



**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](http://www.fda.gov)

Certificate No. CT:XHC3-REZ2

Application Number: 1666-19

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 Medical Eye Bank & Research Center of Eastern Virginia, Inc., located at 600 Gresham Dr, Norfolk, VA 23507, USA, manufactured the following product(s):**

Product Name

Whole cornea (corneoscleral disc)

Whole cornea processed or segmented (e.g. DSAEK, DMEK; a.k.a. anterior posterior segments)

Whole globe (whole eye)

Whole sclera

Half sclera

Quarter sclera

Long-term preserved cornea or corneal segment

Country Destination: CHINA

The product(s) described above and the plant(s) where it is produced are subject to the jurisdiction of the FDA under the Federal, Food, Drug, and Cosmetic Act.

It is certified that the above listed product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last inspection showed that the plant(s) at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

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 August 16, 2019 to August 15, 2021.

