



# Certificate

No. Q5 074544 0012 Rev. 03

**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; Design and Development, Production, Distribution, Installation and Servicing of In Vitro Diagnostic Instruments for Clinical Chemistry, Immunochemistry, Hematology and Sample Processing; Design and Development, Production and Distribution of Ultrasonic Scalars, High-Speed Turbine Dental Handpieces, LED Light Curing Device and Ultrasonic Scaler Tips**

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 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:Q5 074544 0012 Rev. 03](http://www.tuvsud.com/ps-cert?q=cert:Q5_074544_0012_Rev.03)

**Report No.:** GZ2316301

**Valid from:** 2023-10-17

**Valid until:** 2026-09-13

**Date,** 2023-10-18



Christoph Dicks  
Head of Certification/Notified Body

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**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, Production 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;  
Design and Development, 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

Design and Development, Production and Distribution of Ultrasonic  
Scalers, High-Speed Turbine Dental Handpieces, LED Light Curing  
Device, Ultrasonic Scaler Tips;  
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;  
Distribution, Installation and Servicing of In Vitro Diagnostic Instruments  
for Clinical Chemistry, Immunochemistry, Hematology 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, Production and Distribution of In Vitro  
Diagnostic Instruments and Reagents for Clinical Chemistry of Rapid  
Tests

**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, Production of In Vitro Diagnostic Instruments  
for Clinical Chemistry (Automatic Chemistry Analyzer and Electrolyte  
Analyzer) and Immunochemistry (Chemiluminescent Immunoassay  
Analyzer)