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 seventeenth of November, 2023

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

8. No. 24007311-32

9. Seal/Stamp:

10. Signature:

Chana M Turner

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. 500-10-2023

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)	**Name of Manufacturer/Distributor, Address**
See Attached List	See Attached List
(One Page)	(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,

Cesar Perez

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 October 19, 2023 to October 18, 2025.

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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...ificate No. 500-10-2023
...rtificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Manufacturer

Legal Manufacturer
BECTON DICKINSON INFUSION THERAPY SYSTEMS INC.
9450 South State Street
Sandy, UT
USA 84070

Manufacturing Site
BECTON DICKINSON INFUSION THERAPY SYSTEMS INC.
S.A. de C.V.
PERIFERICO LUIS DONALDO
COLOSIO No. 579
NOGALES, Sonora
MEXICO 84048

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

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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COLOSIO No. 579
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MEXICO 84048

Name of Product(s)
380510 BD Q-Syte BNS
385100 BD Q-Syte™ Luer Access Split Septum
385101 BD Q-Syte™ Extension Set 15 cm (6 IN) 1.14 ml Std Bore
385102 BD Q-Syte™ Extension Set 15 cm (6 IN) 0.34 ml Micro Bore
385103 BD Q-Syte™ Luer Access Split Septum
385104 BD Q-Syte™ Extension Set 15 cm (6 IN) 1.14 ml Std Bore
385105 BD Q-Syte™ Extension Set 15 cm (6 IN) 0.34 ml Micro Bore
385106 BD Q-Syte™ Vial Access Adapter
385108 BD Q-Syte™ Vial Access Adapter
385150 BD Q-Syte™ Extension Set 15 cm (6 IN) 0.60 ml
385151 BD Q-Syte™ Extension Set 15 cm (6 IN) 0.25 ml
385152 BD Q-Syte™ Extension Set 15 cm (6 IN) 1.00 ml
385153 BD Q-Syte™ Extension Set 36 cm (14 IN) 0.55 ml
385154 BD Q-Syte™ Power Injectable Extension Set 15 cm
385155 BD Q-Syte™ Bi-Extension Set 15 cm (6 IN) 1.60 ml
385156 BD Q-Syte™ Tri-Extension Se 15 cm (6 IN) 2.25 ml
385157 BD Q-Syte™ Bi-Extension Set 15 cm (6 IN) 0.45 ml
385158 BD Q-Syte™ Tri-Extension Set 15 cm (6 IN) 0.80 ml
385161 BD Q-Syte™ Bi-Extension Set 15 cm (6 IN) 1.60 ml
385162 BD Q-Syte™ Tri-Extension Set 15 cm (6 IN) 2.25 ml
385163 BD Q-Syte™ Extension Set 15 cm (6 IN) 0.45 ml
385164 BD Q-Syte™ Tri-Extension Set 15 cm (6 IN) 0.80 ml
385165 BD Q-Syte™ Y Extension Set 20 cm (8 IN) 1.40 ml
385166 BD Q-Syte™ Dual Y Extension Set 50 cm (20 IN) 3.20 ml
----------END OF PRODUCT LIST----------