

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Shenzhen Landwind Bioengineering
Co., Ltd.**
Floor9, Block4 A4, Nanshan iPark
No. 1001 Xueyuan Road, Nanshan District
Shenzhen
518055 Guangdong
China

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

**Design and Development, Manufacture, Distribution,
Installation and Service of Auto Hematology Analyzers,
Automat Biochemistry Analyzers**
(see attachment for sites 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: 2016-09-18
Certificate Registration No.: SX 60113187 0001
An audit was performed. Report No.: 17058317 001
This Certificate is valid until: 2019-02-28

Certification Body



Date 2016-09-18



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

**Attachment to
Certificate**

Registration No.: SX 60113187 0001
Report No.: 17058317 001

Organization: Shenzhen Landwind Bioengineering
Co., Ltd.
Floor9, Block4 A4, Nanshan iPark
No. 1001 Xueyuan Road, Nanshan District
Shenzhen
518055 Guangdong
China

Scope:

Sites included:

Floor9, Block4 A4, Nanshan iPark, No 1001 Xueyuan Road,
Nanshan District, 518055, Shenzhen, China

Activities related to design and development, distribution,
installation and service

Floor2, Block11, Honglong High-tech Industrial Area,
Langxin Community, Shiyan Town, Bao'an District,
518108, Shenzhen, China

Activities related to manufacture

Certification Body



Date: 2016-09-18



TÜVRheinland®

LGA

Precisely Right.

**Business Stream Products
Certification Department**

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Shenzhen Landwind Bioengineering
Co., Ltd.
Floor9, Block4 A4, Nanshan iPark
No. 1001 Xueyuan Road, Nanshan Dist
518055 SHENZHEN
CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date September 18, 2016

Application for : QMS
Certificate No. : SX 60113187 Sheet 0001
Device : Only for QM-System audit
Test requirement : EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

Dear Madame or Sir,

Your Quality Management System has been tested and found to be in accordance with the above mentioned requirements.

Enclosed please find the certificate
No. SX 60113187 0001.

Kind regards

Certification body

X. Ren

Test sample: no documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

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