

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 third of November, 2023

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

8. No. 23064647-19

9. Seal/Stamp:

10. Signature:

Sonya N. Johnson



**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. 11478-7-2023

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

(Two Pages)

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 July 19, 2023 to July 18, 2025.



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

Name of Manufacturer

BECTON, DICKINSON & CO.
150 S 1st Ave
BROKEN BOW, NE
USA 68822

Name of Manufacturer/Distributor

Legal Manufacturer

BECTON DICKINSON
1 Becton Dr
FRANKLIN LAKES, NJ
USA 07417

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



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Name of Manufacturer

BECTON, DICKINSON & CO.

150 S 1st Ave

BROKEN BOW, NE

USA 68822

Name of Manufacturer/Distributor

Legal Manufacturer

BECTON DICKINSON

1 Becton Dr

FRANKLIN LAKES, NJ

USA 07417

Name of Product(s)

362753 BD Vacutainer® CPT™ Cell Preparation Tube with Sodium Heparin
362760 BD Vacutainer® CPT™ Cell Preparation Tube with Sodium Citrate
362761 BD Vacutainer® CPT™ Cell Preparation Tube with Sodium Citrate
362788 BD Vacutainer® PPT™ Plasma Preparation Tube K2E 9.0 mg
362791 BD Vacutainer® PPT™ Plasma Preparation Tube K2E (EDTA) 9.0 mg
362799 BD Vacutainer® PPT™ Plasma Preparation Tube K2E 15.8 mg
362800 BD Vacutainer® PPT™ Plasma Preparation Tube K2E 15.8 mg
363080 BD Vacutainer® 9NC 0.109M Plus Blood Collection Tubes
363083 BD Vacutainer® Buffered Sodium Citrate (9NC) Blood Collection Tubes
363705 BD Microtainer® MAP Microtube Automated Process K2 EDTA 1.0 mg,
363706 BD Microtainer® MAP Microtube Automated Process K2 EDTA 1.0 mg,
364305 BD Vacutainer® Blood Collection Tubes Buffered Sodium Citrate 0.3mL - 0.109M
364606 BD Vacutainer® ACD Solution A Blood Collection Tubes
364816 BD Vacutainer® ACD Solution B Blood Collection Tubes
364943 BD Vacutainer® Urinalysis Transfer Straw Kit
364944 BD Vacutainer® C&S Boric Acid Kit Sodium Borate/Formate
364946 BD Vacutainer® Urinalysis Cup Kit
364951 BD Vacutainer® C&S Preservative Urine Tube
364953 BD Vacutainer® C&S Transfer Straw Kit
364954 BD Vacutainer® C&S Cup Kit - C&S Preservative Plus Urine Tube
364956 BD Vacutainer® Urine Complete Cup Kit
364957 BD Vacutainer® Urine Complete Cup Kit
364958 BD Vacutainer® Boric Acid Sodium Borate/Formate C&S Urine Tube
364959 BD Vacutainer® C&S Boric Acid Kit Sodium Borate/Formate Plus Urine Tube
364966 BD Vacutainer® Urine Transfer Straw
364979 BD Vacutainer® Urinalysis Urine Tube
364980 BD Vacutainer® Urinalysis Conical Urine Tube No Additive
364981 BD Vacutainer® Urinalysis Cup Kit
364989 BD Vacutainer® Urinalysis Cup Kit
364990 BD Vacutainer® Urinalysis Transfer Straw Kit
364991 BD Vacutainer® Urinalysis Transfer Straw Kit
364992 BD Vacutainer® Urine Analysis Preservative Tube
365000 BD Vacutainer® Z (No Additive) Urine Tube - Conical
365017 BD Vacutainer® Urinalysis Preservative Urine Tube
366430 BD Vacutainer® Serum Blood Collection Tubes
366560 BD Vacutainer® Buffered Sodium Citrate (9NC) Blood Collection Tubes
366667 BD Vacutainer® Lithium Heparin (LH) 56 USP Units Blood Collection Tubes
367001 BD Vacutainer® Blood Alcohol Determinations Sodium Fluoride: 100mg Potassium Oxalate: 20mg
367587 BD Vacutainer® Sodium Fluoride: 3 mg. Na2 EDTA: 6mg
367671 BD Vacutainer® Sodium Heparin (NH) 33 USP = 33 IU Blood Collection Tubes
367683 BD Vacutainer® Lithium Heparin (LH) 78 USP Units Blood Collection Tubes
367729 BD Vacutainer® Sodium Fluoride: 30mg Blood Collection Tubes
367746 BD Vacutainer® Buffered Sodium Citrate 0.4 mL /0.129M Blood Collection Tubes
367835 BD Vacutainer® K2 EDTA (K2E) 5.4mg Blood Collection Tubes



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Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 2

367841 BD Vacutainer® K2 EDTA (K2E) 3.6mg Blood Collection Tubes
367842 BD Vacutainer® K2 EDTA (K2E) 3.6mg Blood Collection Tubes
367843 BD Vacutainer® K2 EDTA (K2E) 3.6mg Blood Collection Tubes
367844 BD Vacutainer® K2 EDTA (K2E) 7.2mg Blood Collection Tubes
367855 BD Vacutainer® K2 EDTA (K2E) 5.4 mg Blood Collection Tubes
367856 BD Vacutainer® K2 EDTA (K2E) 5.4mg Blood Collection Tubes
367859 BD Vacutainer® K2 EDTA (K2E) 5.4 mg Blood Collection Tubes
367861 BD Vacutainer® K2 EDTA (K2E) 7.2mg Blood Collection Tubes
367862 BD Vacutainer® K2 EDTA (K2E) Plus Blood Collection Tubes
367863 BD Vacutainer® K2 EDTA (K2E) 10.8mg Blood Collection Tubes
367871 BD Vacutainer® Sodium HeparinN (NH) 75 USP Units Blood Collection Tubes
367872 BD Vacutainer® Blood Collection Tubes
367874 BD Vacutainer® Sodium HeparinN (NH) 158 USP Units Blood Collection Tubes
367878 BD Vacutainer® Sodium HeparinN 95 USP Units Blood Collection Tubes
367880 BD Vacutainer® Lithium HeparinN (LH) 158 USP Units Blood Collection Tubes
367884 BD Vacutainer® Lithium HeparinN 75 USP Units Blood Collection Tubes
367886 BD Vacutainer® Lithium HeparinN (LH) 95 USP Units Blood Collection Tubes
367899 BD Vacutainer® K2 EDTA (K2E) 10.8mg Blood Collection Tubes
367921 BD Vacutainer® Sodium Fluoride 5mg Potassium Oxalate 4 mg (FX) Blood Collection Tubes
367922 BD Vacutainer® Sodium Fluoride 10mg Potassium Oxalate 8 mg (FX) Blood Collection Tubes
367925 BD Vacutainer® Sodium Fluoride 15mg Potassium Oxalate 12 mg (FX) Blood Collection Tubes
367960 BD Vacutainer® PST™ Gel and Lithium HeparinN (LH) 56 Units Blood Collection Tubes
367961 BD Vacutainer® PST™ Gel and Lithium HeparinN (LH) 65 Units Blood Collection Tubes
367962 BD Vacutainer® PST™ Gel and Lithium HeparinN (LH) 83 Units Blood Collection Tubes
367963 BD Vacutainer® PST™ Gel and Lithium HeparinN (LH) Blood Collection Tubes
367964 BD Vacutainer® PST™ Gel and Lithium HeparinN (LH) 126 Units Blood Collection Tubes
368021 BD Vacutainer® K2 EDTA 7.2mg Blood Collection Tubes
368033 BD Vacutainer® Sodium Fluoride: 10 mg. Potassium Oxalate: 8 mg Blood Collection Tubes
368035 BD Vacutainer® PST™ Blood Collection Tubes
368036 BD Vacutainer® PST™ Blood Collection Tubes
368037 BD Vacutainer® Sodium HeparinN Blood Collection Tubes
368039 Vacutainer® Brand Tube Chemistry and Selective Hematology Determinations,
368040 BD Vacutainer® Lithium HeparinN Blood Collection Tubes
368047 BD Vacutainer® K2 EDTA 3.6mg Blood Collection Tubes
368049 BD Vacutainer® K2 EDTA 10.8 mg Blood Collection Tubes
368054 BD Vacutainer® K2 EDTA 5.4mg Blood Collection Tubes
368056 BD Vacutainer® PST™ Gel and Lithium HeparinN (LH) 56 Units Blood Collection Tubes
368380 BD Vacutainer® Trace Element Serum Plus Blood Collection Tubes
368381 BD Vacutainer® Trace Element Serum Blood Collection Tubes
368587 BD Vacutainer® Sodium Fluoride 10mg Potassium Oxalate 8 mg (FX) Blood Collection Tubes
368589 BD Vacutainer® K2 EDTA (K2E) 18 mg Blood Collection Tubes
368660 BD Vacutainer® Serum Blood Collection Tubes
368661 BD Vacutainer® K2 EDTA (K2E) 10.8 mg Blood Collection Tubes
368920 BD Vacutainer® FX 5mg 4mg Plus Blood Collection Tubes
368921 BD Vacutainer® FX 10mg 8mg Plus Blood Collection Tubes
369741 BD Vacutainer® ESR Blood Collection Tubes

—END OF PRODUCT LIST—





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