Certificate No. CT:JCX4-BR5A

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

Application Number: 0892-25

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:

Sight Society of Northeastern New York, Inc., located at 4 Tower Place, Suite 601, Albany, NY 12203, USA, manufactured and distributed the following Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps):

Product Name Whole Cornea

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

Mansle

Office of Compliance and Biologics Quality

Center for Biologics Evaluation and Research

Food and Drug Administration

This certificate is valid from April 15, 2025 to April 14, 2027.

