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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

# EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

## No. G1 052126 0043 Rev. 03

**Manufacturer:**

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

**Product Category(ies):**

**Blood Glucose Plus Blood Pressure Monitoring System, Blood Glucose Plus Blood Pressure Meter, Thermometer, Blood Pressure Meter, Blood Pressure Monitoring System, Vital Signs Monitor, Pulse Oximeter, Nebulizer, Lancing Device With Sterile Blood Lancet, Sterile Blood Lancet, ECG Recorder, SpO2 Sensor, Temperature Monitor, Electronic Nasal Aspirator, Electric Breast Pump and Manual Breast Pump.**

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 categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** TW2001103

**Valid from:** 2020-03-23
**Valid until:** 2024-05-26

**Date,** 2020-03-23

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Podoleanu Nicolai
Date: 2025.02.13 13:27:28 EET
Reason: MoldSign Signature
Location: Moldova


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

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A4 / 07.17

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

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

Product Service

# Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

## No. GCQ 052126 0071 Rev. 00

**Manufacturer:**

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

**This Confirmation Statement is only valid in combination with the following EC Certificate (MDD):**

**G1 052126 0043 Rev. 03**

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (MDD).
It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2021 or later.
The conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 on medical devices for placing devices on the market and putting into service apply. For details and confirmation statement validity see: www.tuvsud.com/ps-cert?q=cert:GCQ 052126 0071 Rev. 00

**Report No.:** TW2201101

**Valid until:** 2024-05-26

Christoph Dicks
Head of Certification/Notified Body

**Issue Date:** 2023-03-02


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Product Service

## Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

## No. GCQ 052126 0071 Rev. 00

**Product Category(ies):** Blood Glucose Plus Blood Pressure Monitoring System, Blood Glucose Plus Blood Pressure Meter, Thermometer, Blood Pressure Meter, Blood Pressure Monitoring System, Vital Signs Monitor, Pulse Oximeter, Nebulizer, Lancing Device With Sterile Blood Lancet, Sterile Blood Lancet, SpO2 Sensor, Temperature Monitor, Electronic Nasal Aspirator, Electric Breast Pump and Manual Breast Pump.

**Description of Change:** Remove the product category ECG Recorder



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TaiDoc Technology Corporation
Liu Jessica
B1-7F, No. 127, Wugong 2nd Road, Wugu Dist.
24888 NEW TAIPEI CITY
TAIWAN

| Ihre Zeichen/Nachricht vom | Unsere Zeichen/Name | Tel.-Durchwahl/E-Mail | Fax-Durchwahl | Datum | Seite |
|---|---|---|---|---|---|
| CBW 52126 | PS:MHS<br>Wang Wilson | +886 2 2898 6818 ext.208<br>wilson.wang1@tuvsud.com | | 15. Januar 2024 | 1 von 4 |

**TÜV SÜD Product Service GmbH**
**Confirmation Letter**
**CL 052126 0072 Rev. 00**

**Reference: TW2301109_CL/TW2301109**

To whom it may concern,

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.**

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: TW-MF-000017956

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive..
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further copies, amendments and / or changes of the confirmation letter according to effort.

For certificate validity see **www.tuvsud.com/ps-cert?q=cert: CL 052126 0072 Rev. 00**

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-01-15

TÜV SÜD Product Service GmbH
Medical and Health Services

Wilson Wang
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Fatlume Bahtiri
2024.01.16 09:05:13
+01'00'

Fatlume Bahtiri
Application Reviewer

**Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified during application review) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| **Thermometer**<br><br>**Basic UDI-DI:**<br>**04698711101112PR,**<br>**04698730101112QE** | ☐ Class III<br>☐ Class IIb implantable (non-exempted)<br>☐ Class IIb / Class IIb implantable (exempted)<br>☒ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☒ N/A<br><br>or<br><br>☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: | ☒ Certification as follows:<br>Certificate: G1 052126 0043 Rev. 03<br>NB: 0123<br>Certificate: GCQ 052126 0071 Rev. 00<br>NB: 0123<br><br>or<br><br>☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)<br>Evidence #1; CA#<br>Evidence #2; CA# |
| **Pulse Oximeter**<br><br>**Basic UDI-DI:**<br>**04698712818200UX** | ☐ Class III<br>☐ Class IIb implantable (non-exempted)<br>☐ Class IIb / Class IIb implantable (exempted)<br>☒ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☒ N/A<br><br>or<br><br>☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: | ☒ Certification as follows:<br>Certificate: G1 052126 0043 Rev. 03<br>NB: 0123<br>Certificate: GCQ 052126 0071 Rev. 00<br>NB: 0123<br><br>or<br><br>☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)<br>Evidence #1; CA#<br>Evidence #2; CA# |
| **Sterile Blood Lancet**<br><br>**Basic UDI-DI:**<br>**04698705500000SB** | ☐ Class III<br>☐ Class IIb implantable (non-exempted)<br>☐ Class IIb / Class IIb implantable (exempted)<br>☒ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☒ N/A<br><br>or<br><br>☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: | ☒ Certification as follows:<br>Certificate: G1 052126 0043 Rev. 03<br>NB: 0123<br>Certificate: GCQ 052126 0071 Rev. 00<br>NB: 0123<br><br>or<br><br>☐ Evidence that a competent authority of a Member State had |

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified during application review) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| | | | granted acc. MDR, Art.59 (1) or Art.97 (1)<br>Evidence #1; CA#<br>Evidence #2; CA# |
| **Blood Pressure Monitoring System/Meter**<br><br>**Basic UDI-DI: 04698726303132UF** | ☐ Class III<br>☐ Class IIb implantable (non-exempted)<br>☐ Class IIb / Class IIb implantable (exempted)<br>☒ Class IIa<br>☐ Class I devices in sterile condition<br>☐ Class I devices with measuring function<br>☐ Class III implantable custom-made-device | ☐ N/A<br><br>or<br><br>☐ Identification of the corresponding device under MDD/AIMDD Individual Article number: | ☒ Certification as follows:<br>Certificate: G1 052126 0043 Rev. 03<br>NB: 0123<br>Certificate: GCQ 052126 0071 Rev. 00<br>NB: 0123<br><br>or<br><br>☐ Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)<br>Evidence #1; CA#<br>Evidence #2; CA# |

**Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

| Device name or Basic UDI-DI (under MDR application) | MDR Device classification (as proposed by the manufacturer and verified during application review) | If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device | MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification |
|---|---|---|---|
| ☒ N/A | ☒ N/A | ☒ N/A | ☒ N/A |

## Confirmation Letter Version History

| Date | TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter | Action |
|---|---|---|
| 2024-01-15 | TW2301109 | Initial issue |

Manufacturer (with Stamp): TaiDoc Technology Corporation

| Input: Devices on Appendix A/B/C (Only for the device(s) covered by the confirmation letter) | | | | Output: Devices on Confirmation Letter | Device Basic UDI-DI | MDR Device Classification | Legacy Device or Not | Substitute Device or Not | Clarify the device name differences between Appendix ABC Directives and Regulation (if applicable) |
|---|---|---|---|---|---|---|---|---|---|
| Device Name under MD Directive (MEDF0315.01) | Device Models | Device Name under MD Regulation (MEDF0325.01) | Device Models | | | | | | |
| MDD Cert. No.: G1 052126 0043 Rev. 03 | | MDR Cert. No.: N/A | | | | | | | |
| Thermometer | TD-1107 | Ear Thermometer | TD-1107 | Thermometer | 04698711101112PR | IIa | YES | N/A | For clear clarification, we add the body site information the device intended to apply to the device name. |
| Thermometer | TD-1241 | Non-contact Forehead Thermometer | TD-1241 | Thermometer | 04698730101112QE | IIa | YES | N/A | For clear clarification, we add the body site information the device intended to apply and its function feature to the device name. |
| Thermometer | TD-1242 | Non-contact Forehead Thermometer | TD-1242 | Thermometer | 04698730101112QE | IIa | YES | N/A | For clear clarification, we add the body site information the device intended to apply and its function feature to the device name. |
| Thermometer | TD-1261 | Ear Thermometer | TD-1261 | Thermometer | 04698711101112PR | IIa | YES | N/A | For clear clarification, we add the body site information the device intended to apply to the device name. |
| Pulse Oximeter | TD-8255 | Fingertip Pulse Oximeter | TD-8255 | Pulse Oximeter | 04698712818200UX | IIa | YES | N/A | For clear clarification, we add the body site information the device intended to apply to the device name. |
| Sterile Blood Lancet | TD-5084 | Sterile Lancets | TD-5084 | Sterile Blood Lancet | 04698705500000SB | IIa | YES | N/A | Because of marketing requests, we take the device names of similar devices as the reference and update the device name of the company. |
| Blood Pressure Monitoring System/Meter | TD-3128 | Blood Pressure Monitor | TD-3128 | Blood Pressure Monitoring System/Meter | 04698726303132UF | IIa | YES | N/A | Because of marketing requests, we take the device names of similar devices as the reference and update the device name of the company. |
| Blood Pressure Monitoring System/Meter | TD-3129 | Blood Pressure Monitoring System | TD-3129 | Blood Pressure Monitoring System/Meter | 04698726303132UF | IIa | YES | N/A | Because of marketing requests, we take the device names of similar devices as the reference and update the device name of the company. |
| Blood Pressure Monitoring System/Meter | TD-3140 | Blood Pressure Monitor | TD-3140 | Blood Pressure Monitoring System/Meter | 04698726303132UF | IIa | YES | N/A | Because of marketing requests, we take the device names of similar devices as the reference and update the device name of the company. |

Name and Function of the undersigned: Jim Jan, Management Representative

Signature with Stamp: Jim Jan

Date: 2023-09-06

TaiDoc

B1-7F., No.127, Wugong 2nd Road., 24868 Wugu Dist., New Taipei City, Taiwan