



Certificate No. 7805-4-2025-1

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. 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 May 01, 2025 to April 30, 2027.



To verify the authenticity of the information on this certificate, you may scan the QR code or visit www.access.fda.gov/fecv/CDRH.



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

Name of Owner Operator

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

Name of Manufacturer

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

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





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

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Name of Manufacturer

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 Miami Lakes, FL
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Name of Product(s)

- DemeSILK- Silk Nonabsorbable Suture
- DemeLON - Nylon Nonabsorbable Suture
- DemeBOND -Polyester Nonabsorbable Suture
- DemeLENE - Polypropylene Nonabsorbable Surgical 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- Rapid Absorbable Suture Poly(glycolic/L-Lactide)-PGLA
- DemeSTEEL-Stainless Steel Nonabsorbable 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
- Smartloops-Polyester Nonabsorbable Suture
- UR24T Urine Collection Apparatus (UCA)
- DemeTUBE- Tube, Collection, Capillary Blood
- DemeTUBE-System, Blood Collection, Vacuum-Assisted, Manual
- Spigot Guard - Urine Collection Bag Drain Cap

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

