

Certificate

No. Q5 052126 0062 Rev. 05

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_052126_0062_Rev._05

Report No.: TW2101101

Valid from: 2021-12-23

Valid until: 2023-10-19

Date, 2021-12-23



Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ♦ CERTIFICATE ♦ 認證書 ♦ CERTIFICADO ♦ CERTIFICAT

Certificate

No. Q5 052126 0062 Rev. 05

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 and Distribution
of Blood Glucose Monitoring System, Blood Glucose
Plus Blood Pressure Monitoring System, Blood Glucose
Meter, Blood Glucose Plus Blood Pressure Meter,
Thermometer, Blood Pressure Meter, Blood pressure
Monitoring System, Blood Pressure Monitor, Blood Glucose
Test Strip, Blood Glucose Control Solution, Lancing Device
with Sterile Blood Lancet, Sterile Blood Lancet, Lancing
Device, Vital Signs Monitor, Pregnancy Test and Test
Strip, Digital Pregnancy Test, Pulse Oximeter, Nebulizer,
TeleHealth Gateway, Lens Filter, Scale Plus Body Fat
Monitor, Ovulation Test System, Digital Ovulation Test,
Ovulation Test and Test Strip, ECG Recorder, Thermal
Printer for Medical Monitoring Device, Hemoglobin A1c
Analyzer, Hemoglobin A1c Reagent Cartridge, β -Ketone
Test Strip, SpO2 Sensor, Blood Glucose Plus β -Ketone
Meter, Blood Glucose Plus β -Ketone Monitoring System,
 β -Ketone Meter, β -Ketone Monitoring System, Blood
glucose Plus β -Ketone Control Solution, Blood glucose,
total cholesterol and uric acid multi-Meter, Blood glucose,
total cholesterol and uric acid multi-Monitoring system,
Total Cholesterol control solution, Uric acid control
solution, Total Cholesterol Test Strip, Uric Acid Test
Strip, Hemoglobin A1c control solution, Pen Needle,
Temperature Monitor, Multi-dose Delivery Device,
Multi-functional Monitoring System, β -Ketone control
solution, Hemoglobin Monitoring System, Hemoglobin
Meter, Hemoglobin Test Strip, Lactate Monitoring
System, Lactate Meter, Lactate Test Strip,
Lactate Control Solution, Safety Pen Needle,
Electronic Nasal Aspirator, Electric Breast Pump,
Manual Breast Pump, Uric Acid Monitoring System,
Medical Information Management Application (for mobile devices),
Telehealth System, Nebulizer Accessory, Reusable NIBP Cuff,
Blood Glucose Sensor Module, Rapid test (colloidal gold method) for
infectious diseases, Triglycerides Test Strip and Triglycerides Control
Solution.

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, Production and Distribution of Blood Glucose
Monitoring System, Blood Glucose Plus Blood Pressure Monitoring
System, Blood Glucose Test Strip, Blood Glucose Control Solution.