

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**General Life Biotechnology  
Co., Ltd.**  
5F, No. 240, Shinshu Rd.,  
Shin Juang Dist.,  
New Taipei City 242  
Taiwan

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 Monitoring Systems and  
Wireless Intravenous Sensor Systems  
(see attachment for products included)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2003 + AC:2009**

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

Certificate Registration No.: SX 60038721 0001

An audit was performed. Report No.: 10027745 002

This Certificate is valid until: 08.04.2015



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln  
und Medizinprodukten  
ZLG-ZQ-995.00.01-46

Certification Body



  
Dr. H. Lüdemann

Date 14.06.2011

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

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**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to**  
**Registration No.:** SX 60038721 0001  
**Report No.:** 10027745 002

**Organization:** General Life Biotechnology  
Co., Ltd.  
5F, No. 240, Shinshu Rd.,  
Shin Juang Dist.,  
New Taipei City 242  
Taiwan

**Scope:**

**Products:**

- Blood Glucose, Total Cholesterol, and Triglyceride Multi-Monitoring Systems
- Blood Glucose, Uric Acid, and Total Cholesterol Multi-Monitoring Systems
- Blood Glucose and Uric Acid Dual-Monitoring Systems
- Blood Glucose and Total Cholesterol Dual-Monitoring Systems
- Uric Acid and Total Cholesterol Dual-Monitoring system
- Blood Glucose Monitoring System
- Uric Acid Monitoring System
- Total Cholesterol Monitoring System
- Hb Hemoglobin Test Systems
- Blood Glucose, Total Cholesterol, and Triglyceride Meters
- Blood Glucose, Uric Acid, and Total Cholesterol Meters
- Blood Glucose and Uric Acid Dual Meters
- Blood Glucose and Total Cholesterol Dual Meters
- Uric Acid and Total Cholesterol Dual Meters
- Blood Glucose Meters



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5F, No. 240, Shinshu Rd.,  
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New Taipei City 242  
Taiwan

**Scope:** Products:

- Uric Acid Meters
- Total Cholesterol Meters
- Hb Hemoglobien Meters
- Glucose Test Strips
- Uric Acid Test Strips
- Total Cholesterol Test Strips
- Hemoglobien Test Strips
- Triglyceride Test Strips
- Glucose Control Solutions
- Uric Acid Control Solutions
- Total Cholesterol Control Solutions
- Triglyceride Control Solutions
- Hemoglobien Control Solutions
- Wireless IV Sensor Systems
- Wireless IV Sensors
- Sensor Cables
- Sensor Tapes



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