



Certificate No. 3265-4-2016

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, 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)

See Attached List

(One Page)

Name of Manufacturer/Distributor, Address

See Attached List

(One Page)

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 May 27, 2016 to May 26, 2018.





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Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Manufacturer

UNILENE, SAC
Napo 450
Lima 05, Lima PERU 05

Name of Distributor

Unilene Sutures and Complements
1443 Ricardo Avenue
Fort Myers, FL USA 33901

----END OF MANUFACTURER/DISTRIBUTOR LIST----





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Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1

Name of Manufacturer

UNILENE, SAC

Napo 450

Lima 05, Lima PERU 05

Name of Distributor

Unilene Sutures and Complements

1443 Ricardo Avenue

Fort Myers, FL USA 33901

Name of Product(s)

Polyglycolic Acid, Synthetic Absorbable Suture

Vital Sutures, Sutumed, Suturex,

Sukol, Surgi Sutures, Galenex

Polyglactin, Synthetic Absorbable Suture

Vital Sutures, Sutumed, Suturex,

Sukol, Surgi Sutures, Galenex

Polydioxanone, Synthetic Absorbable Suture

Vital Sutures, Sutumed, Suturex,

Sukol, Surgi Sutures, Galenex

Polyglecaprone, Synthetic Absorbable Sutures

Vital Sutures, Sutumed, Suturex,

Sukol, Surgi Sutures, Galenex

Black Braided Silk, Non Absorbable Suture

Vital Sutures, Sutumed, Suturex,

Sukol, Surgi Sutures, Galenex

Nylon (Polyamide), Non Absorbable Suture

Vital Sutures, Sutumed, Suturex,

Sukol, Surgi Sutures, Galenex

Polypropylene, Non Absorbable Suture

Vital Sutures, Sutumed, Suturex,

Sukol, Surgi Sutures, Galenex

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

