

Certificate



**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2156856-1

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

Scope: Design and Development, Manufacture and Distribution of Blood Glucose Meters, Uric Acid Test Strips, Multi-Monitoring Meters, Blood Glucose Test Strips, Total Cholesterol Test Strips, Urine Glucose Test Strips, Urine Uric Acid Test Strips, Lipid Profile Test Strips, Hemoglobin Test Strips, Blood Glucose Control Solution, Uric Acid Control Solution, Total Cholesterol Control Solution, Urine Glucose Control Solution

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.

Report No.: 10918986-100
Effective date: 2022-01-17
Expiry date: 2024-11-15
Issue date: 2022-01-17



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



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The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Guilin Royalyze Medical Instrument Co., Ltd. 18 Li River Road, Qixing District, Guilin, 541004 Guangxi P.R. China	License holder; Distribution of Blood Glucose Meters, Uric Acid Test Strips, Multi-Monitoring Meters, Blood Glucose Test Strips, Total Cholesterol Test Strips, Urine Glucose Test Strips, Urine Uric Acid Test Strips, Lipid Profile Test Strips, Hemoglobin Test Strips, Blood Glucose Control Solution, Uric Acid Control Solution, Total Cholesterol Control Solution, Urine Glucose Control Solution
/02	c/o Guilin Royalyze Medical Instrument Co., Ltd. 13 Lushan Road, Lushan Industrial Park, Xicheng Economic Development Zone, Guilin, 541199 Guangxi P.R. China	Design and Development, Manufacture of Blood Glucose Meters, Uric Acid Test Strips, Multi-Monitoring Meters, Blood Glucose Test Strips, Total Cholesterol Test Strips, Urine Glucose Test Strips, Urine Uric Acid Test Strips, Lipid Profile Test Strips, Hemoglobin Test Strips, Blood Glucose Control Solution, Uric Acid Control Solution, Total Cholesterol Control Solution, Urine Glucose Control Solution

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