

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 2029595-1

Manufacturer: General Life Biotechnology
Co., Ltd.
6, 7F., No. 669, Jhongjheng Rd., Shin Juang Dist.,
New Taipei City 242
Taiwan

Products:

- 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 Systems
- Total Cholesterol Monitoring Systems
- Hb Hemoglobin Test Systems
- Blood Glucose, Uric Acid, 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
- Uric Acid Meters
- Total Cholesterol Meters

The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 238540366-030

Effective date: 2022-05-18

Expiry date: 2025-05-26

Issue date: 2022-05-18



Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

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Annex IV excluding (4, 6)

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Manufacturer: General Life Biotechnology
Co., Ltd.
6, 7F., No. 669, Jhongjheng Rd., Shin Juang Dist.,
New Taipei City 242
Taiwan

- Hb Hemoglobin Meters
- Glucose Test Strips
- Uric Acid Test Strips
- Total Cholesterol Test Strips
- Hb Hemoglobin Test Strips
- Glucose Control Solutions
- Uric Acid Control Solutions
- Total Cholesterol Control Solutions
- Hb Hemoglobin Control Solutions
- β -Ketone Monitoring System
- Blood Glucose and β -Ketone Dual-Monitoring System
- β -Ketone Meter
- Blood Glucose and β -Ketone Dual Meter
- β -Ketone Test Strip
- β -Ketone Control Solution

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Co., Ltd.
6, 7F., No. 669, Jhongjheng Rd., Shin Juang Dist.,
New Taipei City 242
Taiwan

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	General Life Biotechnology Co., Ltd. 5F, No. 240, Shinshu Road Shin Juang Dist., New Taipei City 242 Taiwan	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 Systems; Total Cholesterol Monitoring Systems; Hb Hemoglobin Test Systems; Blood Glucose, Uric Acid, 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; Uric Acid Meters; Total Cholesterol Meters;

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New Taipei City 242
Taiwan

The scope of certification includes the following manufacturing sites:

Hb Hemoglobin Meters; Glucose Test Strips;
Uric Acid Test Strips; Total Cholesterol Test
Strips; Hb Hemoglobin Test Strips; Glucose
Control Solutions; Uric Acid Control
Solutions; Total Cholesterol Control
Solutions; Hb Hemoglobin Control Solutions;
 β -Ketone Monitoring System; Blood Glucose
and β -Ketone Dual-Monitoring System; β -
Ketone Meter; Blood Glucose and β -Ketone
Dual Meter; β -Ketone Test Strip; β -Ketone
Control Solution

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