



Certificate No. 217-1-2016

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

Name of Manufacturer

Mesa Laboratories Bozeman Manufacturing Facility
10 Evergreen Dr
BOZEMAN, MT USA 59715

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 12, 2016 to January 11, 2018.



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Name of Manufacturer

Mesa Laboratories Bozeman Manufacturing Facility
10 Evergreen Dr
BOZEMAN, MT USA 59715

Name of Product(s)

EZTest Steam (EZS/5, EZS/6)
EZTest Gas (EZG/6)
Smart-Read EZTest Steam (SEZS/5, SEZS/6)
Smart-Well Incubator (SWI-201)
EZTest Incubator Model 1410 (I1410)
EZTest Hydrogen Peroxide (EZH/5I, EZH/6, EZH/6I)
Smart-Read EZTest Steam Test Pack (SRSP/25, SRSP6/25)
MesaStrip Biological Indicator for Steam (SGMS/5, SGMS/6)
MesaStrip Biological Indicator For EtO/Dry Heat (SGMG/6)
MesaStrip Biological Indicator for Radiation (SGMR/6)
MesaStrip Biological Indicator for Dual Species (SGMD/56, SGMD/66)
Releasat Gas Biological Indicator Culturing Set (RG/100)
Releasat Gas Media Only (RM/100)
Releasat Steam Biological Indicator Culturing Set (RS/100)
Releasat Steam Media Only (PM/100)
MagnaAmp Biological Indicator (MA/5, MA/6)
SterilAmp II Biological Indicator (SA/4, SA/5, SA/6)
SterilAmp II Biological Indicator, 18 mm (SA18/6)
SterilAmp II '5230' Biological Indicator for Low Temperature Steam (SASU/6)
DriAmp Culturing Set with Releasat Medium (DH/50)
Population Assay Kit (PAK-1)
Spore Suspension DSM 4181 Bacillus subtilis--Ethanol (SS4181E/6, SS4181E/7)
Spore Suspension DSM 4181 Bacillus subtilis--Aqueous (SS4181A/4, SS4181A/7, SS4181A/8)
Spore Suspension Bacillus subtilis '5230'--Ethanol (SS5230E/7)
Spore Suspension Bacillus cereus--Ethanol (SSBCE/6, SSBCE/7)
Spore Suspension Bacillus cereus--Aqueous (SSBCA/5, SSBCE/6, SSBCE/7, SSBCE/7)
Spore Suspension Bacillus thuringiensis--Aqueous (SSBTA/5)
Spore Suspension Clostridium sporogenes--Ethanol (SSCSPE/3, SSCSPA/4, SSCSPA/6)
Spore Suspension Clostridium sporogenes--Aqueous (SSCSPA/3, SSCSPA/4, SSCSPA/5, SSCSPA/6)
Spore Suspension Bacillus atrophaeus--Ethanol (SSGE/6)
Spore Suspension Bacillus atrophaeus--Aqueous (SSGA/6)
Spore Suspension Bacillus licheniformis--Ethanol (SSLFE/3, SSLFE/6, SSLFE/7)
Spore Suspension Bacillus megaterium--Ethanol (SSME/4, SSME/6)
Spore Suspension Bacillus megaterium--Aqueous (SSMA/6, SSMA/7)
Spore Suspension Bacillus pumilus--Ethanol (SSRE/4, SSRE/6, SSRE/7)
Spore Suspension Bacillus pumilus--Aqueous (SSRA/4, SSRA/6, SSRA/7)
Spore Suspension Geobacillus stearothermophilus--Ethanol (SSSE/5, SSSE/6)
Spore Suspension Geobacillus stearothermophilus--Aqueous (SSSA/5, SSSA/6)
Spore Suspension Bacillus smithii--Ethanol (SSSIE/6)
Spore Suspension Bacillus smithii--Aqueous (SSSIA/6, SSSIA/7)
Gas Strip, 1 x 25 mm (A1X25/6, A1X25/6G)
Gas Strip, 2 x 10 mm (A2X10/6, A2X10/6G)
Gas Strip, 2 x 19 mm (A2X19/6, A2X19/6G)
Gas Strip, 3 x 25 mm (A3X25/6, A3X25/6G)
Radiation Strip, 2 x 10 mm (P2X10/7)
Radiation Strip, 2 x 19 mm (P2X19/6)
Steam Strip, 1 x 25 mm (S1X25/2, S1X25/3, S1X25/4, S1X25/5, S1X25/6)
Steam Strip, 2 x 10 mm (S2X10/5, S2X19/6)
Steam Strip, 2 x 19 mm (S2X19/5, S2X19/6)
Steam Strip, 3 x 25 mm (S3X19/5, S3X19/6)
Spore Disc Biological Indicator for Radiation (DPSSC/3, DPSSC/4, DPSSC/6, DPSSC/7)



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Spore Disc Biological Indicator for Steam (DS6R/6, DS6R/6G)

Spore Disc Biological Indicator for Gas (DASS/6, DA6R/6, DA6R/6G)

Tyvek/Tyvek packaged biological indicator, GST inoculated SS disc (35.HMV-091)

Bare metal biological indicator, GST inoculated SS ribbon (35.SBC-327)

Tri-scale biological indicator--Tyvek packaged, GST inoculated SS carriers (LOG-456)

Tyvek/Tyvek packaged biological indicator, B. atrophaeus inoculated SS disc (GRS-090)

Sterile Tyvek Transfer Pockets (BMWK-090)

G. stearothersophilus suspension calibrated for gaseous hydrogen peroxide (LPT-606)

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



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