

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
Dirui Industrial Co., Ltd.
95 Yunhe Street
New & High Tech.
Development Zone
Changchun
Jilin Province 130012
China

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

Design and Development, Manufacture and Distribution of
In vitro Diagnostic Medical Test Systems
(see attachment for products included)

Proof has been furnished that the requirements specified in

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

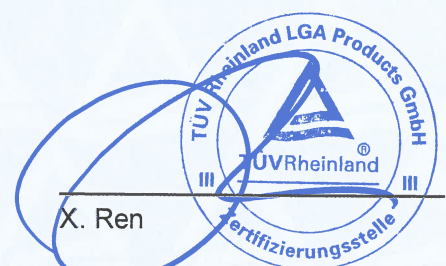
are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2017-03-02
Certificate Registration No.: SX 60116875 0001
An audit was performed. Report No.: 15047317 006
This Certificate is valid until: 2019-02-28

Certification Body



Date 2017-02-23



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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60116875 0001
Report No.: 15047317 006

Organization: Dirui Industrial Co., Ltd.
95 Yunhe Street
New & High Tech.
Development Zone
Changchun
Jilin Province 130012
China

Scope:

Products:

- Urine Analysis Systems (Reagents, Analyzers, Controls)
- Hematology Test Systems (Reagents, Analyzers, Controls)
- Clinical Chemistry Test Systems (Reagents, Analyzers, Controls)
- Fecal Test Systems (Reagents, Analyzers, Controls)

Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2017-02-23

