

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, Office of Regulatory Programs*

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

Certified

5. at Washington, D.C.

6. the *seventh of October, 2020*

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

8. No. *20043083-1*

9. Seal/Stamp:

10. Signature:

Patrick O. Hatchett

Patrick O. Hatchett

Certificate No. 11958-7-2020

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

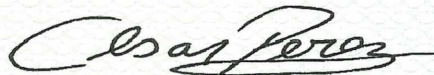
See Attached List

(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 23, 2020 to July 22, 2022.



Permit No. 11958-7-2020

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

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

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



Government - Name of Product(s) Attachment Page 1 of 1

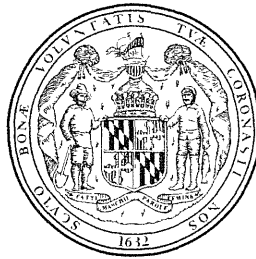
Name of Manufacturer
BD MEDICAL - DIABETES CARE
1329 West Highway 6
HOLDREGE, NE USA 68949

Name of Product(s)

305930 - BD SafetyGlide Insulin Syringe, 1mL - 29G x 1/2" (0.33mm x 13mm)
305934 - BD SafetyGlide Insulin Syringe, 1/2mL - 30G x 5/16" (0.3mm x 8mm)
305937 - BD SafetyGlide Insulin Syringe, 1mL - 31G x 5/16 TW (0.25mm x 8mm)
928855 - Insulin Syringe, 0.3mL - 30G X 8mm
324910 - Insulin Syringe, 0.3mL - 31G X 6mm
928854 - Insulin Syringe, 0.5mL - 30G X 8mm
324911 - Insulin Syringe, 0.5mL - 31G X 6mm
928853 - Insulin Syringe, 1.0mL - 30G X 8mm
324912 - Insulin Syringe, 1.0mL - 31G X 6mm
326784 - Insulin Syringe, 1.0mL - 30G X 8mm

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





The State of Maryland

Office of the Secretary of State

This Apostille is not valid for use anywhere within the United States of America, its territories or possessions.

This Apostille does not certify the content of the document for which it is issued.

Apostille

(Convention de La Haye du 5 Octobre 1961)

1. Country: United States of America
This public document
2. has been signed by **Barbara H. Meiklejohn**
3. acting in the capacity of **Clerk of the Circuit Court for Montgomery County**
4. bears the seal/stamp of the **Circuit Court for Montgomery County**

Certified

5. at Annapolis, Maryland
6. the **28th day of August, 2020**
7. by The Secretary of State of Maryland
8. **No. 525462**
9. Seal



10. Signature

Secretary of State

July 31, 2020

LETTER OF EXPLANATION

To whom it may concern,

We, Becton Dickinson and Company, as legal manufacturer of the following medical devices hereby confirm that the following US product codes reflected on the Certificate to Foreign Government, No. **11958-7-2020** are equivalent to the product codes to be registered. The only difference in the catalogs are due to the region-specific brand names, language, regulatory labeling requirements, and/or product count. A comparison table and corresponding labels have been enclosed for further reference.

State of Maryland, Montgomery County, Sct.

In the Office of the Clerk of the Circuit Court for Montgomery County

I, Barbara H. Meiklejohn, Clerk of the Circuit Court for Montgomery County, Maryland, a court of record, hereby certify that **VISHAL SONI** was a commissioned/ appointed and qualified Notary Public commencing on the 30th day of March, 2017.

In Testimony Whereof, I have hereunto set my hand and affixed the seal of the Circuit Court for Montgomery County this 25th day of August, 2020.



Barbara H. Meiklejohn
Clerk of the Circuit Court for Montgomery County



July 31, 2020

LETTER OF EXPLANATION

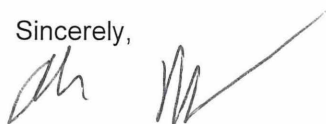
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US CFG Product Code	Product Description	Product Code(s) to be Registered
928855	Insulin Syringe, 0.3mL – 30G X 8mm	328322
324910	Insulin Syringe, 0.3mL – 31G X 6mm	324916
928854	Insulin Syringe, 0.5mL – 30G X 8mm	328325
324911	Insulin Syringe, 0.5mL – 31G X 6mm	324917
928853	Insulin Syringe, 1.0mL – 30G X 8mm	328328
324912	Insulin Syringe, 1.0mL – 31G X 6mm	324918
326784	Insulin Syringe, 1.0mL – 30G X 8mm	326732

We agree to undertake any further clarification as may be required in relation to the clarification of the above products.

Sincerely,

 31-July-2020

Adam Haas

International Regulatory Affairs Specialist

BD Medical – Diabetes Care

Becton Dickinson and Company

