

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by CAPT Sean M. Boyd

3. acting in the capacity of Deputy Director for Regulatory Affairs, Office of Compliance

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

Certified

5. at Washington, D.C.

6. the twenty-fourth of January, 2018

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

8. No. 18016521-1

9. Seal/Stamp:



10. Signature:

Zelda Daley

Zelda Daley



**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. 4614-1-2018

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.

CAPT Sean M. Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from January 16, 2018 to January 15, 2020.





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

Name of Owner Operator

BECTON, DICKINSON & CO.
One Becton Drive
Franklin Lakes, NJ USA 07417

Name of Manufacturer

Manufacturing Facility

BD MEDICAL - DIABETES CARE
1329 West Highway 6
HOLDREGE, NE USA 68949

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





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Name of Product(s)

326678 - BD Ultra-Fine™ Insulin Syringe 1mL 31G x 6mm
326679 - BD Ultra-Fine™ Insulin Syringe 0.5mL 31G x 6mm
326680 - BD Ultra-Fine™ Insulin Syringe 0.3mL 31G x 6mm

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

