

APPROVAL
EC Directive 98/79/EC Annex IV, Article 3
Full Quality Assurance System
In vitro diagnostic medical devices

Registration No.: HL 60038720 0001

Report No.: 10027745 002

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

Scope: Design/Development and Manufacture of in vitro Diagnostic
Monitoring Systems for Self-Testing

(see attachment for products included)

Replaces Approval, Registration No.: HL 60028961 0001

Date of Expiry: 08.04.2015

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex IV, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex IV, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Date 14.06.2011



Notified Body


Dr. H. Lüdemann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: HL 60038720 0001
Report No.: 10027745 002

Manufacturer: 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 Systems
- Blood Glucose Monitoring Systems
- Uric Acid Monitoring System
- Total Cholesterol Monitoring System
- 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

Date 14.06.2011



Certification Body


Dr. H. Lüdemann

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: HL 60038720 0001
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Manufacturer: General Life Biotechnology
Co., Ltd.
5F, No. 240, Shinshu Rd.,
Shin Juang Dist.,
New Taipei City 242
Taiwan

Scope: Products:

- Blood Glucose Meters
- Uric Acid Meters
- Total Cholesterol Meters
- Glucose Test Strips
- Uric Acid Test Strips
- Total Cholesterol Test Strips
- Triglyceride Test Strips
- Glucose Control Solution
- Uric Acid Control Solution
- Total Cholesterol Control Solution
- Triglyceride Control Solution

Date 14.06.2011



Certification Body


Dr. H. Lüdemann