



**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

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

Certificate No. CT:K6WD-EBY9

Application Number: 1171-25

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 World Vision Institute, located at 1410 N. 21st St., Tampa, FL 33605, USA, manufactured and distributed, and Lions World Vision Institute, located at 1410 N. 21st St., Tampa, FL 33605, USA, distributed the following Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps):

Product Name

OptiGraft Sterile Ophthalmic Allograft

Human Cornea

Human Sclera

TransplantREADY CAIRS

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 _____

Maria C. H. Anderson
Deputy 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 20, 2025 to June 19, 2027.

