



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 14 02 52126 034

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):**

Blood glucose measuring systems for self testing
Pregnancy and Ovulation test systems

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.:

610211430101

Valid from:

2014-06-22

Valid until:

2019-06-21

Date, 2014-06-16

Hans-Heiner Junker



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

Page 1 of 2



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Model(s):

1. Blood Glucose Measuring Systems For Self-Testing
2. Pregnancy Test Systems
3. Ovulation Test Systems

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)

Facility(ies):

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

TaiDoc Technology Corporation
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Lujhu Township, 33852 Taoyuan County, TAIWAN