APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by Robert A. Sausville

3. acting in the capacity of Director, Division of Case Management

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

Certified

5. at Washington, D.C.

6. the fourteenth of September, 2023

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

8. No. 23056864-1

9. Seal/Stamp:

10. Signature:

Kenneth W Kimich

Kenneth W Kimich

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

...V-VNVT

Application Number: 1607-22

CERTIFICATE TO FOREIGN GOVERNMENT

...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:

DCI Donor Services - Tissue Bank, located at 566 Mainstream Dr., Ste. 300, Nashville, TN 37228, USA, manufactured the following Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps):

Product Name	
Achilles	00201603
Achilles Pre	06900003
Patella	04001603
Patella Hemi	04001303
Patella Pre	04800003
Peroneus	09600003
Tibialis Anterior	07804203
Tibialis Post	07804303
Semitendinosus	04700003
Gracilis	06100003
CortCan 1-4 15cc	00800618

Product Name	
Achilles ST	00201619
Achilles Pre ST	06900019
Patella ST	04001619
Patella Hemi ST	04001319
Patella Pre ST	04800019
Peroneus ST	09600019
Tibialis Anterior ST	07804219
Tibialis Post ST	07804319
Semitendinosus ST	04700019
Gracilis ST	06100019
CortCan 4-10 15cc	00900618

Country Destination: ECUADOR

The product(s) described above and the establishment(s) where it is produced are subject to FDA jurisdiction and regulated solely under section 361 of the Public Health Service Act (PHS Act) and regulations promulgated thereunder. The company listed above has certified to the FDA that the HCT/P meets the requirements of FDA regulation, Title 21, Code of Federal Regulations Part 1271, Human Cells, Tissues, and Cellular and Tissue-Based Products.

It is certified that the above listed HCT/P may be marketed in, and legally exported from, the United States of America at this time. The company listed above is subjected to periodic inspections. The last inspection showed that the plant(s) at that time, appeared to be in compliance with the requirements of FDA regulation, Title 21, Code of Federal Regulations Part 1271.

Signature _____

Robert A. Sausville
Director
Division of Case Management
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
Food and Drug Administration

This certificate is valid from August 17, 2022 to August 16, 2024.