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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

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. 02

Manufacturer:

TaiDoc Technology Corporation
B1-7F, No. 127, Wugong 2nd Road, Wugu 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. 02

Report no.: TW2101101

Valid from: 2021-12-23
Valid until: 2024-05-26
Date, 2021-12-23

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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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,I1
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 ß-Ketone Monitoring System
TD-41XX, TD-42XX (X=0-9, A-Z or blank)
Blood Glucose Plus ß-Ketone Meter :
TD-41XX, TD-42XX (X=0-9, A-Z or blank)
Blood glucose Plus ß-Ketone control solution:
TD-49XX (X=0-9, A-Z or blank)

6. ß-Ketone Monitoring System
TD-41XX, TD-42XX (X=0-9, A-Z or blank)
ß-Ketone Meter
TD-41XX, TD-42XX (X=0-9, A-Z or blank)
ß-Ketone Test Strip
TD-463X (X=0-9, A-Z or blank)
ß-Ketone control solution
TD-49XX (X=0-9, A-Z or blank)

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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)
14. Triglycerides Test Strip
TD-46XX (X=0-9, A-Z or blank)
15. Triglycerides Control Solution
TD-49XX (X=0-9, A-Z or blank)

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Facility(ies):

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TaiDoc Technology Corporation
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Digitally signed by Zagareanu Tatiana
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