



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Certificate No. 25133-1-2014

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
(8 Pages)

Name of Manufacturer/Distributor, Address

Manufacturer
Mesa Laboratories, Inc.
Omaha Manufacturing Facility
8607 Park Drive
Omaha, Nebraska 68127

Distributor
Mesa Laboratories, Inc.
Omaha Manufacturing Facility
8607 Park Drive
Omaha, Nebraska 68127

Manufacturer
SteriTech Products Mfg., Co., Inc.
74 Inverness Drive East
Englewood, Colorado 80112

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.

Leila M. Lawrence
Chief, Export Branch
Division of International Compliance Operations
Office of Compliance
Center for Devices and Radiological Health

This certificate expires 24 months
from the date notarized.

COUNTY OF MONTGOMERY
STATE OF MARYLAND

Subscribed and sworn to before me this 27 day of Dec month 2014 year.

CATHRYN N MORRIS
Notary Public-Maryland
Montgomery County
My Commission Expires
January 04, 2017



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Name of Product(s)

Name of Manufacturer/
Distributor, Address

***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

Manufacturer:
Mesa Laboratories, Inc.
Omaha Manufacturing Facility
8607 Park Drive
Omaha, NE 68127

***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

END OF PAGE



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Name of Product(s)

Name of Manufacturer/
Distributor, Address

Combined Spore Strips
Biological Indicator

5-1000
5-5025
5-5100
5-66100

Manufacturer:
Mesa Laboratories, Inc.
Omaha Manufacturing Facility
8607 Park Drive
Omaha, NE 68127

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

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Name of Product(s)

Name of Manufacturer/
Distributor, Address

B. pumilus Suspension
Biological Indicator

SUS-7-4
SUS-7-5
SUS-7-6
SUS-7-7
SUS-7-8
SUS-7-9

Manufacturer:
Mesa Laboratories, Inc.
Omaha Manufacturing Facility
8607 Park Drive
Omaha, NE 68127

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

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Name of Product(s)

Name of Manufacturer/
Distributor, Address

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

Manufacturer:
Mesa Laboratories, Inc.
Omaha Manufacturing Facility
8607 Park Drive
Omaha, NE 68127

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

ProPACT
Biological indicator
C-3-PA-24

ProLine Steam
Biological indicator
PL-3-6-15

ProLine EO
Biological indicator
PL-1-6-15

Prospore D-H
Biological Indicator
DH/50

G. stearotherophilus threads
Biological indicator
3-5100TT
3-6100TT

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Name of Product(s)

Name of Manufacturer/
Distributor, Address

B. atrophaeus threads
Biological indicator
1-6100TT
1-4100TT
1-7100TT

Manufacturer:
Mesa Laboratories, Inc.
Omaha Manufacturing Facility
8607 Park Drive
Omaha, NE 68127

G. stearothermophilus metal discs
Biological indicator
3-5100ST
3-6100ST
3A-6100ST

B. atrophaeus metal discs
Biological indicator
1-6100ST
1-2100ST
1-3100ST
1-4100ST
1-5100ST

G. stearothermophilus wires
Biological indicator
3-6100WT
3-6100WT-L

G. stearothermophilus metal strips
Biological indicator
3-5100AT
3-6100AT
3A-6100AT

B. atrophaeus metal strips
Biological indicator
1-6100AT
1-2100AT
1-3100AT
1-4100AT
1-5100AT

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Name of Product(s)

Name of Manufacturer/
Distributor, Address

Prepared Tryptic Soy Broth Media
Tryptic Soy Broth Bacteriological
growth media

TSB-1000

TSB-500

TSB-BP13

TSB-BP16

TSB-C16

TSB-PR13

TSB-PR16

Manufacturer:
Mesa Laboratories, Inc.
Omaha Manufacturing Facility
8607 Park Drive
Omaha, NE 68127

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<u>Name of Product(s)</u>	<u>Name of Manufacturer/ Distributor, Address</u>
Dry Heat Indicator Labels Chemical indicator CI-DHI	Distributor: Mesa Laboratories Omaha Manufacturing Facility 8607 Park Drive Omaha, NE 68127
ProChem SSE Chemical indicator CI-SSE	Manufacturer: SteriTec Products Mfg., Co., Inc. 74 Inverness Drive East Englewood, CO 80112
ProChem SSI Chemical indicator CI-SINT	
ProChem EXT Chemical indicator CI-EXT	
ProChem BD Test Pack Air removal test CI-BDTLF CI-BDTLF20	
ProChem OK Chemical indicator CI-OK	
ProChem BD 121 Chemical indicator CI-BDTLF121	
Bowie-Dick Type Test Sheets Air removal test CI-BD110	
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Name of Product(s)

Name of Manufacturer/
Distributor, Address

BI Test Pack
Biological Indicator Test Pack
BITP30

EtO Process Indicator Tape
Chemical indicator
CI-ETP

CI-STP-EA

Autoclave Process Indicator Tape
Chemical Indicator

CI-STP
CI-STP-EA
CI-STP-12
CI-STP12-EA
CI-STP-24
CI-STP24-EA

Distributor:
Mesa Laboratories
Omaha Manufacturing Facility
8607 Park Drive
Omaha, NE 68127

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

END OF PRODUCT LIST

