



# Certificate

No. Q5 052126 0062 Rev. 06

**Holder of Certificate:** **TaiDoc Technology Corporation**  
B1-7F, No. 127, Wugong 2nd Road, Wugu Dist.  
24888 New Taipei City  
TAIWAN

**Certification Mark:**



**Scope of Certificate:** **Design and development, Production, Servicing and Distribution of**

- **In Vitro Diagnostic Reagents and Instruments (Blood Glucose, Hemoglobin A1c, Hemoglobin, Lactate,  $\beta$ -Ketone, Blood Glucose plus  $\beta$ -Ketone, Total Cholesterol, Uric Acid, Triglycerides, Multiple functional clinical chemistry, Pregnancy, and Ovulation)**
- **In Vitro Diagnostic Control Solution (Blood Glucose, Total Cholesterol, Uric Acid, Hemoglobin A1c,  $\beta$ -Ketone, Lactate, Triglycerides, Blood Glucose plus  $\beta$ -Ketone, and Multiple functional clinical chemistry)**
- **In Vitro Diagnostic Rapid Test Reagent (colloidal gold method) for Infectious Diseases**
- **Blood Pressure Monitoring System, Blood Glucose plus Blood Pressure Monitoring System, Reusable NIBP Cuff, Thermometer (Intermittent and Continuous), Ear Thermometer Probe Cover, Vital Signs Monitor, ECG Recorder, Pulse Oximeter, SpO2 Sensor, Nebulizer, Nebulizer Accessory, TeleHealth Gateway, TeleHealth System, Medical Information Management Application (for Mobile Devices), Scale Plus Body Fat Monitor, Thermal Printer for Medical Monitoring Device, Sterile Blood Lancet, Lancing Device, Multi-dose Delivery Device, Safety Pen Needle, Pen Needle, Electronic Nasal Aspirator, Breast Pump (Electric and Manual), Blood Glucose Sensor Module.**

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

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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 052126 0062 Rev. 06](http://www.tuvsud.com/ps-cert?q=cert:Q5_052126_0062_Rev_06)

**Report No.:** TW2201101

**Valid from:** 2023-03-02

**Valid until:** 2026-03-01

**Date,** 2023-03-02



Christoph Dicks

Head of Certification/Notified Body

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**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):** **TaiDoc Technology Corporation**  
B1-7F, No. 127, Wugong 2nd Road, Wugu Dist., 24888 New  
Taipei City, TAIWAN

**Wugu factory:**

Design and development, Production, Servicing and Distribution of  
- In Vitro Diagnostic Reagents and Instruments (Blood Glucose, Hemoglobin A1c, Hemoglobin, Lactate,  $\beta$ -Ketone, Blood Glucose plus  $\beta$ -Ketone, Total Cholesterol, Uric Acid, Triglycerides, Multiple functional clinical chemistry, Pregnancy, and Ovulation)  
- In Vitro Diagnostic Control Solution (Blood Glucose, Total Cholesterol, Uric Acid, Hemoglobin A1c,  $\beta$ -Ketone, Lactate, Triglycerides, Blood Glucose plus  $\beta$ -Ketone, and Multiple functional clinical chemistry)  
- In Vitro Diagnostic Rapid Test Reagent (colloidal gold method) for Infectious Diseases  
- Blood Pressure Monitoring System, Blood Glucose plus Blood Pressure Monitoring System, Reusable NIBP Cuff, Thermometer (Intermittent and Continuous), Ear Thermometer Probe Cover, Vital Signs Monitor, ECG Recorder, Pulse Oximeter, SpO2 Sensor, Nebulizer, Nebulizer Accessory, TeleHealth Gateway, TeleHealth System, Medical Information Management Application (for Mobile Devices), Scale Plus Body Fat Monitor, Thermal Printer for Medical Monitoring Device, Sterile Blood Lancet, Lancing Device, Multi-dose Delivery Device, Safety Pen Needle, Pen Needle, Electronic Nasal Aspirator, Breast Pump (Electric and Manual), Blood Glucose Sensor Module.

**TaiDoc Technology Corporation**

1F & 2F & 3F, No. 12, Lane 5, Sec. 2, Nanshan Rd., Lujhu District, 33852 Taoyuan City, TAIWAN

**Taoyuan factory:**

Design and development, and Production of In Vitro Diagnostic Reagents (Blood Glucose)