



Certificate No. CT:ZTBX-5VP7

Application Number: 1066-22

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:

**Lions VisionGift, located at 2201 Se 11th Ave, Portland, OR 97214, USA, manufactured, and Lions VisionGift, located at 2201 Se 11th Ave, Portland, OR 97214, USA, distributed the following Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps):**

Product Name  
halo sterile grafts

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 May 19, 2022 to May 18, 2024.

