DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Certificate No. 2275-4-2012

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 Cosmetic Act (the Act). Such product(s), which is not approved for marketing in the United States, may be legally exported 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
(1 Page)

Manufacturing Location
Ellis Ophthalmic Technologies, Inc.
147-39, 175 Street, Suite #128
Jamaica, NY 11434

Ann M. Ferriter
Director
Division of Risk Management Operations
Office of Compliance
Center for Devices and Radiological Health

This certificate expires 24 months from the date notarized.

COUNTY OF MONTGOMERY
STATE OF MARYLAND

Subscribed and sworn to before me this 8 day of May month 2012 year.

Cathryn N. Morris

CATHRYN N. MORRIS
NOTARY PUBLIC STATE OF MARYLAND
County of Montgomery
My Commission Expires January 4, 2013

Certificate of Exportability [Section 802] Attachment Page 1 of 1.

Name of Product(s)	Manufacturing Location
Lens Intraocular Galaxy Lens Es 501 Galaxy Lens Es 501 Galaxy Lens Es 701 Galaxy Lens Es 901 Galaxy Fold Center Fix Galaxy Fold Center Fit Galaxy Fold Ultra Smart Galaxy Fold Ultra Smart –M Galaxy Fold SUPERPHOB.	Ellis Ophthalmic Technologies, Inc 147-39, 175 Street, Suite #128 Jamaica, NY 11434.
" END OF PRODUCT LIST"	