

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by *Cesar A. Perez*

3. acting in the capacity of *Director, 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-third of October, 2023*

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

8. No. *23064014-1*

9. Seal/Stamp:

10. Signature:

Matthews

Veda Matthews



**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH



U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 9317-5-2023

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 May 19, 2023 to May 18, 2025.



E04521307



**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 9317-5-2023

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

Name of Manufacturer

BD Caribe LTD.
RD 31, KM 24.3
Juncos, PR
USA 00777

Name of Manufacturer/Distributor

Legal Manufacturer

BECTON DICKINSON
1 Becton Dr
FRANKLIN LAKES, NJ
USA 07417

---END OF MANUFACTURER/DISTRIBUTOR LIST---



E04521308



**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 9317-5-2023

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

Name of Manufacturer

BD Caribe LTD.

RD 31, KM 24.3

Juncos, PR

USA 00777

Name of Manufacturer/Distributor

Legal Manufacturer

BECTON DICKINSON

1 Becton Dr

FRANKLIN LAKES, NJ

USA 07417

Name of Product(s)

365963 BD Microtainer® Z (No Additive Tubes)
365965 BD Microtainer® Tubes with LH (Lithium Heparin)
365967 BD Microtainer® SST™
365974 BD Microtainer® Tubes with K2E (K2EDTA)
365975 BD Microtainer® K2E Tubes
365976 BD Microtainer® Tube Extender
365978 BD Microtainer® SST™ - Amber
365985 BD Microtainer® PST™ Tubes with LH (Lithium Heparin)
365987 BD Microtainer® PST™ Tubes with LH (Lithium Heparin)
365992 BD Microtainer® Tubes with FE (Sodium Fluoride/Disodium EDTA)
368100 BD Microtainer® Quikheel™ Premie Lancet
368101 BD Microtainer® Quikheel™ Lancet
36490200 BD Vacutainer® Luer-Lok™ Access Device Holder
with Pre-Attached Multiple Sample Adapter
36488000 BD Vacutainer® Blood Transfer Device Holder
with Pre-Attached Multiple Sample Female Luer Adapter
364902 BD Vacutainer® Luer-Lok™ Access Device Holder
with Pre-Attached Multiple Sample Adapter
364880 BD Vacutainer® Blood Transfer Device Holder
with Pre-Attached Multiple Sample Female Luer Adapter
36481000 BD Vacutainer® Blood Transfer Device Holder
with Pre-Attached Multiple Sample Female Luer Adapter

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



79095 ARGEN 07-19-23
188845 BD DIAGNOSTIC SYSTEM

E04521309