



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 15 03 52126 042

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.

Report No.: TW1501116

Valid from: 2015-06-26
Valid until: 2019-06-21

Date, 2015-06-29

Hans-Heiner Junker



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

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Model(s):

Models:

1. Blood Glucose Measuring Systems For Self-Testing (GMDN 16488) (GMDN 30854):
Blood Glucose Monitoring System (GMDN 16488) (GMDN 30854)
TD-41XX, TD-42XX (X=0-9, A-Z or blank), MEDISAFE EX Blood Glucose Meter (GMDN 16488) (GMDN 30854)
TD-41XX, TD-42XX (X=0-9, A-Z or blank), Blood Glucose Plus Blood Pressure Monitoring System (GMDN 47655)
TD-32XX (X=0-9, A-Z or blank), MD-300, Blood Glucose Plus Blood Pressure Meter (GMDN 47654)
TD-32XX (X=0-9, A-Z or blank), MD-300, Blood Glucose Test Strip (GMDN 30221)
TD-43XX (X=0-9, A-Z or blank), Blood Glucose Control Solution (GMDN 41819)
TD-49XX (X=0-9, A-Z or blank),
2. Pregnancy Test Systems (GMDN 40155):
Digital Pregnancy Test (GMDN 40155)
TD-52XY (X=0-4, Y=0-9, A-Z or blank), Pregnancy Test and Test Strip (GMDN 40155)
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: (GMDN 30515)
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:(GMDN 33256)
TD-463X (X=0-9, A-Z or blank),
5. Blood Glucose Plus β -Ketone Monitoring System : (GMDN 58168)
TD-41XX, TD-42XX (X=0-9, A-Z or blank)
Blood Glucose Plus β -Ketone Meter : (GMDN 58168)
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:(GMDN 30222)
TD-464X (X=0-9, A-Z or blank)
10. Uric Acid Test Strip:(GMDN 30183)
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
TD-49XX (X=0-9, A-Z or blank)

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 Township, 33852
Taoyuan County, TAIWAN

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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.

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