



# EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)  
(List A and B and devices for self-testing)

**No. V1 052126 0069 Rev. 00**

**Manufacturer:**

**TaiDoc Technology Corporation**

B1-7F, No. 127, Wugong 2nd Road, Wugong Dist.

24888 New Taipei City

TAIWAN

**Product Category(ies): In Vitro diagnostic devices for self testing  
including Blood Glucose Monitoring System  
for self-testing**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. 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:V1\\_052126\\_0069\\_Rev.00](http://www.tuvsud.com/ps-cert?q=cert:V1_052126_0069_Rev.00)

**Report no.:** TW2001101

**Valid from:** 2020-10-21

**Valid until:** 2021-09-22

**Date,** 2020-10-21

Christoph Dicks  
Head of Certification/Notified Body



# EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)  
(List A and B and devices for self-testing)

**No. V1 052126 0069 Rev. 00**

## Model(s):

### 1. Blood Glucose Measuring Systems For Self-Testing

Blood Glucose Monitoring System

TD-41XX, TD-42XX (X=0-9, A-Z or blank), MEDISAFE EX, E1,11

Blood Glucose Meter

TD-41XX, TD-42XX (X=0-9, A-Z or blank)

Blood Glucose Test Strip

TD-43XX (X=0-9, A-Z or blank)

Blood Glucose Control Solution

TD-49XX (X=0-9, A-Z or blank)

### 2. Blood Glucose Plus Blood Pressure Monitoring System

TD-32XX (X=0-9, A-Z or blank), MD-300,

Blood Glucose Plus Blood Pressure Meter

TD-32XX (X=0-9, A-Z or blank), MD-300,

### 3. Pregnancy Test Systems

Digital Pregnancy Test

TD-52XY (X=0-4, Y=0-9, A-Z or blank)

Pregnancy Test and Test Strip

TD-53XY (X=0-4, Y=0-9, A-Z or blank),

TD-45XY (X=0-4, Y=0-9, A-Z or blank)

### 4. Ovulation Test Systems

Digital Ovulation Test

TD-52XY (X=5-9, Y=0-9, A-Z or blank)

Ovulation Test and Test Strip

TD-45XY (X=5-9, Y=0-9, A-Z or blank),

TD-53XY (X=5-9, Y=0-9, A-Z or blank)

### 5. Blood Glucose Plus $\beta$ -Ketone Monitoring System

TD-41XX, TD-42XX (X=0-9, A-Z or blank)

Blood Glucose Plus  $\beta$ -Ketone Meter :

TD-41XX, TD-42XX (X=0-9, A-Z or blank)

Blood glucose Plus  $\beta$ -Ketone control solution:

TD-49XX (X=0-9, A-Z or blank)

### 6. $\beta$ -Ketone Monitoring System

TD-41XX, TD-42XX (X=0-9, A-Z or blank)

$\beta$ -Ketone Meter

TD-41XX, TD-42XX (X=0-9, A-Z or blank)

$\beta$ -Ketone Test Strip

TD-463X (X=0-9, A-Z or blank)

$\beta$ -Ketone control solution

TD-49XX (X=0-9, A-Z or blank)



# EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)  
(List A and B and devices for self-testing)

**No. V1 052126 0069 Rev. 00**

## 7. Blood glucose, total cholesterol and uric acid multi-Monitoring system

TD-41XX, TD-42XX (X=0-9, A-Z or blank)

Blood glucose, total cholesterol and uric acid multi Meter

TD-41XX, TD-42XX (X=0-9, A-Z or blank)

## 8. Total Cholesterol Test Strip

TD-464X (X=0-9, A-Z or blank)

## 9. Total Cholesterol control solution

TD-49XX (X=0-9, A-Z or blank)

## 10. Multi-functional Monitoring System

TD-41XX, TD-42XX (X=0-9, A-Z or blank)

## 11. Hemoglobin Monitoring System

TD-42XX (X=0-9, A-Z or blank)

Hemoglobin Meter

TD-42XX (X=0-9, A-Z or blank)

Hemoglobin Test Strip

TD-46XX (X=0-9, A-Z or blank)

## 12. Lactate Monitoring System

TD-42XX (X=0-9, A-Z or blank)

Lactate Meter

TD-42XX (X=0-9, A-Z or blank)

Lactate Test Strip

TD-46XX (X=0-9, A-Z or blank)

Lactate Control Solution

TD-49XX (X=0-9, A-Z or blank)

## 13. Uric Acid Monitoring System

TD-41XX (X=0-9, A-Z or blank)

Uric Acid Test Strip:

TD-465X (X=0-9, A-Z or blank)

Uric acid control solution

TD-49XX (X=0-9, A-Z or blank)



# EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)  
(List A and B and devices for self-testing)

**No. V1 052126 0069 Rev. 00**

## Facility(ies):

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

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