

STATE OF NORTH CAROLINA



Department of The
Secretary of State

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. COUNTRY: UNITED STATES OF AMERICA
2. This Public Document
has been signed by MARY YANG
3. acting in the capacity of NOTARY PUBLIC
COMMISSION EXPIRES 10/4/2026
4. bears the seal/stamp of COUNTY OF MECKLENBURG, NORTH CAROLINA

CERTIFIED

5. at Raleigh, North Carolina
6. the 2ND DAY OF SEPTEMBER, 2022
7. by Secretary of State or Deputy Secretary of State, State of North Carolina
8. No. 18392
9. Seal/Stamp
10. Signature



Scan to verify online.

by:

William W. Toole

William W. Toole
Deputy Secretary of State

Claine J. Marshall

Secretary of State

Certification# 8385150731

Verify the issuance of this Apostille Certification# 18392 at <https://www.sosnc.gov/verify>

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TRUE COPY

I, Greg Miller, do hereby swear or affirm that the attached is a true copy of
(Document Owner)

- EC Certificate for OK Biotech Co., Ltd.
(Description of Document)

and that this copy contains no alterations from the original.

Greg Miller

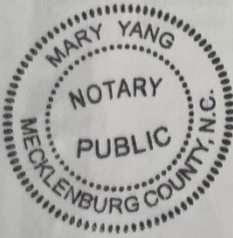
Principal's Signature

MECKLENBURG County, North Carolina

I, MARY YANG, a Notary Public for MECKLENBURG County,
North Carolina, do hereby certify that GREG MILLER personally appeared
(Name of Principal)

before me this day and acknowledged the due execution of the foregoing instrument.

Witness my hand and official seal, this the 26TH day of AUGUST, 20 22.



(Official Seal)

Official Signature of Notary:

Mary Yang
Notary Public

Notary's Printed Name:

MARY YANG

My Commission Expires:

OCTOBER 4, 2026



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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 063505 0062 Rev. 04

Manufacturer:

OK Biotech Co., Ltd.

No. 91, Sec. 2, Gongdao 5th Road
30070 Hsinchu City
TAIWAN

Product Category(ies): In Vitro diagnostic devices for self testing
including Blood Glucose Monitoring System
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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V1_063505_0062_Rev_04

Report no.:

TW2100806

Valid from:

2022-03-21

Valid until:

2025-05-26

Date, 2022-03-21

Christoph Dicks
Head of Certification/Notified Body



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 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zlg.de
 ZLG-BS-245.10.07



Product Service

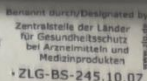
EC Certificate

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 063505 0062 Rev. 04

Model(s):

- Blood Glucose Monitoring System:**
 Including Blood Glucose Meter
 Blood Glucose Test Strips & Control Solution
- PalmDoc I
 - PalmDoc II
 - Prodigy AutoCode
 - Prodigy AutoCode Eject
 - Prodigy Choice
 - Prodigy Pocket
 - Prodigy Preferred
 - Prodigy Voice
 - Prodigy Astro
 - GlucoDoc voice (Model: GD-V)
 - GlucoDoc compact (Model: GD-C)
 - Ht one LUMINA
 - EmpErOr Concept
 - Sneha Sure
 - Quick & Care
 - Quick & Care - Direct
 - Diacont
 - DIAGNO-CHECK Smart
 - VOX
 - Solus V2
 - BIONANO
 - Avital
 - SuperCheck Plus
 - Model No. OK-XY (X=0-99 or blank, Y=A-Z or blank)
 - MediCare Blood Glucose Monitoring System-LIS
 (Model: BG-101)
 - MediCare Blood Glucose Monitoring System-LIS Smart
 (Model: BG-102)
 - Medicare Blood Glucose Monitoring System-LIS Max
 (Model: BG-103)
 - PlusCheck (Model: OK-24D)
- Blood Glucose Test Strips**
- UniStrip1



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)

Facility(ies):

OK Biotech Co., Ltd.
No. 83 & No. 85, Sec. 2, Gongdao 5th Road, 30070 Hsinchu City,
TAIWAN

OK Biotech Co., Ltd.
No.158, Lane 99, Puding Road, 30072 Hsinchu City, TAIWAN

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

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