



**Certificate No. 8514-4-2020**

**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**

TEKIA, INC.  
17 Hammond suite 414  
Irvine, CA USA 92618

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 April 27, 2020 to April 26, 2022.**





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

**Manufacturing Location**

TEKIA, INC.  
17 Hammond  
suite 414  
Irvine, CA USA 92618

**Name of Product(s)**

Hydrophobic acrylic Intraocular Lenses. Tek-Lens III: Model 900  
Tek-Clear Intraocular Lenses. Models: 500, 500S  
Single piece hydrophilic acrylic Intraocular Lenses. Tek-Lens II Models: 811, 811Y, 820, 820Y, 872, 872Y, 872S,  
872YS. MeyeLens Models: 260, 460.  
Three piece hydrophilic acrylic Intraocular Lenses. Tek-Lens II Models: 617, 617Y, 618, 618Y. MeyeLens Model:  
360

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

