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:RNZG-SCPZ

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: GERMANY

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.