X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3635 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to
Registration No.: SX 60106308 0001
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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: 2018-11-23