



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 0054 Rev. 01

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

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.: TW1901154

Valid from: 2020-01-08

Valid until: 2021-09-22

Date, 2020-01-08

Christoph Dicks
 Head of Certification/Notified Body



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Model(s):

Models:

1. Multi-functional Monitoring System
 TD-41XX, TD-42XX (X=0-9, A-Z or blank)
2. B-Ketone control solution
 TD-49XX (X=0-9, A-Z or blank)
3. 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)
4. 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)
5. Uric Acid Monitoring System
 TD-41XX (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 District,
 33852 Taoyuan City, TAIWAN