

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

Barry Linder, MD, MS President Eyedetec Medical, Inc. 9000 Crow Canyon Rd Ste S348, Suite S 348 Danville, CA 94506

AUG 2 6 2015

Dear Dr. Barry Linder, MD, MS:

This is in response to your Certificate to Foreign Government request. This Certificate to Foreign Government only attests to the status of your product under the Federal Food, Drug, and Cosmetic Act. You are responsible for assuring that your product, when exported to these countries, is in compliance with all other US laws and regulations regarding export of such products to these specific countries. Enclosed are the certificates that you requested. If you have any additional questions, please let us know.

Export Branch
Division of International Compliance Operations
Office of Compliance
Center for Devices and Radiological Health
301-796-7400
exportcert@cdrh.fda.gov

Enclosure:

1 Certificate(s)

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CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into HONG KONG SAR, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

EyeGiene Insta-Warmth warm eye compress

Name of Manufacturer/Distributor, Address

Name of Manufacturer
Specification Developer
EYEDETEC MEDICAL, INC.
9000 Crow Canyon Road Suite S 348
Danville, CA USA 94506

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections.

Carl Fischer, Ph.D.

Director

Division of International Compliance Operations

Office of Compliance

Center for Devices and Radiological Health

This certificate is valid from August 26, 2015 to August 25, 2017.

