

**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 twenty-third of December, 2024

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

8. No. 25013781-9

9. Seal/Stamp:

10. Signature:



Patrick O. Hatchett





**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. 1287-11-2024-1

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:

<u>Name of Product(s)</u>	<u>Name of Manufacturer/Distributor, Address</u>
See Attached List (One Page)	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.

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 November 07, 2024 to November 06, 2026.



To verify the authenticity of the information on this certificate, you may scan the QR code or visit [www.access.fda.gov/fecv/CDRH](http://www.access.fda.gov/fecv/CDRH).



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Certificate No. 1287-11-2024-1  
Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

**Name of Manufacturer**  
**Manufacturing Site**  
embecta medical I LLC  
1329 West Highway 6  
Holdrege, NE  
USA 68949

**Legal Manufacturer**  
Embecta Medical II LLC  
300 Kimball Drive  
Parsippany, NJ  
USA 07054

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





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USA 68949

**Legal Manufacturer**

Embecta Medical II LLC  
300 Kimball Drive  
Parsippany, NJ  
USA 07054

**Name of Product(s)**

- 328322 Insulin Syringe - 0.3mL, 30G x 8mm
- 328325 Insulin Syringe - 0.5mL, 30G x 8mm
- 328328 Insulin Syringe - 1mL, 30G x 8mm
- 328400 Insulin Syringe - 1mL, 30G x 12.7mm
- 328401 Insulin Syringe - 0.5mL, 31G x 8mm
- 328403 Insulin Syringe - 0.3mL, 31G x 8mm
- 328418 Insulin Syringe - 1mL, 31G x 8mm
- 328438 Insulin Syringe - 0.3mL, 31G x 8mm
- 328468 Insulin Syringe - 0.5mL, 31G x 8mm
- 324913 Insulin Syringe - 0.3mL, 31G x 6mm
- 324914 Insulin Syringe - 0.5mL, 31G x 6mm
- 324915 Insulin Syringe - 1mL, 31G x 6mm
- 324916 Insulin Syringe - 0.3mL, 31G x 6mm
- 324917 Insulin Syringe - 0.5mL, 31G x 6mm
- 324918 Insulin Syringe - 1mL, 31G x 6mm
- 326678 Insulin Syringe - 1mL, 31G x 6mm
- 326679 Insulin Syringe - 0.5mL, 31G x 6mm
- 326709 Insulin Syringe - 1mL, 30G x 12.7mm
- 326713 Insulin Syringe - 0.5mL, 31G x 8mm
- 326732 Insulin Syringe - 1mL, 30G x 8mm
- 326778 Insulin Syringe - 0.3mL, 31G x 8mm
- 326779 Insulin Syringe - 0.5mL, 31G x 8mm
- 326780 Insulin Syringe - 1mL, 30G x 12.7mm
- 326781 Insulin Syringe - 0.5mL, 31Gx 8mm
- 326782 Insulin Syringe - 1mL, 30G x 12.7mm
- 326785 Insulin Syringe - 0.3mL, 31G x 6mm
- 326786 Insulin Syringe - 0.5mL, 31G x 6mm
- 326787 Insulin Syringe - 1mL, 31G x 6mm

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

