

Anexa 13 Glucometru (caracteristici de bază), PLUS Multi-MonitoringSystem, General Life Biotechnology

Specificatie tehnica solicitata	Specificatie tehnica oferita
Glucometru (caracteristici de bază) Cod 151200 Descriere Analizatoare de glicemie mobile (portabile) pentru folosirea acasă, în biroul medicului, mașini de ambulanță sau spitale. Parametru Specificația Metoda Electrochimică Tip probă Capilar Volumul minimal al probei $\leq 0.7 \mu\text{L}$ Gama de măsurare 1-30,0 mmol/L Gama hematocritului 25-60 % Timpul de măsurare ≤ 10 sec. Ecran LCD da Calibrarea Fără calibrare sau calibrare automată Oprere automată da Memoria numărul de teste ≥ 300 Data/ora și rezultatul probei da Baterie internă da Autonomie de la baterie ≥ 700 teste Indicator baterie descărcată da Păstrarea datelor din memorie la înlocuirea bateriei da Accesorii, consumabile Toate accesoriile și consumabile să fie compatibile da Baterie 1 buc. Geantă de transport pentru glucometru si accesorii (ace, dispozitiv de întepare, teste) da Dispozitiv de întepare cu nivel reglabil de strapungere da Ace sterile de unică utilizare ≥ 400 buc. Teste cu termenul de valabilitate min. 18 luni ≥ 400 buc.	Glucometru (caracteristici de bază) Cod 151200 Descriere Analizatoare de glicemie mobile (portabile) pentru folosirea acasă, în biroul medicului, mașini de ambulanță sau spitale. Parametru Specificația Metoda Electrochimică Tip probă Capilar Volumul minimal al probei - $0.7 \mu\text{L}$ Gama de măsurare 1.1-33.3 mmol/L Gama hematocritului 25-60 % Timpul de măsurare -5 sec. Ecran LCD da Calibrarea Fără calibrare Oprere automată da Memoria numărul de teste -360 Data/ora și rezultatul probei da Baterie internă da Autonomie de la baterie ≥ 700 teste Indicator baterie descărcată da Păstrarea datelor din memorie la înlocuirea bateriei da Accesorii, consumabile Toate accesoriile și consumabile să fie compatibile da Baterie 1 buc. Geantă de transport pentru glucometru si accesorii (ace, dispozitiv de întepare, teste) da -1 buc; Dispozitiv de întepare cu nivel reglabil de strapungere da -1 buc Ace sterile de unică utilizare - 400 buc. Teste cu termenul de valabilitate min. 18 luni - 400 buc.

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.

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Fuxiu Sheng
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.

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

- 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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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

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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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

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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Certificate



Quality Management System
EN ISO 13485:2016

Registration No.: SX 2029595-1

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

Scope: Design and Development, Manufacture and Distribution of in vitro
diagnostic clinical chemical medical devices used in monitoring of blood
glucose and blood analytes, including self-testing and near patient/point of
care

TÜVRheinland

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

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Issue date: 2022-03-09



A circular blue seal for TÜV Rheinland LGA Products GmbH. The seal contains the TÜV Rheinland logo and the text "TÜV Rheinland LGA Products GmbH" and "Zertifizierungsstelle". A blue ink signature is written across the seal.
Fuxiu Sheng
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate



Quality Management System
EN ISO 13485:2016

Registration No.: SX 2029595-1

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

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o General Life Biotechnology Co., Ltd. 5F, No. 240, Shinshu Road Shin Juang Dist., New Taipei City 242 Taiwan	Design and Development, Manufacture and Distribution of in vitro diagnostic clinical chemical medical devices used in monitoring of blood glucose and blood analytes, including self-testing and near patient/point of care

TÜVRheinland

Report No.: 238520647-040
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Fuxiu Sheng
TÜVRheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

PLUS Multi-MonitoringSystem

BeneCheck PLUS Multi-MonitoringSystem is just like your personal Dr. at home. You can check your Glucose, Total Cholesterol, and Uric Acid in 1 minute! With Auto-Strip Recognition function, the system will recognize the inserted strip while testing, which makes self testing easy and delightful. Also, the meter is Swiss designed. BeneCheck brings chic and healthy to you!

- 3in1 Multi-Function
- Auto Strip Recognition
- Total Check, Total

Care



SPECIFICATION

	GLU Blood Glucose Strip	CHOL Total Cholesterol S	UA Uric Acid Strip
Principle	ElectrochemicalBio sensor	ElectrochemicalBios ensor	ElectrochemicalSens or
Test Sample	Fingertip	Fingertip	Fingertip
Measuring Time	5 Seconds	26 Seconds	15 Seconds
Measuring Range	20 - 600 mg/dL (1.1 - 33.3 mmol/L)	100 - 400 mg/dL (2.59 - 10.35 mmol/L)	3- 20 mg/dL (0.18 - 1.19 mmol/L)
Sample Volume	0.7 µL	10 µL	1 µL
Memory	360 Test Results	50 Test Results	50 Test Results

UnopenedShelf Life :

(frommanufacturingday)

BloodGlucose - 24 months

Total Cholesterol - 16 months

Uric Acid-18 Months

OpenedShelf Life :

BloodGlucose - 3 months

Total Cholesterol - 3 months

Uric Acid - 3 months