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

September 25, 2024

Sara Kerr
Miracles In Sight
3900 Westpoint Blvd, Suite F
Winston Salem, NC 27103

Application Number: 1619-24

To Whom It May Concern

Enclosed are three (3) export certificates as requested in your communication of September 05, 2024, that was received in our office on September 05, 2024.

These certificate(s) attest 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

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Certificate No. CT:ZTAR-F3EU

Application Number: 1619-24

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:

Miracles In Sight, located at 3900 Westpoint Blvd, Suite F, Winston Salem, NC 27103, USA, manufactured and distributed, and Miracles In Sight, located at 3900 Westpoint Blvd, Winston Salem, NC 27103, USA, distributed the following Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps):

Product Name
Human Corneas

Country Destination: SWITZERLAND

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
Food and Drug Administration

This certificate is valid from September 25, 2024 to September 24, 2026.

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
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Certificate No. CT:TEYX-GB6Z

Application Number: 1619-24

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:

Miracles In Sight, located at 3900 Westpoint Blvd, Suite F, Winston Salem, NC 27103, USA, manufactured and distributed, and Miracles In Sight, located at 3900 Westpoint Blvd, Winston Salem, NC 27103, USA, d stributed the following Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps):

Product Name
Human Corneas

Country Destination: ISRAEL

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
Food and Drug Administration

This certificate is valid from September 25, 2024 to September 24, 2026.

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:6DP6-HBRY

Application Number: 1619-24

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:

Miracles In Sight, located at 3900 Westpoint Blvd, Suite F, Winston Salem, NC 27103, USA, manufactured and distributed, and Miracles In Sight, located at 3900 Westpoint Blvd, Winston Salem, NC 27103, USA, distributed the following Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps):

Product Name
Human Corneas

Country Destination: SAUDI ARABIA

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
Food and Drug Administration

This certificate is valid from September 25, 2024 to September 24, 2026.