CERTIFICADO ◆ 인증서 ◆ CERTIFICATO ◆ 認証書 ◆ CERTIFICATE ◆ 认证证书 ◆ ZERTIFIKAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

# Certificate

## No. Q5 074544 0012 Rev. 04

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

**Certification Mark:**




**Scope of Certificate:** **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents for Clinical Chemistry, Immunochemistry, Hematology, Infectious Diseases and Sample Processing, In Vitro Diagnostic Calibrators and Control Materials for Clinical Chemistry, Hematology and Immunochemistry;**
**Design and Development, Production, Servicing, Installation, and Distribution of In Vitro Diagnostic Instruments for Clinical Chemistry, Hematology, Immunochemistry and Sample Processing;**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 074544 0012 Rev. 04

**Report No.:** GZ26016301

**Valid from:** 2026-09-14
**Valid until:** 2029-09-13

**Date,** 2026-09-10

Christoph Dicks
Head of Certification/Notified Body


TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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## No. Q5 074544 0012 Rev. 04

**Applied Standard(s):**

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

**Facility(ies):**

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

Design and Development and Production of in vitro diagnostic reagents for Clinical Chemistry, Hematology, Infectious Diseases and Sample Processing and in vitro diagnostic calibrators and control materials for Clinical Chemistry and Hematology;
Production of in vitro diagnostic reagents, calibrators and control materials for Immunochemistry;
Design and Development and Production of in vitro diagnostic instruments for Clinical Chemistry, Hematology and Sample Processing;
Warehousing

**URIT Medical Electronic Co., Ltd.**
No. D-02, Information Industry District, High-tech Zone, 541004 Guilin, Guangxi, PEOPLE'S REPUBLIC OF CHINA

Distribution of in vitro diagnostic reagents for Clinical Chemistry, Hematology, Immunochemistry, Infectious Diseases and Sample Processing and in vitro diagnostic calibrators and control materials for Clinical Chemistry, Hematology and Immunochemistry;
Servicing, Installation and Distribution of in vitro diagnostic instruments for Clinical Chemistry, Hematology, Immunochemistry and Sample Processing;

**URIT Medical Electronic Co., Ltd.**
NO.4 East Alley, Jiuhua Road, 541001 Guilin, Guangxi, PEOPLE'S REPUBLIC OF CHINA

Design and development and Production of in vitro diagnostic reagents and in vitro diagnostic instruments for Clinical Chemistry of Rapid test;

**URIT Medical Electronic Co., Ltd.**
1F & 2F of Building No.1, Building No.2, No. GX-G08, East Side of Donghuan Road, Qixing District, 541004 Guilin, Guangxi, PEOPLE'S REPUBLIC OF CHINA

Design and Development of in vitro diagnostic reagents, calibrators and control materials for Clinical Chemistry and Immunochemistry.
Design and Development and Production of in vitro diagnostic instruments for Clinical Chemistry and Immunochemistry;
Warehousing


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