



FOR INDUSTRIAL USE ONLY  
CERTIFICATE OF ANALYSIS

Reorder No: SA/6

*Geobacillus stearothermophilus* 7953<sup>(1)</sup>

Biological Indicator for Steam Sterilization of solutions at 121°C.

Culture: 55 – 60°C. The supplied bacteriological medium will meet requirements for growth promoting ability.

Lot No: SA-732 Manufacture Date: 2024-01-19

Expiration: 2025-07-19

Heat Shocked Population:  $1.9 \times 10^6$  Spores / Unit

Assayed Resistance:

	D-Value	Survival	Kill	
Steam 121°C	1.6 <sup>(2)</sup>	6.67 <sup>(3)</sup>	16.03 <sup>(3)</sup>	min
F <sub>0</sub>		8.00 <sup>(4)</sup>	14.00 <sup>(4)</sup>	min

Z-value: 8.9°C

Units are manufactured in compliance with Mesa Laboratories' quality standards, USP, and ISO 11138 guidelines and all appropriate subsections.

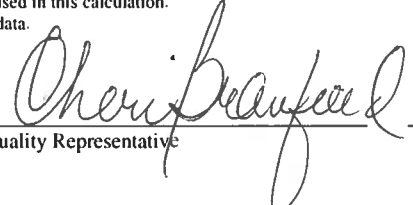
<sup>(1)</sup> Culture is traceable to a recognized culture collection identified in USP and ISO 11138.

<sup>(2)</sup> Resistance was calculated using the Fraction Negative method. The D-value is reproducible only when exposed and cultured under the exact conditions used to obtain results reported here.

<sup>(3)</sup> Survival/Kill values are calculated according to a formula in USP and ISO 11138. A D-value rounded to four decimal places is used in this calculation.

<sup>(4)</sup> Empirically derived data.

Certified by:

 23 Jan 2024  
Quality Representative Date



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Biological Indicators for Monitoring Steam Sterilization of Liquids

INSTRUCTIONS FOR USE

Sterilization:

1. Place SterilAmp® II inside representative liquid containers to be sterilized. Package or seal as usual.
2. Locate test samples in areas of the load considered most difficult to sterilize or in convenient areas that have been validated. Identify test samples as to location in sterilizer.
3. After sterilizing, send SterilAmp II and products to test laboratory along with at least one non-sterilized SterilAmp II marked POSITIVE CONTROL.

Test Laboratory:

1. All SterilAmp II are fully self-contained BIs which do not require subculture.
2. Procedure:
  - a. SterilAmp II may be left in the sterilized container or transferred to a rack or container which allows visual observation during incubation.
  - b. Incubate SterilAmp II for 48 hours at 55-60°C.
  - c. The 48-hour incubation time was validated according to the CDRH Guidance for Industry and FDA Staff: Biological Indicator (BI) Premarket Notification [510(k)] Submissions, issued October 4, 2007. The CDRH RIT protocol for validation of RIT may or may not meet each user's requirements for regulatory compliance. Users should therefore confirm regulatory requirements for reduced incubation time, or incubate for 7 days.
  - d. Observe daily for growth:  
Yellow and/or turbid = growth = non-sterile  
Purple = no growth = sterile  
SterilAmp II should show "no growth" if sterilization has been achieved.  
If color change to yellow or presence of turbidity occurs in SterilAmp II cultures, it indicates that the spores have survived the sterilization process and are non-sterile.
3. Controls:
  - a. **Positive:** At least one positive control should be included in each test series. Incubate a non-sterilized SterilAmp II with test series. Color change from purple to yellow, or presence of turbidity, indicates that the medium possesses suitable growth promoting qualities and that the SterilAmp II contains viable spores. If positive control does not grow, do not use the units from that package. Contact Mesa Labs.
  - b. **Negative:** The distinguishing characteristic of the negative control is a 2 mm stainless steel bead that is placed in the glass tube before it is sealed. The negative control is placed in the sterilizer load along with units that contain spores. Color changes due to thermal degradation can be observed and compared. This documents the normal shift in color from the process.

Storage and Disposal:

1. Refrigerate at 2 – 8°C. Protect from light.
2. Incinerate or autoclave at 121°C for not less than 30 minutes.
3. SterilAmp II biological indicators have a shelf life of 18 months 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.

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**LIMITATION 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 capital, cost of substitute products, facilities, service or replacement power, downtime cost, caused by such Products, or claims of the users for such damages. Buyer for itself, its successors and assigns, hereby agrees 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 injuries to employees of the Buyer or ultimate user 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 to Services furnished hereunder, shall in no case exceed the price of the specified Product, system, component or service which gives rise to the claim.