U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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

Certificate No. 11067-6-2023

CERTIFICATE OF EXPORTABILITY SECTION 802

The Food and Drug Administration certifies that the product(s) described below is subject to its jurisdiction under the Federal Food, Drug, and Cosmetics Act (the Act). Such product(s), which is not approved for marketing in the United States, may be legally exported to foreign countries provided it meets the requirements of Section 802 of the Act.

Under Section 802 of the Act, a drug or device not approved for marketing in the United States may be exported if it is manufactured, processed, packaged, and held in substantial conformity with current good manufacturing practice requirements. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such 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 below. The company has certified to the Food and Drug Administration that:

* the product(s) accords to the specifications of the foreign purchaser;
* the product(s) is not in conflict with the laws of the country to which it is intended for export;
* the shipping package for the product(s) is labeled on the outside that it is intended for export; and
* the product(s) is not sold or offered for sale in the United States.

Based on the information above, the product(s) listed below may be exported pursuant to Section 802 of the Act.

Name of Product

See Attached List
(One Page)

Manufacturing Location

ELLIS OPHTHALMIC TECHNOLOGIES, INC
147-39, 175 Street Suite No. 128
Jamaica, NY USA 11434

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from June 28, 2023 to June 27, 2025.

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Certificate of Exportability Section 802 - Name of Product(s) Attachment Page 1 of 1

Manufacturing Location
ELLIS OPHTHALMIC TECHNOLOGIES, INC
147-39, 175 Street
Suite No. 128
Jamaica, NY USA 11434

Name of Product(s)
Intraocular Lens and Accessories
Galaxy Lens Es701
Galaxy Lens Es501
Galaxy Lens Es901
Galaxy Fold Center Fix
Galaxy Fold Center Fit
Galaxy Fold Ultrasmart
Galaxy Fold Ultrasmart -M
Galaxy Fold M -Diff
Galaxy Fold Superphob AE-01
Galaxy Fold Superphob AEM-01
Galaxy Fold Superphob Infocus AE INFO
Injector & Cartridge for Intraocular Lens
----------END OF PRODUCT LIST----------