

# Sterility Assurance **Product Guide**

Africa, Asia, Australia, North and South America





Thank you for choosing Mesa Labs as your partner in sterility assurance.

This product guide includes a detailed selection of sterilization indicators, accessories and services to ensure the utmost safety and efficacy of healthcare related products.

All of our products and services help maintain critical environments for hospitals, pharmaceutical and medical device manufacturers, blood banks, laboratories, pharmacies and industrial facilities. Mesa has over 35 years of experience in material compatibility, sterilization science, validation approaches and cycle optimization, and we will work with you to make sure your unique sterilization requirements are being met.

As we remain committed to our purpose of protecting the vulnerable, let us know how we can help you provide greater control in your sterility program.

Gary M. Owens

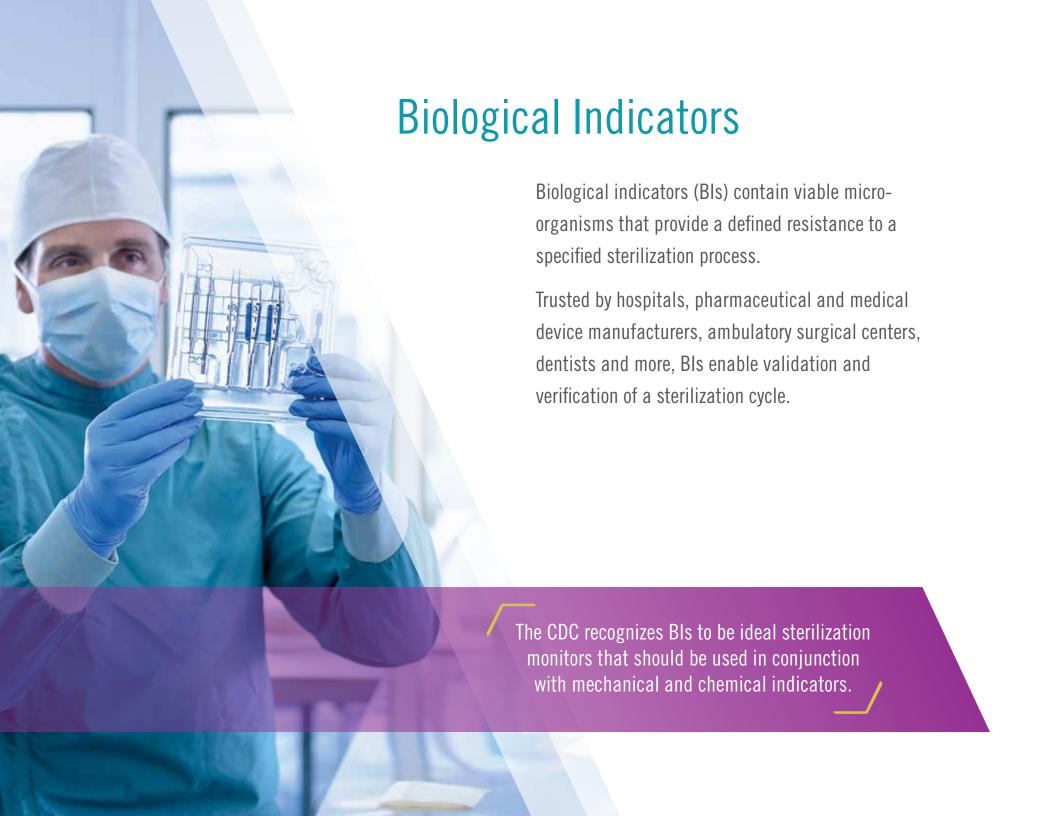
President and CEO

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### **Dry Heat Sterilization**

One of the earliest forms of sterilization practiced, dry heat sterilization is accomplished by conduction, where heat is absorbed by the exterior surface and passed inward to the next layer. Dry heat sterilization is ideal for heat-stable items such as glass, stainless steel, nonaqueous liquids, powders, etc. The essential cell components are destroyed and the organism is killed by oxidizing molecules.



#### **CHEMICAL INDICATORS - DRY HEAT**

Classification: Dry Heat - Type 4

Item	Part Number	Packaging
DryChecks Strips	DRY CHECKS STRIPS	250/bag
Indicator Labels (Dry Heat) 510(k) Cleared at 160°C	CI-DHI	1,000/roll

#### **INDUSTRIAL USE BIS AND CULTURE MEDIA**

Population: 10<sup>6</sup> • ATCC Number 9372

Item	Part Number	Packaging
Cotton Thread: 19mm x 1.5mm B. Atrophaeus	1-6100TT	100/package in Tyvek/Mylar
Paper Discs: 6mm	1-10006mm	1000/bulk
B. Atrophaeus	1-61006mm	100/package

#### **DRIAMP CULTURING KIT**

Population: 10<sup>6</sup> • ATCC Number 9372

Item // / / /	Part Number	Packaging
DriAmp Biological Indicator Culturing Set	DH/50	Box of 50 DriAmp Ampoules with 50 Releasat® Media Tubes

#### **DRIAMP CULTURING MEDIA**

Item	Part Number	Packaging
Releasat® Media with Phenol Red for EtO/Dry Heat/ClO <sub>2</sub> 3.6ml Fill Volume in 16mm x 100mm Tubes	RG/100	100/box



### **Dry Heat Sterilization**

#### **MESASTRIPS**

A MESAStrip contains bacterial spores on a paper carrier sealed within a convenient, peel-open envelope.

Population: 10<sup>6</sup> • ATCC Number 9372

Dimensions: Strip 0.25in x 1.0in, glassine envelope 1.03in x 3.0in

Item	Part Number	Packaging
B. Atrophaeus	SGMG/6	100/bag

#### **MICRO STRIPS**

Micro Strips can be used in areas where other BIs are too large.

Population: 10<sup>6</sup> • ATCC Number 9372

Item	Part Number	Packaging
1mm x 25mm	A1X25/6	100/package, bulk
B. Atrophaeus	A1X25/6G	In Glassine, 100/package
2mm x 10mm	A2X10/6	100/package, bulk
B. Atrophaeus	A2X10/6G	In Glassine, 100/package



Custom Bls are also available. Contact Customer Service for more information.

#### **SPORE STRIPS**

The Spore Strip is inoculated with bacterial spores on a paper carrier sealed within a convenient, peel-open glassine envelope.

Dimensions: Strip 1.5in x 0.25in, glassine envelope 1.03in x 3.0in

Item	Part Number	Packaging	Population	ATCC Number
	1-6100	100/bag		
B. Atrophaeus	1-6500	500/bag	106	9372
	1-1000	1000/bag		
Spore Strip Combined: Test B. Atrophaeus & G. Stearothermophilus	5-1000T	1000/bag		
Spore Strip Combined: Control B. atrophaeus & G. Stearothermophilus	5-1000C	1000/bag	106 / 105	9372 & 7953
Spore Strip Combined B. Atrophaeus & G. Stearothermophilus	5-5100	100/bag		



#### **SPORE SUSPENSIONS**

Mesa Labs' Bacillus Atrophaeus Spore Suspensions are calibrated suspensions of bacterial spores appropriate for direct inoculation of products or preparing custom BIs for monitoring dry heat and EtO sterilization processes.

ATCC Number 9372 • Diluent: 40% Ethanol • Package Configuration: 10 ml vial

Item	Part Number	Population	
	SSGE/4	10 <sup>4</sup> / 0.1 ml	
	SSGE/5	10 <sup>5</sup> / 0.1 ml	©MesaLabs
Bacillus Atrophaeus	SSGE/6	10 <sup>6</sup> / 0.1 ml	Retrieve Lineaglacturing Facility Di Brintpace Desig
	SSGE/7	10 <sup>7</sup> / 0.1 ml	Britanias, MT 59715 Britalian atrophicas 9572
	SSGE/8	10 <sup>8</sup> /0.1 ml	For Laboratory Co (bit) Not for Drug Un  STORE IN PRESERT THAN 1812 OF COSTON THAN 1812 OF COSTON THAN 1812 OF COSTON TO COSTO



### Ethylene Oxide (EtO) / Gas Sterilization

EtO sterilization is one of the most common sterilization methods for medical device manufacturing including specialty device kits used for surgical procedures. The chemical process consists of four primary variables: gas concentration, humidity, temperature, and time. EtO is an alkylating agent that disrupts the DNA of microorganisms, which prevents them from reproducing.



#### **EZTEST**

EZTest is a self-contained BI that contains bacterial spores on a paper carrier, packaged within a small, thermoplastic culture tube with a sealed-glass ampoule. The specially-formulated soybean casein digest culture medium contains a color indicator, which turns a dramatic yellow when spores grow. Visual results within 24 hours (steam or  $\rm H_2O_2$ ) or 48 hours (EtO).

Population: 10<sup>6</sup> • ATCC Number 9372

Item		Part Number	Packaging
B. Atrophaeus	EZG/6	100/box	
510(k) Cleared		EZG/625	25/box

#### **INDUSTRIAL USE BIS**

Population: 10<sup>6</sup> • ATCC Number 9372

Item	Part Number	Packaging
Cotton Thread: 19mm x 1.5mm B. Atrophaeus	1-6100TT	100/package in Tyvek/ Mylar
Paper Discs: 6mm	1-10006mm	1000/bulk
B. Atrophaeus	1-61006mm	100/package

#### **MESASTRIPS**

MESAStrip contains bacterial spores on a paper carrier sealed within a convenient, peel-open envelope.

Dimensions: Strip 1.0in x 0.25in, glassine envelope 1.03in x 3.0in. Population:  $10^6 \bullet ATCC$  Number 9372

Item \ / / \ / /	Part Number	Packaging
MESAStrip for EtO/Dry Heat B. Atrophaeus	SGMG/6	100/bag



#### **MEDIA AND KITS**

Item	Part Number	Population	ATCC Number	Packaging
Releasat® Biological Indicator Culturing Set for EtO	RG/100	106	9372	Box of 100 MESAStrips with 100 Releasat Media Tubes
Releasat® Media with Phenol Red for EtO/Dry Heat/ClO <sub>2</sub> 3.6ml Fill Volume in 16mm x 100mm Tubes	RM/100	N/A	N/A	100/box
Tryptic Soy Broth with Bromocresol Purple 16mm Tubes	TSB-BP16	N/A	N/A	100/box

#### **MICRO STRIPS**

At 2mm x 10mm or 1mm x 25mm, Micro Strips can be used in areas where other BI's are too large.

Population: 10<sup>6</sup> • ATCC Number 9372

Item	Part Number	Packaging
Micro Strips: 1mm x 25mm B. Atrophaeus	A1X25/6	100/package, bulk
	A1X25/6G	In glassine, 100/package
Micro Strips: 2mm x 10mm	A2X10/6	100/package, bulk
B. Atrophaeus	A2X10/6G	In glassine, 100/package



Consistent and proper use of BIs help prevent healthcare-aquired infections. Mesa's accredited third-party lab can augment or fully support your sterility program.



#### **SPORE STRIPS**

The Spore Strip is inoculated with bacterial spores on a paper carrier sealed within a convenient, peel-open envelope. Dimensions: Strip 0.25in x 1.5in, glassine envelope 1.03in x 3.0in.

Item	Part Number	Population	ATCC Number	Packaging
	1-6100	106	9372	100/bag
B. Atrophaeus	1-6500	106	9372	500/bag
	1-1000	106	9372	1000/bag
Spore Strip Combined: Test B. Atrophaeus & G. Stearothermophilus	5-1000T	106 / 105	9372 & 7953	1000/bag
Spore Strip Combined: Control B. Atrophaeus & G. Stearothermophilus	5-1000C	106 / 105	9372 & 7953	1000/bag
Spore Strip Combined B. Atrophaeus & G. Stearothermophilus	5-5100	106 / 105	9372 & 7953	100/bag



#### **SPORE SUSPENSION - BACILLUS ATROPHAEUS**

Mesa's Bacillus Atrophaeus Spore Suspensions are calibrated suspensions of bacterial spores appropriate for direct inoculation of products or preparing custom BIs for monitoring dry heat and EtO sterilization processes.

Package Configuration: 10 ml Vial ATCC Number 9372 • Diluent: 40% Ethanol

Part Number	Population	No.
SSGE/4	10 <sup>4</sup> / 0.1 ml	MesaLabs
SSGE/5	10 <sup>5</sup> / 0.1 ml	Beessum Manufacturing Facility 10 Evergroom Drive
SSGE/6	10 <sup>6</sup> /0.1 ml	Bozeman, MT 59715  Bacillus atrophaese
SSGE/7	10 <sup>7</sup> / 0.1 ml	For Laboratory Use Oah
SSGE/8	10 <sup>8</sup> / 0.1 ml	Not for Drug Use STORE IN FREEZER MULE WELL REPORE USING MPDCLAYE REPORE DISPOSAL

### Process Challenge Devices (PCDs)

Mesa PCD® Technology products consist of commercial spore strips, discs or self-contained BIs in a proprietary EtO barrier pouch. For greater efficiency, PCDs packaged with self-contained biological indicators, enable you to see the results, without waiting for multi-day incubation periods or sending the indicator to the lab for results.

#### **BARE BI PCDS**

Part Number	BI Manufacturer	BI Type	Packaging
PCD 0.6	211	Attest™ Self-Contained BI	300/package
PCD 09	- 3M	Attest Rapid Readout BI	300/package
1-10006mm		BI Disc, 1-10006mm	1000/package
1-61006mm	MESA	BI Disc, 1-10006mm	100/package
EZG/6		EZTest Self-Contained BI	100/package
PCD 0.7	Steris	Spore Strip in Glassine	500/package

To learn more about Mesa PCD® Technology, download the PCD Selection Guide at info.mesalabs.com/PCDselect



### **EtO Sterlization**

#### STANDARD PCDS

Packaging: 100

Part Number	BI Manufacturer	Description	Nominal D-Value
Type 3 - Least	Resistance		
PCD 3.13	MESA	EZTest Self-Contained BI	3
PCD 3.2	Steris	Spore Strip without Glassine	3
PCD 3.5	MESA	Spore Strip in Glassine	4
PCD 3.6	3M	Attest Self-Contained BI	5
PCD 3.9	3M	Attest Rapid Readout BI	5
Type 5 - Low I	Resistance		
PCD 5.1	MESA	BI Disc, 1-10006mm	4
PCD 5.13	MESA	EZTest Self-Contained BI	13
PCD 5.2	Steris	Spore Strip without Glassine	4
PCD 5.5	MESA	Spore Strip in Glassine	6
PCD 5.62	3M	Attest Self-Contained BI	13
PCD 5.92	3M	Attest Rapid Readout BI	13
Type 4 - Medi	um Resistance		
PCD 4.1	MESA	BI Disc, 1-10006mm	21
PCD 4.13	MESA	EZTest Self-Contained BI	50
PCD 4.19	MESA	Mini Spore Strip in Glassine	32
PCD 4.2	Steris	Spore Strip without Glassine	21
PCD 4.5	MESA	Spore Strip in Glassine	32 / \ /
PCD 4.6	3M	Attest Self-Contained BI	50
PCD 4.7	Steris	Spore Strip in Glassine	32 / \
PCD 4.9	3M	Attest Rapid Readout BI	50

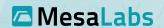


#### **STANDARD PCDS**

Packaging: 100

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Part Number	BI Manufacturer	Description	Nominal D-Value
Type 6 - Medi	um Resistance		
PCD 6.1	MESA	BI Disc, 1-10006mm	12
PCD 6.13	MESA	EZTest Self-Contained BI	35
PCD 6.2	Steris	Spore Strip without Glassine	12
PCD 6.5	MESA	Spore Strip in Glassine	17
PCD 6.6	3M	Attest Self-Contained BI	35
PCD 6.7	Steris	Spore Strip in Glassine	17
PCD 6.9	3M	Attest Rapid Readout BI	35
Type 7 - Medi	um Resistance		
PCD 7.1	MESA	BI Disc, 1-10006mm	9
PCD 7.13	MESA	EZTest Self-Contained BI	26
PCD 7.2	Steris	Spore Strip without Glassine	9
PCD 7.5	MESA	Spore Strip in Glassine	14
PCD 7.6	3M	Attest Self-Contained BI	26
PCD 7.7	Steris	Spore Strip in Glassine	14
PCD 7.9	3M	Attest Rapid Readout BI	26
Type 2 - Most	Resistance		<u> </u>
PCD 2.1	MESA	BI Disc, 1-10006mm	28
PCD 2.12	MESA	Spore Strip without Glassine	28
PCD 2.13	MESA	EZTest Self-Contained BI	58
PCD 2.2	Steris	Spore Strip without Glassine	28
PCD 2.5	MESA	Spore Strip in Glassine	37
PCD 2.6	3M	Attest Self-Contained BI	58
PCD 2.7	Steris	Spore Strip in Glassine	37
PCD 2.9	3M	Attest Rapid Readout BI	58
			·/·/ /





### **Specialty Sterilization Processes**

Mesa offers BIs for specialty sterilization processes, including chlorine dioxide (ClO<sub>2</sub>), gamma irradiation and hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>).



### Chlorine Dioxide (CIO<sub>2</sub>) Sterilization

Chlorine dioxide, known for producing less harmful byproducts than chlorine, is commonly used as a sterilizer, oxidizer or disinfectant. It efficiently kills pathogenic microorganisms and spore-forming bacteria but also prevents and removes bio film.

#### **MEDIA**

Item	Part Number	Packaging	/ \
Releasat® Media with Phenol Red for			
EtO/Dry Heat/ClO <sub>2</sub> 3.6ml Fill Volume in	RM/100	10 <sup>4</sup> / 0.1 ml	
16mm x 100mm Tubes			

#### **MESASTRIP**

MesaStrip contains bacterial spores on a filter paper carrier sealed within a convenient, peel-open envelope.

Dimensions: Strip 0.25in x 1.0in, glassine envelope 1.03in x 3.0in. Population: 10<sup>6</sup> • ATCC Number 9372

Item	Part Number	Packaging
B. Atrophaeus - in Tyvek/Mylar	ACD/6	100/bag

### Gamma Irradiation Sterilization

Exposing products to a Cobalt 60 radiation field. gamma irradiation is known for its quick turnaround times, easy penetration of packaging and is ideal for many types of materials.



#### **INDUSTRIAL USE BIS**

Item	Part Number	Population	ATCC Number	Packaging
Chairless Charl Disa Zana D. D. Danilles	DPSSC/3	$10^{3}$	27142	100/package in clear plastic
Stainless Steel Disc: 7mm - B. Pumilus	DPSS/6C	106	27143	100/package in clear plastic

#### **MESASTRIP**

MesaStrip contains bacterial spores on a filter paper carrier sealed within a convenient, peel-open envelope.

Dimensions: Strip 1.0in x 0.25in, glassine envelope 1.03in x 3.0in.

ATCC Number: 27142

Item	Part Number	Population	Packaging
B. Pumilis	SGMR/6	106	100/bag
	SGMR/7	107	100/bag

### Ozone (O<sub>3</sub>) Sterilization

#### **SPORE STRIPS**

		///	<u> </u>	
Item	Part Number	Population	ATCC Number	Packaging
Bacillus Subtilis Spore Strip in Tyvek envelopes	AOZ/3T	$10^{3}$	35021	100/package
Desillus Atrophosus Chara Chrin in Tinch annalance	OZA/4T	104	9372	100/package
Bacillus Atropheaus Spore Strip in Tyvek envelopes	AOZ/6T	106	9372	100/package



### Hydrogen Peroxide (H<sub>2</sub>O<sub>2</sub>) Sterilization

#### **APEX**

APEX BI products are designed specifically for the pharmaceutical, food and medical device industries, utilizing  $H_2O_2$  vapor sterilization. The stainless steel carrier is used in multiple processes including isolator and filling line applications.

Item	Part Number	Population	ATCC Number	Packaging
Stainless Steel Discs in Tyvek/Tyvek	GRS-090E3	103	9372	100/package
B. Atrophaeus - 9mm Diameter.	GRS-090	106	9372	100/package
	HMV-091E3	103	12980	100/package
Stainless Steel Discs in Tyvek/Tyvek G. Stearothermophilus - 9mm Diameter.	KCD-404	104	12980	100/package
a. c.ca. ccpac	HMV-091	106	12980	100/package
Bare Metal BI Stainless Steel Ribbon G. Stearothermophilus - 6mm x 80mm.	SBC-327	106	12980	100/package
Tri-Scale BI; Tyvek Package BI with 10 <sup>4</sup> , 10 <sup>5</sup> and 10 <sup>6</sup> Stainless Steel Carriers G. Stearothermophilus - 9mm Diameter.	LOG-456	10 <sup>4</sup> , 10 <sup>5</sup> , 10 <sup>6</sup>	12980	50/package
Stainless Steel Discs in Tyvek/Tyvek	NAS-152E3	103	7953	100/package
G. Stearothermophilus - 9mm Diameter.	NAS-152	106	7953	100/package
Sterile Tyvek Transfer Pockets for SBC-327	BMWK-750	N/A	N/A	100/package
Spore Suspension for Gaseous Hydrogen	LAU-196	10 <sup>7</sup> / 0.1 ml	12980	10 ml vial
Peroxide - G. Stearothermophilus	LPT-606	10 <sup>7</sup> / 0.1 ml	7953	10 ml vial
Releasat Purple Media, for Use with G. Stearothermophilus Products 3.6ml Fill Volume in 16mm x 100mm Tubes	PM/100	N/A	N/A	100 units



**EZTest** 

### STERRAD® H<sub>2</sub>O<sub>2</sub>

The STERRAD $^{\circ}$ H $_2$ O $_2$  sterilization cycle is a low-temperature process that uses hydrogen peroxide gas plasma technology for sterilization. The process provides gentle sterilization for delicate instruments in about an hour or less. Temperatures do not exceed 50 $^{\circ}$ C, and sterilization occurs in a low moisture environment.



#### **EXPOSURE™**

ExpoSure is a BI intended for use in the STERRAD Sterilizer. ExpoSure has received its 510(k) clearance making it suitable for healthcare and non-healthcare settings. Its 24-hour incubation time and flexibility make it a powerful tool to help your facility maintain compliance and patient safety. ExpoSure can be used in conjunction with existing incubators (55-60°C).

Population: 10<sup>6</sup> • ATCC Number 7953

Item	Part Number	Packaging
G. Stearothermophilus 510(k) Cleared	EXPO/6	30 indicators per box; 1 crusher

#### **EZTEST**

EZTest is a self-contained BI that contains bacterial spores on a paper carrier, packaged within a small, thermoplastic culture tube with a sealed-glass ampoule, specially-formulated soybean casein digest culture medium containing a color indicator, which turns a dramatic yellow when spores grow. Visual results within 24 hours (steam or H<sub>2</sub>O<sub>2</sub>) or 48 hours (EtO).

ATCC Number 7953 • Packaging: 100/box

	<del>\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ </del>	$ \rightarrow$ $\rightarrow$ $\rightarrow$ $\rightarrow$	Geobacillus M
Item	Part Number	Population	Lot HZ
C Staaratharmanhilus	EZH/5	105	Exp. 20
G. Stearothermophilus	EZH/6	-10 <sup>6</sup>	

#### MESA PCD TECHNOLOGY

PCD patented products nominally consist of any commercial BI strip, disc or self-contained BI in a proprietary  $H_2O_2$  barrier pouch.

Nominal D-Value: N/A • Available in quantities of 100

BI Type	Part Number	BI Manufacturer
EZTest EZH/6	PCD 8.13	MESA



### **Steam Sterilization**

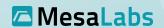
Steam is the most common sterilization method due to its nontoxic, inexpensive and sporicidal process properties. Sterilization is achieved by exposing products to saturated steam at high temperatures (from 121 to 135°C) at a required pressure for a specified amount of time. Saturated steam is a biphasic mixture of  $H_2O$  in gas and liquid phases in thermal equilibrium.

Because of the high heat involved in steam sterilization, it is not appropriate for all materials.



Looking for a custom solution? See page 26 for our custom services and capabilities.





### Liquid Loads

The sterilization of liquids is very different from a porous/hard load, as air removal is not critical. Sterilization is dependent upon steam contacting the container which houses the liquid product, therefore relying on the water inside of the product to create a steam environment within the container where the BI should be placed.

#### **AMPOULES FOR STERILIZATION OF LIQUID LOADS**

ProSpore Ampoule, MagnaAmp and SterilAmp II liquid submersible self-contained BIs and are ideal for validating the steam sterilization of liquid loads. Simply expose the unit to the sterilization process and incubate afterwards. These indicators are validated for 48-hour reduced incubation. However, SterilAmp II 5230 (Part# SASU/6) is validated for 72-hour incubation. Liquid Ampoules are refrigerated and require overnight shipping. See the Accessories page for ProSpore and MagnaAmp incubators.

Item	Part Number	Population	ATCC Number	Packaging
	PS-4-10	104	7953	10/box
	PS-4-50	104	7953	50/box
4 ml ProSpore - 510(k) Cleared 14.75mm x 52mm	PS-5-10	105	7953	10/box
117611111 X 6211111	PS-5-50	105	7953	50/box
	PS-6-50	106	7953	50/box
MagnaAmp - G. Stearothermophilus 10.6mm x 52mm	MA/4	104	7953	50/box plus 10 negative controls
	MA/5	105	7953	50/box plus 10 negative controls
	MA/6	10 <sup>6</sup>	7953	50/box plus 10 negative controls
	SA/4	104	7953	100/bag plus 10 negative controls
SterilAmp II - G. Stearothermophilus 6.75mm x 26.5mm	SA/5	105	7953	100/bag plus 10 negative controls
6.7611117 × 26.511111	SA/6	106	7953	100/bag plus 10 negative controls
0. 14 1. 0.01 1. 10	SA18/5	105	7953	100/bag plus 50 negative controls
SterilAmp II - G. Stearothermophilus 18mm	SA18/6	106	7953	100/bag plus 10 negative controls
SterilAmp II 5230 - B. Subtilis "5230" Low Temp (110°C-118°C) 6.75mm x 26.5mm	SASU/6	106	35021	100/bag plus 50 negative controls



#### **SPORE SUSPENSIONS**

Mesa Spore Suspensions are calibrated suspensions of bacterial spores appropriate for direct inoculation of products or preparing custom BIs for monitoring steam, EtO, dry heat,  $H_2O_2$ , irradiation and other industrial sterilization processes.

Packaging: 10 ml vial

Item	Part Number	Population	ATCC Number	Diluent
	SS5230E/4	10 <sup>4</sup> / 0.1 ml	35021	40% Ethanol
	SS5230E/5	10 <sup>5</sup> / 0.1 ml	35021	40% Ethanol
D:!! (C.)-!! "F020"	SS5230E/6	10 <sup>6</sup> /0.1 ml	35021	40% Ethanol
Bacillus Subtilus "5230"	SS5230E/7	10 <sup>7</sup> / 0.1 ml	35021	40% Ethanol
	SS5230A/7	10 <sup>7</sup> / 0.1 ml	35021	Aqueous
	SS5230E/8	10 <sup>8</sup> /0.1 ml	35021	40% Ethanol
	SSSE/4	10 <sup>4</sup> / 0.1 ml	7953	40% Ethanol
	SSSE/5	10 <sup>5</sup> / 0.1 ml	7953	40% Ethanol
Geobacillus Stearothermophilus	SSSE/6	10 <sup>6</sup> / 0.1 ml	7953	40% Ethanol
	SSSE/7	10 <sup>7</sup> / 0.1 ml	7953	40% Ethanol
	SSSA/7	10 <sup>7</sup> / 0.1 ml	7953	Aqueous
	SSCS7955/4	104	7955	40% Ethanol
	SSCS7955/5	105	7955	40% Ethanol
	SSCS7955/6	106	7955	40% Ethanol
	SSCS7955/7	107	7955	40% Ethanol
	SSCS11437/4	104	11437	40% Ethanol
Olastoidi vas Casanasa	SSCS11437/5	105	11437	40% Ethanol
Clostridium Sporogenes	SSCS11437/6	106	11437	40% Ethanol
	SSCS11437/7	107	11437	40% Ethanol
	SSCS19404/4	104	19404	40% Ethanol
	SSCS19404/5	105	19404	40% Ethanol
	SSCS19404/6	106	19404	40% Ethanol
	SSCS19404/7	-10 <sup>7</sup>	19404	40% Ethanol

### Porous/Hard Objects

A porous/hard load refers to the items being sterilized (dry items). These items may be glassware, surgical instruments, syringes, tubing, fabrics, etc.

#### CHEMICAL INDICATORS AND BOWIE-DICK

Item	Part Number	Classification	Packaging
ProChem BD Air Removal Test Pack	CI-BDTLF	Steam - 510(k) Cleared for 3.5 min at 132°C	4 boxes/case (80 packs)
Prochem BD Air Removal Test Pack	CI-BDTLF20	Steam - 510(k) Cleared for 3.5 min at 132°C	20 packs/bo
Bowie-Dick Green Card Test	BD 134	Steam - Type 2	30/pack
AutoCheck Kit II Bowie-Dick Test Pack	CI-AUTOCHECK-KIT-II	Steam - Type 2	30/pack
Bowie-Dick Check II Lead Free Test Pack	CI-BD-CHECK-II	Steam - Type 2	20/pack
Bowie Dick Green Card Test	CI-Greencardt	Steam (pre-vacuum) Type 2	15/pack
Blackcheck Multicritical Process Variable Indicator Strips	CI-BLACKCHECK-C	Steam - Type 4	250/bag
Steri Vapeur 18 Emulating Chemical Integrator	CI-STERIVAPEUR-18	Steam (pre-vacuum) Type 4 & 6 Emulating	250/bag
ProChem SSW Moving Front Integrating Indicator	CI-SSW	Steam - Type 5 Integrating 510(k) Cleared	250/box
Integraph Integrating Chemical Indicator	CI-INTEGRAPH	Steam (pre-vacuum) Type 5 Integrating	250/bag
Chemostrip Emulating Chemcial Indicator	CI-CHEMOSTRIP 134°C/121°C	Steam (pre-vacuum) Type 6 Emulating	250/bag
Bowie Dick Green Card Holder	BD 134 TH	N/A	1 —
			<del>* /                                   </del>



Lead Free Indicator Ink

CONTENTS: 1 TEST

### **Steam Sterilization**

#### **EZTEST**

EZTest is a self-contained BI that contains bacterial spores on a paper carrier, packaged within a small, thermoplastic culture tube with a sealed-glass ampoule, specially-formulated soybean casein digest culture medium containing a color indicator, which turns a dramatic yellow when spores grow. Visual results within 24 hours (steam or H<sub>2</sub>O<sub>2</sub>) or 48 hours (EtO).

#### ATCC Number 7953

Item	Part Number	Population	Packaging
G. Stearothermophilus - 510(k) Cleared	EZS/5	105	100/box
	EZS/525	105	25/box
	EZS/6	106	100/box
	EZS/625	106	25/box
Test Pack G. Stearothermophilus - 510(k) Cleared	STP/25	105	25 test packs/case with 25 controls

#### **INDUSTRIAL USE BIS**

ATCC Number 7953 • Population: 106

Item	Part Number	Population	Packaging
Paper Discs: 6mm G. Stearothermophilus	DS6R/6	106	100/bulk

#### **MEDIA**

Item	Part Number	Packaging
Releasat® Media with Bromocresol Purple for Steam 3.6ml Fill Volume in 16mm x 100mm Tubes	PM/100	100/box
Tryptic Soy Broth with Bromocresol Purple 16mm Tubes	TSB-BP16	100/box





#### **MESASTRIPS**

MESAStrip contains bacterial spores on a paper carrier sealed within a convenient, glassine envelope. Dimensions: Strip 0.25in x 1.0in, glassine envelope 1.03in x 3.0in. • Packaging: 100/bag

Item	Part Number	ATTC Number	Population
	SGMS/3	7953	10 <sup>3</sup>
G. Stearothermophilus	SGMS/5	7953	105
	SGMS/6	7953	10 <sup>6</sup>
B. Subtilis (5230)	SGMSU/6	35021	10 <sup>6</sup>



Micro Strips can be used in areas where other BIs are too large.

Population: 10<sup>6</sup>

Item	Part Number	ATCC Number	Packaging
1mm x 25mm G. Stearothermophilus	S1X25/6	7953	100/package, bulk
	S1X25/6G	7953	In glassine, 100/package
2mm x 10mm G. Stearothermophilus	S2X10/6	7953	100/package, bulk
	S2X10/6G	7953	In glassine, 100/package
1mm x 25mm B. Subtilis "5230"	SU1X25/6	35021	100/package, bulk
	SU1X25/6G	35021	In glassine, 100/package

#### **PROLINE PCD**

ProLine is a process challenge device (PCD) for use in the validation or monitoring of sterilization cycles of tubing ranging from 3.2mm to 15.8mm ID. ProLine contains a paper disc inoculated with bacterial spores of G. Stearothermophilus for steam.

ATCC Number 7953 • Population: 106

Item	Part Number	Packaging
Geobacillus Stearothermophilus	PL-3-6-15	15/box







#### **SMART-READ EZTEST - FDA 510(K) CLEARED**

The Smart-Read® EZTest® Biological Monitoring System allows an organization to release sterile product with true biological confirmation faster and easier than ever before. This unique system uses a real BI – with no added enzyme or chemical integrator – which is incubated, evaluated and documented in one simple, automated operation. Relying only upon bacterial spore growth, the Smart-Read system can detect sterilization failure in as few as three to five hours, and negative results can be confirmed with ten hours of incubation.

#### ATCC Number 7953

Item	Part Number	Population	Packaging
G. Stearothermophilus	SEZS/5		100 count
G. Stearothermophilus	SEZS/525	105	25 count
Smart-Read EZTest Steam Test Pack	SRSP/25		25 test packs/case with 25 controls
G. Stearothermophilus	SEZS/6		100 count
G. Stearothermophilus	SEZS/625	106	25 count
Smart-Read EZTest Steam Test Pack	SRSP6/25		25 test packs/case with 25 controls

<sup>\*</sup>See Smart-Well Incubator Kits in the Accessories section

#### **SPORE STRIPS**

The Spore Strip is inoculated with bacterial spores on a paper carrier sealed within a convenient, peel-open glassine envelope. When Tryptic Soy Broth media (part number TSB-BP16) is used with these Spore Strips and incubated at 60°C +/-2°C, then there is a reduction in incubation time of 24 hrs. If incubated at 55-60°C and/or with regular TSB, then it must be incubated for 7 days.

Dimensions: Strip 0.25in x 1.0in, glassine envelope 1.03in x 3.0in.

Item	Part Number	Population	ATCC Number	Packaging
Spore Strip Combined: B. Atrophaeus & G. Stearothermophilus	5-5100	106/105	9372 & 7953	100/bag
Spore Strip Combined: Test	5-1000T	106/105	9372 & 7953	1,000/bag
B. Atrophaeus & G. Stearothermophilus	5-1000C	106/105	9372 & 7953	1,000/bag
G. Stearothermophilus	3-5100	105	7953	100/bag
	3-1000	105	7953	1,000/bag
	3-6100	106	7953	100/bag
Nylon Vacustat Clip	79-03150	N/A	N/A	







More accessories can be found at mesalabs.com

#### **INCUBATORS**

Item	Part Number	Packaging
Incubator for MagnaAmp	11510	15 cavity
Incubator for ProSpore	11480	11 cavity
Adjustable SCBI Incubator for EZTest	11410	13 cavity

#### **SMART-READ INCUBATOR KITS**

Item	Part Number	Packaging
Smart-Well Incubator Kit (Australian Power)	SWI1710-4	
Smart-Well Incubator Kit (European Power)	SWI1710-3	Includes Incubator,
Smart-Well Incubator Kit (U.K. Power)	SWI1710-5	Printer, Manual & ———————————————————————————————————
Smart-Well Incubator Kit (U.S. Power)	SWI1710-1	/\ \/ /\ \

#### **POPULATION ASSAY KIT**

Item	Part Number	Packaging
Population Assay Glassware and Pipettes Only	PAK-G	Four 19.5mm x 145mm Sterile, flat bottom glass tubes with beads and cap; twelve 16mm x 125mm, sterile borosilicate dilution blank pipettes; two 5 ml pipettes; eight 2 ml pipettes, and eight 1 ml pipettes
Media Only - 240 ml	PAK-M	TSA only



### **Services**

Mesa Labs offers D-value or Survival/Kill testing in state-of-the-art BIER Vessels. The D-value procedures used follow USP/ISO and can be obtained via Limited Holcomb Spearman Karber (fraction negative) method, Survivor Curve (direct enumeration) or with Stumbo-Murphy-Cochran. Mesa can inoculate and perform D-value analysis on small items (e.g. coupons or stoppers), or we can verify a competitor's label claim for D-value, Z-value and population. Isolate identification services available for most aerobic samples.

#### **POPULATION ANALYSIS**

#### **Population Verification Testing**

Confirmation of labeled population on the Certificate of Analysis. Testing involves assaying four unexposed biological indicators individually per manufacturer or Mesa Lab procedures in adherence with ISO standards.

#### **Individual Assays**

Population enumeration on individual exposed or unexposed biological indicators. Testing conducted per manufacture or Mesa Lab procedures.

#### **Pooled Assays**

Population enumeration on four, pooled, custom-inoculated components and confirmation of labeled population on the Certificate of Analysis for MagnaAmp, SterilAmp and ProSpore 4mL Bls. Testing performed according to Mesa Lab procedures.

#### **MAIL-IN SPORE TESTING**

Our Mail-In Spore Testing services are available for steam, chemical vapor, dry heat and EtO sterilization cycles. Our service includes prompt notification on all failed tests and email test results upon completion in our laboratory. We perform a Gram-staining verification on all failed tests. Each test includes a matching control strip.

Weekley	Bi-Weekly	Monthly	Quarterly	
52 tests	26 tests	12 tests	4 tests	

#### **CUSTOM SOLUTIONS**

Custom filled ampoules	\/
Dry Heat D-value on a commercially prepared BI	
EtO D-value on a commercially prepared BI	\
Inoculation of client provided carrier or solution	
Organism Identification 16S rRNA	
Population analysis of a commercially prepared BI	
Steam D-value on a commercially prepared BI	\ /_

#### SURVIVAL/KILL TESTING

Processes	\	/\	\ /	/\	\ /
DryHeat Sterilization					
EtO Sterilization					
Steam Sterilization					

#### **D-VALUE TESTING**

Process	Testing / / / / /
Dry Heat	D-value - Survivor Curve or Spearman/Karber
EtO	D-value - Survivor Curve or Spearman/Karber
Steam	D-value - Survivor Curve or Spearman/Karber





At Mesa, we fulfill our purpose by providing innovative, reliable monitoring and quality assurance products and services. With over 35 years of experience in material compatibility, sterilization science, validation approaches and cycle optimization, we help ensure the safety and efficacy of your products.

### Why Mesa?

- » Technical expertise in consultative services
- » FDA-registered facility, which is ISO 13485:2016 certified.
- » Performance testing, standards development, AAMI and PDA members



### For product or ordering information:

biologicalindicators.mesalabs.com • bicustomerservice@mesalabs.com ph: 406.585.9535 or 877.746.8883 • fx: 406.585.9219

Sterilization and Disinfection Control Manufacturing: 625 Zoot Way, Bozeman, MT 59718 Corporate Headquarters: 12100 West 6th Avenue Lakewood, CO 80228 ph: 800.992.6372 • 303.987.8000 • fx: 303.987.8989

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