ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

TÜV SÜD 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.tuvsud.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


TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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