



U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 8923-5-2020

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 (Zoot)
625 Zoot Way
Bozeman, MT USA 59718

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 June 16, 2020 to June 15, 2022.





Certificate No. 8923-5-2020

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

Name of Manufacturer

Mesa Laboratories Bozeman Manufacturing Facility (Zoot)
625 Zoot Way
Bozeman, MT USA 59718

Name of Product(s)

Biological Indicators (Sterilization Assurance)
EZTest Steam (EZS/5, EZS/525, EZS/6, EZS/625)
EZTest Gas (EZG/6, EZG/625)
Smart-Read EZTest Steam (SEZS/5, SEZS/525, SEZS/6, SEZS/625)
Smart-Well Incubator (SW1710-1, SW1710-3, SW1710-4, SW1710-5)
EZTest Incubator Model 1410 (I1410)
EZTest Hydrogen Peroxide (EZH/5I, EZH/6I)
EZTest Steam Test Pack (STP/25)
Smart-Read EZTest Steam Test Pack (SRSP/25, SRSP6/25)
MesaStrip Biological Indicator Steam (SGMS/3, SGMS/5, SGMS/6)
MesaStrip Biological Indicator EtO/Dry Heat (SGMG/6)
MesaStrip Biological Indicator Radiation (SGMR/6, SGMR/7)
MesaStrip Biological Indicator 5230 (SGMSU/6)
MesaStrip Chlorine Dioxide (ACD/6)
Releasat Gas Biological Indicator Culturing Set (RG/100)
Releasat Red Media Only (RM/100)
Releasat Purple Media Only (PM/100)
MagnaAmp Biological Indicator (MA/4, MA/5, MA/6)
MagnaAmp Negative Control (MANC)
SterilAmp II Biological Indicator (SA/4, SA/5, SA/6)
SterilAmp II Negative Control (SANC)
SterilAmp II Biological Indicator, 18 mm (SA18/6, SA18/NC50)
SterilAmp II 18 mm Negative Control (SANC18)
SterilAmp II '5230' Biological Indicator (SASU/6)
SterilAmp II '5230' Negative Control (SASUNC)
DriAmp Culturing Set with Releasat Medium (DH/50)
Spore Suspension B. subtilis 6633--Aqueous (SS6633A/7)
Spore Suspension B. subtilis 6633--Ethanol (SS6633E/4, SS6633E/5, SS6633E/6)
Spore Suspension B. subtilis 6633--Ethanol (SS6633E/7, SS6633E/8)
Spore Suspension Bacillus subtilis '5230'--Aqueous (SS5230A/7)
Spore Suspension Bacillus subtilis '5230'--Ethanol (SS5230E/4, SS5230E/5, SS5230E/6)
Spore Suspension Bacillus subtilis '5230'--Ethanol (SS5230E/7, SS5230E/8)
Spore Suspension Bacillus atrophaeus--Ethanol (SSGE/4, SSGE/5, SSGE/6, SSGE/7, SSGE/8)
Spore Suspension Bacillus pumilus--Ethanol (SSRE/4, SSRE/5, SSRE/6, SSRE/7, SSRE/8)
Spore Suspension G. stearothermophilus--Ethanol (SSSE/4, SSSE/5, SSSE/6, SSSE/7)
Spore Suspension G. stearothermophilus--Aqueous (SSSA/7)
Spore Suspension B. smithii --SSSME/7
Spore Suspension C. sporogenes -- SSCS19404/4, SSCS19404/5, SSCS19404/6, SSCS19404/7)
Spore Suspension C. sporogenes -- SSCS7955/4, SSCS7955/5, SSCS7955/6, SSCS7955/7)
Spore Suspension C. sporogenes -- SSCS11437/4, SSCS11437/5, SSCS11437/6, SSCS11437/7)
Gas Strip, 1 x 25 mm (A1X25/6, A1X25/6G)
Gas Strip, 2 x 10 mm (A2X10/6, A2X10/6G)
Steam Strip, 1 x 25 mm (S1X25/6, S1X25/6)
Steam Strip, 2 x 10 mm (S2X10/6, S2X10/6G)
5230 Strip, 1 x 25 mm (SU1X25/6)
5230 Strip, 2 x 10 mm (SU2X10/6)
Spore Disc Biological Indicator Radiation (DPSSC/3, DPSS/6C)
Spore Coupon Biological Indicator Dry Heat (CSSA/6)
Spore Disc Biological Indicator Steam (DS6R/6, DS6R/6G)
Stainless Steel Disc in Tyvek/Tyvek, G. stearothermophilus (HMV-091, HMV-091E3, KCD-404)
Stainless Steel Disc in Tyvek/Tyvek, G. stearothermophilus (NAS-152, NAS-152E3)
Stainless Steel Disc in Tyvek/Tyvek, G. stearothermophilus (NAS-152E4)





Certificate No. 8923-5-2020

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

Bare Metal BI, Stainless Steel Ribbon, G. steaerothermophilus (SBC-327)
Tri-scale biological indicator--Tyvek packaged, GST inoculated SS carriers (LOG-456)
Stainless Steel Disc in Tyvek/Tyvek, B. atrophaeus (GRS-090, GRS-090E3)
Sterile Tyvek Transfer Pockets (BMWK-090)
Spore Suspension, G. steaerothermophilus gaseous hydrogen peroxide (LPT-606, LAU-196)
G. steaerothermophilus Spore Strip (3-1000, 3-5100, 3-6100)
B. atrophaeus Spore Strip (1-1000, 1-6100, 1-6500)
Combined Spore Strip (5-5100, 5-1000)
B. atrophaeus Spore Disc (1-61006MM, 1-10006MM)
B. atrophaeus Thread/Suture (1-6100TT)
ProLine Steam PCD (PL-3-6-15)
4 mL ProSpore (PS-4-10, PS-4-50, PS-5-10, PS-5-50, PS-6-50)
ExpoSure (EXPO/6)
Prepared Tryptic Soy Broth Media (TSB-BP16)
DHI Dry Heat Indicator Labels (CI-DHI)
ProChem SSI (CI-SINT)
ProChem OK (CI-OK)
ProChem BD Test Pack (CI-BDTLF, CI-BDTLF20)
ProChem BD 121 Test Pack (CI-BDTLF121, CI-BDTLF121-20)
ProChem BD110 (CI-BD110)
ProChem SSW (CI-SSW)
Population Assay Glassware Only (PAK-G)
Population Assay Media Only (PAK-M)
Power Pack (P6-1000)
Thermometer (IDT2)
Incubator Block Therm. Bushing, 1410 (9505-1410)
EZTest Crusher (Crusher/SGMWNL)
ProSpore Incubator (I1480)
MagnaAmp Incubator (I1510)
Incubator Block Therm. Bushing, 1510 (9505-1510)
Incubator Block Therm. Bushing, 1480 (9505-1480)
Incubator Thermometer--Digital Keychain Thermometer (IDT2)
Black Citizen Printer w/o Power Pack (PTR/BLK)
Printer Power Pack (P4-1000)
Printer Power Pack (P5-1000)
P6 Smart-Well Interchangeable Power Pack (P6-1000)
Printer Cable (RJ45 to DB25) Connects Printer and SW Inc. (9142)
Printer Ribbon/Paper Kit 1 Ink/2 Rolls (9503)
Printer Paper Roll (PTR/PPR)
Printer Ink (PTR/INK)
Mesa PCD--BI Disc 1-10006mm (PCD2.1, PCD3.1, PCD4.1, PCD5.1, PCD6.1, PCD7.1)
Mesa PCD--SGMG/6 no glassine (PCD2.12)
Mesa PCD--EZG/6 SCBI (PCDV.13, PCD2.13, PCD3.13, PCD4.13, PCD5.13, PCD6.13, PCD7.13)
Mesa PCD--EZH/6 SCBI (PCD8.13)
Mesa PCD--A2X10/6G (PCD4.19)
Mesa PCD--SGMG/6 in glassine (PCD2.5, PCD3.5, PCD4.5, PCD5.5, PCD6.5, PCD7.5)
Steris PCD--NA005 BI strip no glassine (PCD2.2, PCD3.2, PCD4.2, PCD5.2)
Steris PCD--NA005 BI strip no glassine (PCD6.2, PCD7.2)
Steris PCD--NA005 BI strip in glassine (PCD2.7, PCD4.7, PCD6.7, PCD7.7)
3M PCD--Attest 1264-S SCBI (PCD2.6, PCD3.6, PCD4.6, PCD5.6, PCD6.6, PCD7.6)
3M PCD--Attest 1264-S RRBI (PCD2.9, PCD3.9, PCD4.9, PCD5.9, PCD6.9, PCD7.9)
Steris Bare BI PCD NA005 in glassine (PCD0.7)
3M Bare BI PCD Attest 1264-S SCBI (PCD0.6)
3M Bare BI PCD Attest 1264-S RRBI (PCD0.9)

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

