



U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 5959-3-2022

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

Name of Manufacturer

DEMETECH CORP.
5980 Miami Lakes Drive
Miami Lakes, FL USA 33014

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. 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 above.

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 March 08, 2022 to March 07, 2024.





**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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

Name of Manufacturer

DEMETECH CORP.
5980 Miami Lakes Drive
Miami Lakes, FL
USA 33014

Name of Product(s)

DemeSILK - Silk Nonabsorbable Suture
DemeLON - Nylon Nonabsorbable Suture
DemeBOND - Polyester Nonabsorbable Suture
DemeLENE - Polypropylene Nonabsorbable Suture
DemeSORB - Absorbable Polyglycolic PGA Suture
DemeGUT Plain - Absorbable Plain Catgut Suture
DemeGUT Chromic - Absorbable Chromic Catgut Suture
DemeDIOX - Absorbable Polydioxanone Surgical Suture
DemeCAPRONE - Absorbable Poliglecaprone 25 Surgical Suture
DemeCRYL - Absorbable Poly(glycolic/L -lactide) PGLA Suture
DemeQUICK - Absorbable Poly(glycolic/L -lactide) PGLA Suture
DemeSTEEL - Nonabsorbable Stainless Steel Surgical Suture
DemeLENE MESH - Mesh Surgical Polymeric
DemeDIOX with Novathreads - Absorbable Polydioxanone Surgical Suture
DemeTECH PTFE - Polytetrafluoroethylene Nonabsorbable Suture
DemeDAC - Polyester Nonabsorbable Suture
DemeFORCE - UHMWPE Nonabsorbable Suture
DemeDIOX Barbed - Absorbable Polydioxanone Surgical Suture
DemeDIOX Barbed with Novathreads - Absorbable Polydioxanone Surgical Suture
DemeMASK - Surgical Mask
DemeMASK - N95 Respirator
SutureGard Suture Retention Device
HemiGard Adhesive Suture Retention Device
SMARTLOOPS - Polyester Nonabsorbable Suture

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

