



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

Certificate No. CT:9KYU-KRKG

Application Number: 1021-26

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:

Precision Ocular Network, located at 500 Robert Jemison Road, Birmingham, AL 35209, USA, Precision Ocular Network, located at 4750 Commercial Park Court, Clemmons, NC 27012, USA, and Precision Ocular Network, located at 102 East Wheeler Street, Manor, TX 78653, USA manufactured the following Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps):

Product Name

Whole cornea

Country Destination: UKRAINE

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 02, 2026 to June 01, 2028.

