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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, 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 June, 2024
- 7. by Assistant Authentication Officer, United States Department of State
- 8. No. 24045289-32

9. Seal/Stamp:

10. Signature:

Veda Matthews



Certificate No. 9828-6-2024-1

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:

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,

CDR Cesar A. Perez, PhD, Director DRP2: Division of Establishment Support

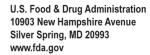
Office of Regulatory Programs

Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from June 11, 2024 to June 10, 2026.









Certificate No. 9828-6-2024-1

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

Name of Manufacturer Manufacturing Site

Aphena Pharma Solutions - Maryland, LLC 7978 Industrial Park Rd EASTON, MD USA 21601

Legal Manufacturer

3M COMPANY 3M Center, 2510 Conway Ave. Bldg. 275-5W-06 Saint Paul, MN USA 55144

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





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

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