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

Product Service

Certificate

No. Q5 052126 0062 Rev. 04

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

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **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, ß-Ketone Test Strip, SpO2 Sensor, Blood Glucose Plus ß-Ketone Meter, Blood Glucose Plus ß- Ketone Monitoring System, ß-Ketone Meter, ß-Ketone Monitoring System, Blood glucose Plus ß-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, ß-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 and Rapid test (colloidal gold method) for infectious diseases.**

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

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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 052126 0062 Rev. 04

Report No.: TW2001109

Valid from: 2021-01-22
Valid until: 2023-10-19

Date, 2021-01-22

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 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, ß-Ketone Test Strip, SpO2 Sensor, Blood Glucose Plus ß-Ketone Meter, Blood Glucose Plus ß- Ketone Monitoring System, ß-Ketone Meter, ß-Ketone Monitoring System, Blood glucose Plus ß-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, ß-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 and Rapid test (colloidal gold method) for infectious diseases.

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.

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