



Certificate No. 9520-12-2015

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

(Two Pages)

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.

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

This certificate is valid from January 11, 2016 to January 10, 2018.





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

Name of Manufacturer

SteriTec Products Mfg., Co., Inc.
74 Inverness Drive East
Englewood, CO USA 80112

Mesa Laboratories Omaha Manufacturing Facility
8607 Park Dr
OMAHA, NE USA 68127

DANA PRODUCTS, INC.
11457 MELROSE AVE
FRANKLIN PARK, IL USA 60131

Name of Distributor

Mesa Laboratories Omaha Manufacturing Facility
8607 Park Dr
OMAHA, NE USA 68127

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





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Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 2

Name of Manufacturer

Mesa Laboratories Omaha Manufacturing Facility
8607 Park Dr
OMAHA, NE USA 68127

Name of Product(s)

G. stearothermophilus Spore Strips Biological Indicator
(3-1000, 3-5025, 3-5100, 3-6100, 3-6100F, 3-7100, RSC-3-06, 3-1100, 3-3100, 3-4100)
B. atrophaeus Spore Strips Biological Indicator
(1-1000, 1-6025, 1-6100, 1-7100, 1-8100, 1-9100, RSC-1-06, 1-3100, 1-4100, 1-5100)
B. pumilus Spore Strips Biological Indicator
(7-6100, 7-7100, 7-8100, 7-9100, 7-2100, 7-3100, 7-4100, 7-5100)
Combined Spore Strips Biological Indicator
(5-1000, 5-5025, 5-5100, 5-66100)
G. stearothermophilus Suspension Biological Indicator
(SUS-3-4, SUS-3-5, SUS-3-6, SUS-3-7, SUS-3A-4, SUS-3A-5, SUS-3A-6, SUS-3A-7,
SUS-3B-4, SUS-3B-5, SUS-3B-6, SUS-3B-7, SUS-3-3, SUS-3-8)
B. atrophaeus Suspension Biological Indicator
(SUS-1-4, SUS-1-5, SUS-1-6, SUS-1-7, SUS-1-8, SUS 1-1, SUS-1-3, SUS-1-9)
B. pumilus Suspension Biological Indicator
(SUS-7-4, SUS-7-5, SUS-7-6, SUS-7-7, SUS-7-8, SUS-7-9)
ProSpore Self-contained Biological Indicator
(PS1-4-100, PS1-4-15, PS1-5-100, PS1-5-15, PS1-5-60NC, PS1-6-100, PS1-6-15,
PS1-6-60NC, PS-4-10, PS-4-50, PS-5-10, PS-5-50, PS-6-50)
ProSpore2 Steam Self-contained Biological Indicator
(PS2-3-5-50, PS2-3-6-50, PS2-3-3-50, PS2-3-4-50)
ProSpore2 EO Self-contained Biological Indicator
(PS2-1-6-50, PS2-1-3-50, PS2-1-4-50, PS2-1-5-50)
ProTest Steam Self-contained Biological Indicator
(PT-3-5-100, PT-3-5-25, PT-3-6-100, PT-3-6-25, PT-3-BITP-30)
ProTest EO Self-contained Biological Indicator
(PT-1-6-100, PT-1-6-25)
ProTest H2O2 Self-contained Biological Indicator
(PTH-3-6-100, PTH-3-6-25)
PAP Kit
(C-3-6-1080P-PA)
ExpoSure
(EXPO/6)
Prepared Tryptic Soy Broth Media Tryptic Soy Broth Bacteriological growth media
(TSB-1000, TSB-500, TSB-BP16, TSB-C16, TSB-PR16)

Name of Manufacturer

SteriTec Products Mfg., Co., Inc.
74 Inverness Drive East
Englewood, CO USA 80112

Name of Distributor

Mesa Laboratories Omaha Manufacturing Facility
8607 Park Dr
OMAHA, NE USA 68127

Name of Product(s)

Dry Heat Indicator Labels Chemical Indicator
(CI-DHI)
ProChem SSE Chemical Indicator
(CI-SSE)
ProChem SSI Chemical Indicator
(CI-SINT)





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Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 2

ProChem EXT Chemical Indicator
(CI-EXT)

ProChem OK Chemical Indicator
(CI-OK)

ProChem BD Test Pack Air removal test
(CI-BDTLF, CI-BDTLF20)

Eto Process Indicator Tape Chemical Indicator
(CI-ETP, CI-ETP-EA)

Autoclave Process Indicator Tape Chemical Indicator
(CI-STP, CI-STP-EA, CI-STP-12, CI-STP12-EA, CI-STP-24, CI-STP24-EA)

Name of Manufacturer

DANA PRODUCTS, INC.
11457 MELROSE AVE
FRANKLIN PARK, IL USA 60131

Name of Distributor

Mesa Laboratories Omaha Manufacturing Facility
8607 Park Dr
OMAHA, NE USA 68127

Name of Product(s)

ProChem SSW Chemical Indicator
(CI-SSW)

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

