

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: United States of America

This public document

2. has been signed by CDR Cesar A. Perez, PhD.

3. acting in the capacity of Director, DRP2: Division of Establishment Support

4. bears the seal/stamp of U. S. Department of Health and Human Services

Certified

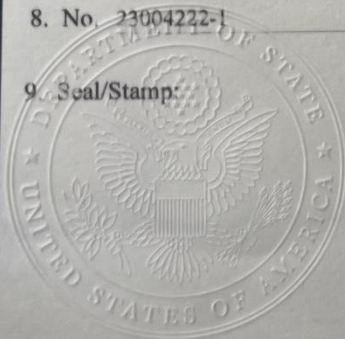
5. at Washington, D.C.

6. the twenty-ninth of November, 2022

7. by Assistant Authentication Officer, United States Department of State

8. No. 23004222-1

9. Seal/Stamp:



10. Signature:

Kenneth W Kimich

Kenneth W Kimich

Certificate No. 12448-8-2022

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(One Page)

Name of Manufacturer/Distributor, Address

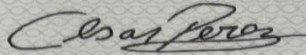
See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,



CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from August 30, 2022 to August 29, 2024.



Certificate No. 12448-8-2022

Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Manufacturer

OK BIOTECH CO., LTD.
NO. 91, SEC. 2
Gongdao 5th Rd.
HSINCHU CITY, Hsinchu
TAIWAN 30070

TIANJIN HUAHONG TECHNOLOGY CO LTD
A01, Plant B, No 278, Hangkong Road, Tianjin Pilot Free Trade
Zone (Air Port Industrial Park)
Tianjin, Tianjin
CHINA 300308

Name of Distributor

PRODIGY DIABETES CARE, LLC
7224 Statesville Road, Suite A
Charlotte, NC
USA 28269

—END OF MANUFACTURER/DISTRIBUTOR LIST—



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Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1

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Tianjin, Tianjin

CHINA 300308

Name of Distributor

PRODIGY DIABETES CARE, LLC

7224 Statesville Road, Suite A

Charlotte, NC

USA 28269

Name of Product(s)

PRODIGY AutoCode® Blood Glucose Monitoring System

PRODIGY Pocket® Blood Glucose Monitoring System

PRODIGY Voice® Blood Glucose Monitoring System

PRODIGY® No Coding Blood Glucose Test Strips

PRODIGY® Control Solution LOW

PRODIGY® Twist Top Lancets

PRODIGY® Adjustable Depth Lancing Device

PRODIGY® Control Solution HIGH

-----END OF PRODUCT LIST-----

