



Certificate No. 27807-4-2015

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  
(1 Page)

Name of Manufacturer/Distributor, Address

**Manufacturer:**

DemeTECH Corporation  
14175 NW 60<sup>th</sup> Ave.,  
Miami Lakes, FL 33014 USA

**Distributor:**

DemeTECH Corporation  
14175 NW 60<sup>th</sup> Ave.,  
Miami Lakes, FL 33014 USA

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.

Carl Fischer, Ph.D.  
Director  
Division of International Compliance Operations  
Office of Compliance  
Center for Devices and Radiological Health

This Certificate is valid from April 27, 2015 to April 27, 2017.



**Certificate to Foreign Government – Attachment (Page 1 of 1 Page)**

**Name of Products(s)**

**Name of Manufacturer/  
Distributor, Address**

DemeTECH Silk (DemeSILK) Non-absorbable Surgical Suture

DemeTECH Nylon (DemeLON) Non-absorbable Surgical Suture

DemeTECH Polyester (DemeBOND) Non-absorbable Surgical Suture

DemeTECH Absorbable Poly (glycolide/L-lactide), (DemeSORB), PGA Surgical Suture

DemeTECH Polypropylene (DemeLENE) Non-absorbable Surgical Suture

DemeTECH Absorbable (DemeGUT) Chromic Catgut and Plain Catgut Surgical Suture

DemeTech Polydioxanone (DemeDIOX) Synthetic Monofilament (PDO) Absorbable Surgical Suture

DemeTech Poligecaprone 25 (DemeCAPRONE), Synthetic Monofilament (PGCL) Absorbable Surgical Suture.

DemeTECH Absorbable Poly (glycolide/L-lactide), (DemeCRYL ) Surgical Suture

DemeTECH Rapid Absorbable (DemeQUICK) Surgical Suture

DemeTECH Stainless Steel (DemeSTEEL) Surgical Suture

DemeTech Staplers, Surgical

DemeTech Scalpels, Blades, Surgical

“END OF PRODUCT LIST”

Manufacturer:  
DemeTECH Corporation  
14175 NW 60th Ave.,  
Miami Lakes FI 33014 USA

Distributor:  
DemeTECH Corporation  
14175 NW 60th Ave.,  
Miami Lakes FI 33014 USA

