

EC Certificate

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

Registration No.: HL 2156856-1

Manufacturer: Guilin Royalyze Medical Instrument Co., Ltd.
18 Li River Road, Qixing District,
Guilin
541004 Guangxi
P.R. China

Products: Multi-Monitoring Meters, Blood Glucose Meters, Blood Glucose Test Strips,
Uric Acid Test Strips, Total Cholesterol Test Strips, Urine Glucose Test
Strips, Blood Glucose Control Solution, Uric Acid Control Solution, Total
Cholesterol Control Solution, Urine Glucose Control Solution, Hemoglobin
Test Strips

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.: 10920440-100

Effective date: 2021-12-10

Expiry date: 2025-05-26

Issue date: 2022-03-22



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.

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Annex IV excluding (4, 6)

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18 Li River Road, Qixing District,
Guilin
541004 Guangxi
P.R. China

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	Guilin Royalyze Medical Instrument Co., Ltd. 13 Lushan Road, Lushan Industrial Park, Xicheng Economic Development Zone, Guilin, 541199 Guangxi P.R. China	Multi-Monitoring Meters, Blood Glucose Meters, Blood Glucose Test Strips, Uric Acid Test Strips, Total Cholesterol Test Strips, Urine Glucose Test Strips, Blood Glucose Control Solution, Uric Acid Control Solution, Total Cholesterol Control Solution, Urine Glucose Control Solution, Hemoglobin Test Strips

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