



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 0042 Rev. 01

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

EC-Representative: MedNet GmbH
Borkstrasse 10, 48163 Muenster, GERMANY

Product Category(ies): Products for self testing as listed in the attachment

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. See also notes overleaf.

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Valid from: 2019-06-22

Valid until: 2024-06-21

Date, 2019-03-22

Stefan Preiß



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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
 Blood Glucose Meter
 TD-41XX, TD-42XX (X=0-9, A-Z or blank),
 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,
 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. 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),
3. 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),
4. β -Ketone Test Strip:
 TD-463X (X=0-9, A-Z or blank),
5. Blood Glucose Plus β -Ketone Monitoring System:
 TD-41XX, TD-42XX (X=0-9, A-Z or blank)
 Blood Glucose Plus β -Ketone Meter :
 TD-41XX, TD-42XX (X=0-9, A-Z or blank)
6. β -Ketone Monitoring System
 TD-41XX, TD-42XX (X=0-9, A-Z or blank)
 β -Ketone Meter
 TD-41XX, TD-42XX (X=0-9, A-Z or blank)
7. Blood glucose Plus β -Ketone control solution:
 TD-49XX (X=0-9, A-Z or blank)
8. 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)
9. Total Cholesterol Test Strip:
 TD-464X (X=0-9, A-Z or blank)
10. Uric Acid Test Strip:
 TD-465X (X=0-9, A-Z or blank)
11. Total Cholesterol control solution
 TD-49XX (X=0-9, A-Z or blank)
12. Uric acid control solution



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

For the product category (ies):

Blood glucose measuring systems for self testing,
 Pregnancy and Ovulation test system, β -Ketone
 Test Strip, 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.

Facility(ies):

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

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

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 ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ CERTIFICADO ♦ CERTIFICAT