Certificate No. CT:3YPN-6M7E

Application Number: 1185-22

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:

DCI Donor Services dba Sierra Donor Services Eye Bank, located at 3940 Industrial Blvd, West Sacramento, CA 95691, USA, and DCI Donor Services dba Sierra Donor Services Eye Bank, located at 566 Mainstream Drive Suite 300, Nashville, TN 37228, USA, manufactured and distributed, DCI Donor Services dba Sierra Donor Services Eye Bank, located at 3940 Industrial Blvd, West Sacramento, CA 95691, USA, distributed the following Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps):

Product Name
Human Cornea
Human Sclera

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 companies 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 companies listed above are 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 June 09, 2022 to June 08, 2024.