



Certificate No. 11871-7-2023

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

(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 July 25, 2023 to July 24, 2025.





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

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

Name of Corporate Headquarters

BIO/DATA CORP.
155 GIBRALTAR RD.
Horsham, PA
USA 19044

Name of Manufacturer/Distributor

Bio/Data Corporation
155 Gibraltar Road
HORSHAM, PA
USA 19044

----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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Name of Manufacturer/Distributor

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Name of Product(s)

106077, Platelet Aggregation Profiler System and Reagents, Model PAP-8E
106842, PDQ, Platelet Function Centrifuge
101312, ADP Reagent, 3 x 0.5 mL
100970, AggRecetin, Ristocetin Reagent, 1.0-1.5 mg/mL
101241, AggRecetin, Ristocetin Reagent, (Bulk) 100 mg
101297, Arachidonic Acid Reagent, 3 x 0.5 mL
101580, Beta/Pak Reagent (ADP, Collagen, and Ristocetin Reagents) 1 x 0.5 mL each
100989, Calcium Chloride Solution Reagent, 0.025 M, 1 x 473 mL
101162, Cephalinex, APTT Reagent (Silica Activated), 20 x 3 mL
101562, Collagen Reagent, 3 x 0.5 mL
101311, Epinephrine Reagent, 3 x 0.5 mL
107117, LTA Check (Performance Monitoring) Reagent Test Kit
102516, Lupus Anticoagulant Confirmation Reagent (LACR), 5 x 1 mL
101258, Lyophilized Platelets Reagent, 1 x10 mL
101595, Lyophilized Platelets Reagent, 3 x 4 mL
101310, Par/Pak II Reagent (ADP, Collagen, and Epinephrine Reagents) 2 x 0.5 mL each
101158, Plastinex, Thromboplastin Reagent, 20 x 4 mL
100994, Sodium Citrate Reagent, 0.11M, 1 x 237 mL
100991, Tris Buffered Saline Reagent, 0.06M, pH 7.5, 1 x 473 mL
103025, vW Factor Assay Reagent (Ristocetin Cofactor Assay), 20 Determinations
101270, vW Abnormal Control Plasma Reagent, 3 x 0.5 mL
106426, vW Normal Control Plasma Reagent, 3 x 0.5 mL
101269, vW Normal Reference Plasma Reagent, 3 x 0.5 mL
106730, vW Select Reagent (Ristocetin Cofactor Assay), 50 Determinations
107146, MagneTube (Stir Bars & Test Tubes), 50 Sets / Box
101375, Profiler Paper, 1 Roll
105598, Printer Paper, 1 Roll
105977, Stir Bars, Macro, 50 / Package
105990, Stir Bars, Micro, 50 / Package
100336, Test Tubes, Macro, 100 / Box
101521, Test Tubes, Micro, 100 / Box
106956, TRAP-6 amide Reagent, 1 x 5 mg
107462, U-46619 (TX A2 Analog) Reagent, 1 x 1 mg
105997, UPTT Reagent, 20 x 3 mL

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

