

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

August 12, 2021

Patrick Johnson Saving Sight 10560 N Ambassador Dr Ste 210 Kansas City, MO 64153

Application Number: 1158-21

Dear Mr. Patrick Johnson:

Enclosed is one (1) export certificate as requested in your communication of July 22, 2021, that was received in our office on July 22, 2021.

This certificate attests to the status of your product under section 361 of the Public Health Service Act (PHS Act). You are responsible for assuring that your product is in compliance with all applicable US laws and regulations, and the requirements of the importing countries.

If we can be of further assistance, please let us know.

Sincerely yours,

Robert A. Sausville

Director

Division of Case Management

Office of Compliance and Biologics Quality

Center for Biologics Evaluation and Research

Food and Drug Administration

Certificate No. CT:C8RA-ER5W

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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:

Saving Sight, located at 10560 N Ambassador Dr Ste 210, Kansas City, MO 64153, USA, manufactured and distributed, and Saving Sight, located at 10560 N Ambassador Dr Ste 210, Kansas City, MO 64153, USA, distributed the following Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps):

Product Name Ocular Tissue

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

Robert A. Sausville

Director

Division of Case Management

Office of Compliance and Biologics Quality

Center for Biologics Evaluation and Research

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This certificate is valid from August 12, 2021 to August 11, 2023.

