

## PRODUCT CHANGE NOTIFICATION

19Jun2019

**Notification ID:** CN-190508

**Notification Type:** Product Testing Change

Dear Customer,

We would like to take this opportunity to notify you of a testing change that has been made to the following Mesa catalog items.

- SGMSU/6

### Testing Change

Historically Mesa performed USP calculated survival and kill testing on SGMSU/6 as a means to confirm the D-value. Due to the wide fractional zone for Mesa's *Bacillus subtilis* '5230' spores on paper carriers the USP calculated survival / kill test is not an appropriate method for confirming D-value. Beginning with lot B5230-160 Mesa will no longer perform USP calculated survival and kill testing.

To support this change Mesa will be removing the USP calculated survival and kill times from the certificate for SGMSU/6 and replacing it with the empirically derived survival and kill times.

This change will also impact the following catalog numbers that listed a reference D-value established using the SGMSU/6 product configuration:

- SU1X25/6
- SU2X10/6

The two items listed above will no longer list the USP calculated survival and kill times on their respective certificates of analysis.

See Attachment 1 for examples of certificates with the changes.

As always, if you have any questions, please contact your Mesa Laboratories Representative.

  
Robert Bradley  
Sr. Director – Bozeman Operations

19 Jun 2019  
Date

  
Nicole Dewald  
Manager – Quality Assurance

19 Jun 2019  
Date

# Attachment 1

## MESASTRIP

BIOLOGICAL INDICATOR  
For Industrial Use Only

### CERTIFICATE OF ANALYSIS

Reorder No:	SGMSU-6		
Bacillus subtilis '5230'	35021 <sup>(1)</sup>		
Biological Indicator for:	Low Temperature Steam Sterilization		
Culture:	Soybean casein digest broth		
Lot No.:	B5230-000	Manufacture Date:	YYYY-MM-DD
Expiration Date:	YYYY-MM-DD		
Heat Shocked Population:	0.0 x 10 <sup>6</sup>	Spores / Unit	
Carrier Size:	1" x 1/2" (25 mm x 6 mm)		
Assayed Resistance:			
	D-Value <sup>(2)</sup>	Survival	Kill
Steam (115°C)	0.0	00.00 <sup>(3)</sup>	00.00 <sup>(3)</sup> min.
Steam (118°C)	0.0	0.0 <sup>(3)</sup>	0.0 <sup>(3)</sup> min.
Steam (121°C)	0.0	0.0 <sup>(3)</sup>	0.0 <sup>(3)</sup> min.
Z-value:	50.0°C		

Units are manufactured in compliance with Mesa Laboratories, Bozeman Manufacturing Facility's quality standards, USP and ISO 11133 guidelines and all appropriate subsections with the exception of determination of resistance characteristics by verification of the survive kill response characteristic. Empirical survive kill is reported instead.

<sup>(1)</sup> Culture is traceable to a recognized culture collection identified as USP and 153 11118  
<sup>(2)</sup> Resistance was determined in an AAMI B2-2 vessel using paper carrier packaged in glassine or nitrogen method. The D-value is reproducible only when exposed and cultured under the exact reported heat. Resistance will vary based upon the heat and carrier specific application.  
<sup>(3)</sup> Empirically derived data.

Certified By: \_\_\_\_\_  
Quality Assurance

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## MESASTRIP

Biological Indicators to demonstrate adequacy of sterilization.

### INSTRUCTIONS FOR USE

#### Sterilization:

- Place spore strips inside representative materials to be sterilized. Package or wrap as usual.
- Locate test packages in areas of sterilizer most difficult to sterilize. Identify test packages as to location in sterilizer.
- After sterilization, forward sufficient spore strips and products to nearby test laboratory along with at least one sterilized spore strip marked POSITIVE CONTROL.

#### Test Laboratory:

- Remove test packages from a clean, dust-free room and within confines of a laminar flow hood. All test packages must be handled with rigid aseptic techniques to avoid contamination.
  - Asseptically withdraw spore strips with sterile forceps and transfer to individual tubes containing sterile soybean casein digest broth. Identify tubes.
  - Incubate spore strips for 3 days at appropriate temperature:
    - Bacillus subtilis '5230' 30-35°C

Observe tubes daily for growth.  
 Turbid = growth = non-sterile  
 Clear = no growth = sterile

- Interpretation: If turbid growth is observed, sterilization has been achieved. If turbid and bacterial growth is observed on all strip cultures, it suggests that the spores have survived the sterilization process and are non-sterile.

#### Control:

- Control: One or more positive controls should be included in each test series. Transfer a non-sterilized spore strip to culture medium and incubate with test series. Turbidity and growth indicates that the medium possesses suitable growth promoting qualities and that the spore strips contain viable spores. If positive control does not grow, do not use units from that package. Contact Mesa Labs.
- Negative: One or two tubes of culture medium incubated with test series. Absence of growth indicates that the medium was sterile prior to sterility testing.

#### Storage and Disposal:

- Store MesaStrip biological indicators at room temperature.
- Do not store these indicators near solvents or other chemicals. Do not desiccate.
- MesaStrip biological indicators have a shelf life which is clearly designated on each package. Return your stock accordingly.

**NOTE:** Do not use after expiration date printed on package. Dispose of expired indicators by autoclaving at 121°C for not less than 30 minutes.

Rev. 4  
Part No. 7501

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Attachment 1

**MESASTRIP**

BIOLOGICAL INDICATOR

For Industrial Use Only

**CERTIFICATE OF ANALYSIS**

Recorder No.:	SU1X24 6
<i>Bacillus subtilis</i> "5230"	35021 <sup>(1)</sup>
Biological Indicator for:	Low Temperature Steam Sterilization
Culture:	Soybean casein digest broth
Lot No.:	B5130-000
Manufacture Date:	YYYY-MM-DD
Expiration Date:	YYYY-MM-DD
Heat Shocked Population:	0.0 x 10 <sup>6</sup> Spores / Unit
Carrier Size:	1 x 25 mm
Assayed Resistance:	
	D-Value <sup>(2)</sup>
Steam (115°C)	0.0 min.
Steam (118°C)	0.0 min.
Steam (121°C)	0.0 min.
Z-value:	00.0°C

Units are manufactured in compliance with Mesa Laboratories, Bozeman Manufacturing Facility's quality standards, USP and ISO 11138 guidelines and all appropriate sub-sections with the exception of determination of resistance characteristics by verification of the survival kill response characteristic.

<sup>(1)</sup> Culture is available in a prepackaged culture collection (dependent on LTP and ISO 11138)  
<sup>(2)</sup> Resistance was determined by an AATM 801 6' water using 10<sup>6</sup> spore strips packaged in plastic  
 function. Negative method. The D-value is reproducible only when exposed and cultured under the  
 results reported here. Resistance will vary based upon the end user's specific application.

Certified by: \_\_\_\_\_  
 Quality Representative

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**MESASTRIP**

Biological Indicators to demonstrate adequacy of sterilization.

**INSTRUCTIONS FOR USE**

- Sterilization:**
- Place spore strips inside representative materials to be sterilized. Package or wrap as usual.
  - Locate packages in areas of sterilizer most difficult to sterilize. Identify test packages as to location.
  - After sterilization, record sufficient spore strips and products to identify test laboratory along with at least one spore strip marked POSITIVE CONTROL.
- Test Lab:**
- A. Spore strip should be:**  
 1. Sterile. Must be conducted with rapid aseptic techniques to avoid "false positive" samples.  
 2. Procedure:  
 a. Aseptically withdraw spore strips with sterile forceps and transfer to individual tubes containing sterile soybean casein digest broth. Identify tubes.  
 b. Incubate spore strips seven days at appropriate temperature.  
*Bacillus subtilis* "5230" 30-35°C  
 Observe tubes daily for growth.  
 Turbid = growth = non-sterile  
 Clear = no growth = sterile
- 7. a.** Cultures should show no growth if sterilization has been achieved. If turbidity and bacterial growth are present in test strip cultures, it suggests that the spores have survived the sterilization process and are non-sterile.
- 7. b.** Positive: One or more positive controls should be included in each test series. Turbidity and growth indicates that the medium possesses suitable growth promoting qualities and that the spore strips contain viable spores. If positive control does not grow, do not use units from that package. Contact Mesa Labs.  
 Negative: One or two tubes of culture medium incubated with test series. Absence of growth indicates that the medium was sterile prior to sterility testing.
- Storage and Disposal:**
- Store MesaStrip biological indicators at room temperature.
  - Do not store these indicators near sterilants or other chemicals. Do not decontaminate.
  - MesaStrip biological indicators have a shelf life which is clearly designated on each package. Return your stock accordingly.
- NOTE:** Do not use after expiration date printed on package. Dispose of expired indicators by autoclaving at 121°C for not less than 10 minutes.

**LIMITS OF LIABILITY AND INDEMNITY:** In no event, whether as a result of breach of contract, warranty or tort (including negligence and strict liability) shall Mesa Labs or its suppliers be liable for any consequential or incidental damages, including, but not limited to, loss of profits or revenues, loss of use of the Products or any associated equipment, loss of the Buyer's Products, damage to associated equipment, cost of repair, cost of substitute products, business interruption or replacement parts. Damages paid, caused by each Product, or claims of the user for such damages. Buyer for itself its successors and assigns, and by agreement to indemnify Mesa Labs and to hold Mesa Labs harmless from any and all liability for such consequential or incidental damages. The responsibility of Mesa Labs for damages due to equities or employees of the Buyer or claims over of the Product, caused by the Product, shall be limited to repair or replacement of the item, at the option of Mesa Labs. The Buyer agrees to indemnify Mesa Labs and hold Mesa Labs harmless from any further damages, indemnity or contribution. Mesa Labs liability for any claim of any kind, including performance or breach thereof, or from the Products or Services furnished hereunder, shall be no more than the price of the specified Product, system, component or service which gives rise to the claim.

# Attachment 1

## MESASTRIP

BIOLOGICAL INDICATOR  
For Industrial Use Only

### CERTIFICATE OF ANALYSIS

Reorder No.:	SUX10 6
<i>Bacillus subtilis</i> '5230'	35021 <sup>(1)</sup>
Biological Indicator for Low Temperature Steam Sterilization	
Culture: Soybean casein digest broth	
Lot No.:	BS230-000
Manufacture Date:	YYYY-MM-DD
Expiration Date:	YYYY-MM-DD
Heat Shocked Population:	0.0 x 10 <sup>6</sup> Spores/Unit
Carrier Size:	2 x 10 mm
Assayed Resistance:	
D-Value <sup>(2)</sup>	
Steam (115°C)	0.0 min.
Steam (118°C)	0.0 min.
Steam (121°C)	0.0 min.
Z-value:	00.0°C

Units are manufactured in compliance with Mesa Laboratories, Bozeman Manufacturing Facility's quality standards, USP and ISO 11133 guidelines and all appropriate subsections with the exception of determination of resistance characteristic by verification of the response characteristic.

<sup>(1)</sup> Subject to the ability to re-quantify culture collection identified as USP and PB7 11118  
<sup>(2)</sup> Resistance is determined in an LALISE 863 B vessel using 10.7 paper strips packaged in glassine (airborne) nitrogen sterilized. The D-value is applicable only when exposed and cultured under the results reported here. Resistance may vary based upon the end user's specific application.

Certified by: \_\_\_\_\_  
Quality Representative Date: \_\_\_\_\_

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## MESASTRIP

Biological Indicators to demonstrate adequacy of sterilization.

### INSTRUCTIONS FOR USE

**Sterilization:**

- Place spore strips inside representative materials to be sterilized. Package or wrap as usual.
- Locate test packages in areas of sterilizer most difficult to sterilize. Identify test packages as to location.
- After sterilization, remove sufficient spore strips and products to identify test laboratory along with at least one spore strip marked **POSITIVE CONTROL**.

**Test Lab. Procedure:**

- Strip should be placed in a dust-free room - and within confines of a laminar flow hood. All transfers and manipulations must be conducted with rapid aseptic techniques to avoid "false positive" samples.
- Procedure:
  - Aseptically withdraw spore strips with sterile forceps and transfer to individual tubes containing soybean casein digest broth. Identify tubes.
  - Incubate spore strips seven days at appropriate temperature (*Bacillus subtilis* '5230' 30-35°C).

Observe tubes daily for growth.  
Turbid = growth = non-sterile  
Clear = no growth = sterile

**Test Results:** Tubes should show no growth if sterilization has been achieved. If turbidity and bacterial growth are observed in test strip culture, it suggests that the spores have survived the sterilization process and are non-sterile.

**Acceptance:**

- Positive:** One or more positive controls should be included in each test series. Transfer a non-sterilized spore strip to culture medium and incubate with test series. Turbidity and growth indicates that the medium possesses suitable growth promoting qualities and that the spore strip contains viable spores. If positive control does not grow, do not use units from that package. Contact Mesa Labs.
- Negative:** One or two tubes of culture medium inoculated with test series. Absence of growth indicates that the medium was sterile prior to sterility testing.

**Storage and Disposal:**

- Store MesaStrip biological indicators at room temperature.
- Do not store these indicators near sterilants or other chemicals. Do not decontaminate.
- MesaStrip biological indicators have a shelf life which is clearly designated on each package. Rotate your stock accordingly.

**NOTE:** Do not use after expiration date printed on package. Dispose of expired indicators by autoclaving at 121°C for not less than 30 minutes.

Rev 2  
Part No. 7987

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