

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

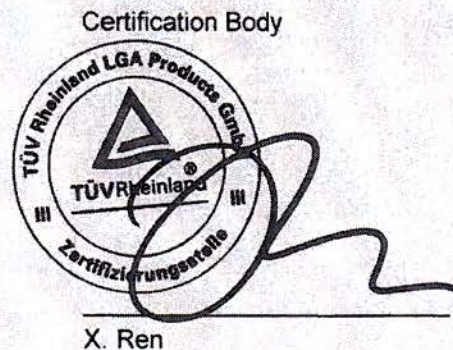
**EN ISO 13485:2012
EN ISO 13485:2012/AC:2012**

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

Effective Date: 2015-11-24
Certificate Registration No.: SX 60106308 0001
An audit was performed. Report No.: 15089783 001
This Certificate is valid until: 2018-11-23



Date 2015-11-24



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 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
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: 2015-11-24

