



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07



Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 074544 0014 Rev. 01

Manufacturer:

URIT Medical Electronic Co., Ltd.

No. D-07

Information Industry District

High-tech Zone

541004 Guilin, Guangxi

PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): In Vitro diagnostic devices for self testing

- **Blood Glucose Monitoring System for self testing**
- **Blood Lipid Monitoring System for self testing**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuv-sud.com/ps-cert?q=cert:V1 074544 0014 Rev. 01

Report no.: GZ2116301

Valid from: 2022-03-01

Valid until: 2024-02-14

Date, 2022-03-01

Christoph Dicks
Head of Certification/Notified Body



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Model(s):

**Blood Glucose Meter,
Blood Glucose Test Strip,
Blood Glucose Control Solution,
Blood Lipid Analyzer,
Blood Lipid Test Strip**

Facility(ies):

URIT Medical Electronic Co., Ltd.
No. D-07, Information Industry District, High-tech Zone, 541004
Guilin, Guangxi, PEOPLE'S REPUBLIC OF CHINA

URIT Medical Electronic Co., Ltd.
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REPUBLIC OF CHINA