



Certificate No. 13839-8-2017

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

Robin W. Newman MSN EdD CPNP
Director
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from August 18, 2017 to August 17, 2019.





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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
Galaxy Fold Center Fix
Galaxy Fold Center Fit
Galaxy Fold Superphob
Galaxy Fold Ultra Smart
Galaxy Fold Ultra Smart - M
Galaxy Fold M-Diff
Galaxy Lens Es 501
Galaxy Lens Es 701
Galaxy Lens Es 901
AE INFO

-----END OF PRODUCT LIST-----

