

# Hygiene Monitoring

## Biological Indicators for Monitoring Sterilization Processes

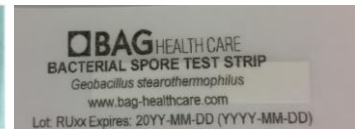
### Product Information



BI\_07\_en

**Spore strips, self-contained units,  
liquid sterilization ampoules  
and spore suspensions**

# BAG-BioStrip



Biological Indicators for Monitoring all Types of Sterilization Processes  
STEAM – DRY – EO – IRRAD – FORM – VH2O2

	Order-No.	Packaging unit
<b>BAG-BioStrip</b> Geobacillus stearothermophilus 10 <sup>5</sup> , ATCC 7953 Spore strips for monitoring steam sterilization processes	7480	100
<b>BAG-BioStrip (White Glassine)</b> Geobacillus stearothermophilus 10 <sup>6</sup> , ATCC 7953 Spore strips for monitoring steam sterilization processes	7478	100
<b>BAG-BioStrip</b> Bacillus atrophaeus 10 <sup>6</sup> , ATCC 9372 Spore strips for monitoring dry heat or ethylene oxide sterilization processes	7481	100
<b>BAG-BioStrip</b> G.stearothermophilus 10 <sup>5</sup> + B.atrophaeus 10 <sup>6</sup> , ATCC 7953/9372 Combined (dual) spore strips for monitoring steam, dry heat or ethylene oxide sterilization processes	7479	100
<b>BAG-BioStrip</b> G.stearothermophilus 10 <sup>5</sup> + B.atrophaeus 10 <sup>6</sup> , ATCC 7953/9372 Combined (dual) spore strips for monitoring steam, dry heat or ethylene oxide sterilization processes,	7385	24 envelopes with 3 spore strips each
<b>BAG-BioStrip</b> G.stearothermophilus 10 <sup>5</sup> + B.atrophaeus 10 <sup>6</sup> , ATCC 7953/9372 Combined (dual) spore strips for monitoring steam, dry heat or ethylene oxide sterilization processes	7386	30 envelopes with 5 spore strips each

**Also available:**

<b>BAG-BioStrip-Validationset</b> G.stearothermophilus $10^3 - 10^7$	74802
<b>BAG-BioStrip</b> B.atrophaeus $10^4 - 10^8$	74812
<b>BAG-BioStrip</b> Bacillus pumilus $10^4 - 10^8$	On request
<b>SporeCoupons &amp; SteelCoupons</b> (H <sub>2</sub> O <sub>2</sub> sterilization) <b>Spore Suspensions</b>	available

Every BAG-BioStrip packaging unit contains an IFU and a Certificate of Analysis including

- Population and strain
- Resistance data: D-value (D<sub>STEAM</sub>, D<sub>EO</sub>, D<sub>DRY</sub>), z-value
- Lot no., manufacturing date, expiry date

BAG biological indicators are manufactured according to EN 866 and ISO 11138.

ATCC is registered trademark of American Type Culture Collection

**BAG-Biostrip – Instructions for Use**

**Sterilization:**

1. Place at least 5 spore strips (according to EN 285 and EN 13060) or required number of spore strips depending on the size of the sterilizer chamber and/or depending on regional requirements or load in the sterilizer.
2. Position spore strips according to individual specifications in the sterilizer chamber. Keep one spore strip as control (growth control) out of the sterilizer.
3. Run sterilization cycle.
4. Incubate spore strips + control strip in a laboratory for microbiology according to the species' requirements (see below).

**Incubation:**

1. Remove spore strip from glassine cover under sterile conditions (laminar flow).
2. Transfer spore strip into 10 to 15 ml of sterile tryptic soy broth (Soybean Casein Digest Broth) and incubate for 7 days:
 

<b>G. stearothermophilus</b>	– STEAM:	at 55 – 60° C
<b>B. atrophaeus</b>	– EO / DRY:	at 30 – 35° C
<b>B. pumilus</b>	– IRRAD:	at 30 – 35° C
3. Check tubes every day during incubation. Final evaluation after 7 days:
 

<b>Turbidity</b>	= growth	= <b>NOT sterile</b>
<b>No turbidity</b>	= no growth	= <b>sterile</b>

 Control strip has to show growth.
4. Documentation of all results. Sterilize all bacteria cultures showing growth.

**Storage:** Dry at room temperature (15 – 27° C)

## Tryptic Soy Broth with Color Change

To reduce the incubation time special culture media ampoules can be used. The Tryptic Soy Broth contains a color change indicator reacting on spore growth after **24 hours**. The color change is from purple to yellow (for *Geobacillus sterothermophilus* spores only).

Available ampoules (100 ampoule per box):

**Order-No. 74956**                      16mm x 100mm (8 ml fill volume)  
(also suitable for inoculated stainless steel discs, e.g. BAG-SporeDisc)



biostrip\_flyer\_01\_eng

# MicroStrips (10 x 2 mm)

Sporestrips to control sterilization-processes



Standard spore strips are 38mm x 6mm (1 ½ X ¼ inches) making them difficult to use in lumens or other small area. At 2mm X 10mm, **MicroStrips** can be used in areas where other BI's are too large. Our **MicroStrips** are available inoculated with *Bacillus atrophaeus* or with *Geobacillus stearothermophilus*

	Ref.:	Packing-Unit:
<b>MicroStrips</b> Geobacillus stearothermophilus 10 <sup>6</sup> , ATCC 7953	73731	100
<b>MicroStrips</b> Bacillus atrophaeus 10 <sup>6</sup> , ATCC 9372	73732	100

Every Micro Strip packaging unit contains an IFU and a Certificate of Analysis including

- Population and strain
- Resistance data: D-value , z-value
- Lot no., manufacturing date, expiry date

BAG biological indicators are manufactured according to EN 866 and ISO 11138.

## Instructions for use:

### Sterilization:

Act like with SporeStrips

### Incubation:

Act like with SporeStrips

**Storage:** Dry at room temperature  
**Expiry:** 24 month from date of manufacture

microStrips\_01\_eng  
 Country of origin: USA, manufactured by MESA

# Apex-Disc H<sub>2</sub>O<sub>2</sub>

Sporedisc for monitoring the Plasma- and Hydrogeneperoxide (H<sub>2</sub>O<sub>2</sub>)-Sterilization

Order-No.: 73955

Packing-Unit: 100

## Product description:

On a sporedisc of "Apex Disc H<sub>2</sub>O<sub>2</sub>" there are spores of *Geobacillus stearothermophilus* ATCC 12980 with a population of  $>1.0 \times 10^6$  ( $10^4$  on request). The carrier of the spores is a stainless-steel-disc with a diameter of 8,8 mm and a height of 0,2 mm wrapped in Tyvek<sup>®</sup>. The stainless-steel-discs are not absorbing and will reach the ambient-temperature quickly. The Tyvek<sup>®</sup>-wrapping is equipped with a hole to hang it into the sterilizer.

## Instructions for use:

1. Place **Apex Disc H<sub>2</sub>O<sub>2</sub>** into the sterilization chamber at various locations. The printed side must face outside.
2. Run the sterilization cycle as normal.
3. Remove the **Apex Disc H<sub>2</sub>O<sub>2</sub>** from the sterilization load and aseptically (use of laminar flow hood or similar equipment) remove spore disc from pouch and transfer into a sterile tube of CSP-Bouillon.
4. Incubate processed discs + one control for 7 days at 55-60°C.
5. Check and record results daily for Growth/No Growth. Final evaluation after 7 days:  
**Turbidity** = growth = **NOT sterile**  
**No turbidity** = no growth = **sterile**
6. Control disc has to show growth. If needed identify spores.
7. Documentation of all results. Sterilize all bacteria cultures showing growth.

## Zertifikate:

Every Micro Strip packaging unit contains an IFU and a Certificate of Analysis including

- Population and strain
- Resistance data: D<sub>H<sub>2</sub>O<sub>2</sub></sub>-value , z-value
- Lot no., manufacturing date, expiry date

BAG biological indicators are manufactured according to EN 866 and ISO 11138

**Storage:** Dry at room temperature

ApexH2O2\_01-eng  
Country of origin: USA, manufactured by MESA

# APEX Ribbon

Bare stainless steel ribbons for monitoring H<sub>2</sub>O<sub>2</sub> – sterilization-processes  
G. stearothersophilus 10<sup>6</sup> ATCC 12980

Packing Unit: 100

## Product description:

The metal-ribbons (0,635 x 6,985cm) are thin,(malleable) formable and inoculated on one side. Because of its small size this indicator could be placed everywhere where SporeCoupons or Discs couldn't be placed.



## Process Evaluation:

- Place biological indicators in locations previously determined to be the most difficult to sterilize. Areas experiencing minimal gas flow or poor gas distribution include enclosure comers, areas in and around equipment, and locations among disposable materials to be used in the enclosure. Note that the inoculated area on the carrier is visible and is at the opposite end of the stainless steel (SST) strip that projects from the Tyvek pockets. The flexible nature of the SST carrier gives the user several options for placement in the test enclosure. The investigator can use tape at the uninoculated end to attach the BI to a surface. Alternatively, the uninoculated end may be bent into a hook to permit hanging from selected locations. **The inoculated area should be placed to face outward during a process cycle.**
- Validation and mapping processes generally require multiple indicators at numerous sites in an enclosure.
- Conduct the sterilization and aeration cycle.
- Using aseptic technique, remove the indicators and deliver them, plus one or more unexposed control indicators, to the laboratory for sterility testing.

## Culturing Procedures:

- Culture in a laminar flow hood. Observe strict aseptic technique at all times. Minimally, sterile gloves should be worn Include donning hoods, masks, and gowns as appropriate for the facility and circumstances.
- Using sterile forceps aseptically remove the exposed indicator from the test site (or withdraw it from the Sterile Transfer Pocket, if used). Use sterile scissors to cut the inoculated end of the stainless steel indicator and allow it to drop into a tube containing sterile Soybean Casein Digest Medium (SCDM) / Tryptic Soy Broth (TSB).
- Aseptically culture the control carrier(s) last.
- Select one or more tubes of the same lot of culture medium to serve as negative controls.
- Incubate test and control tubes for 7 days at 55-60°C. Observe daily for evidence of growth (turbidity).



## Interpretation:

### Turbidity:

- For test indicators, turbidity suggests that the sterilization was incomplete and that at least one spore survived the process.
- For positive control indicators, turbidity indicates that viable spores were present and capable of outgrowth in the culture medium used.
- In negative control tubes, turbidity indicates that viable organisms may have been present in the growth medium. Contact your supplier.

### No turbidity:

- For test indicators, lack of turbidity indicates sterilization was complete and no spores survived the process.
- In negative control tubes, lack of turbidity indicates no other viable organisms were present in the culture medium.
- For positive control indicator, no turbidity suggests no viable organisms were present on the carrier or that the media may be inhibiting the outgrowth of the test organism. Contact your supplier

## Certificates:

Every **APEX Ribbon** packaging unit contains an IFU and a Certificate of Analysis including

- Population and strain
- Resistance data: D-value
- Lot no., manufacturing date, expiry date
- 

BAG biological indicators are manufactured according to ISO 11138.

**Storage:** Dry at 2-8° C

apxribb\_01\_eng  
Country of origin: USA, manufactured by MESA

# MESA SteelCoupon & Crosstex SporeCoupon

Inoculated Spore Disc (7 x 32,8 x 0,45) for Monitoring Sterilization Processes with Plasma/Hydrogene Peroxide (H<sub>2</sub>O<sub>2</sub>), Dry Heat, Steam and EO

## Specifications:

The Coupons are stainless steel discs inoculated with spores. Packaging material is Tyvek<sup>®</sup>/Mylar. Custom made products on request.



## Instructions for Use:

1. Place the appropriate Coupon into the sterilization chamber at various locations. The Coupons should not be removed from their primary packaging (Tyvek pouch). Depending on chamber size at least 10 Coupons should be used per cycle and 1 Coupon should be saved as a positive-control.
2. Run the sterilization cycle as normal.
3. Remove BAG-SporeDisc from the sterilization load and aseptically (use of laminar flow hood or similar equipment) remove the Coupon from pouch and transfer into a sterile tube of growth media.
4. Incubate processed Coupons + one control for 7 days at 55-60°C.
5. Check and record results daily for Growth/No Growth. Final evaluation after 7 days:  
**Turbidity** = growth = **NOT sterile**  
**No turbidity** = no growth = **sterile**
6. Control Coupon has to show growth. If needed identify spores.
7. Documentation of all results. Sterilize all bacteria cultures showing growth.

**Storage:** Dry at room temperature (2° C)

Every Coupon packaging unit contains an IFU and a Certificate of Analysis including

- Population and strain
- Resistance data: D-value
- Lot no., manufacturing date, expiry date

BAG biological indicators are manufactured according to ISO 11138.

ATCC is registered trademark of American Type Culture Collection

## MESA SteelCoupon

MESA SteelCoupons for:	Ref.:	PU:
<b>Steam-Sterilization</b>		
G. stearothermophilus, 10 <sup>6</sup> , ATCC 7953	7435	100
G. stearothermophilus, 10 <sup>3</sup> , ATCC 7953	7436	on request
<b>Dry Heat-Sterilization</b>		
Bacillus atrophaeus, 10 <sup>5</sup> , ATCC 9372	74341	on request
Bacillus atrophaeus, 10 <sup>6</sup> , ATCC 9372	7434	100
Bacillus atrophaeus, 10 <sup>4</sup> , ATCC 9372	74342	on request
<b>Irradiation-Sterilization</b>		
Bacillus pumilus, 10 <sup>3</sup> , ATCC 27142	74371	on request
Bacillus pumilus, 10 <sup>6</sup> , ATCC 27142	74374	on request
<b>EO-Sterilization</b>		
Bacillus atrophaeus, 10 <sup>6</sup> , ATCC 9372	7434	100

Country of origin: USA, manufactured by MESA

## Crosstex SporeCoupons

Crosstex SporeCoupons for:	Ref.:	PU:
<b>H<sub>2</sub>O<sub>2</sub>-Sterilization</b>		
G. stearothermophilus, 10 <sup>6</sup> , ATCC 7953	74376	100
<b>Dry heat sterilization</b>		
Bacillus atrophaeus, 10 <sup>6</sup> , ATCC 9372	74375	100
<b>EO-Sterilization</b>		
Bacillus atrophaeus, 10 <sup>6</sup> , ATCC 9372	74375	100
<b>Steam sterilization</b>		
G. stearothermophilus 10 <sup>6</sup> , ATCC 7953	73956	100

Country of origin: USA, manufactured by Crosstex

Custom made spore-populations on request

spo\_coup\_01\_eng

# Crosstex Glass Fiber SporeDisc

Inoculated Spore Disc for Monitoring Sterilization Processes

B. atrophaeus 10<sup>6</sup> ATCC Ref.: 7440 PU: 100  
G. stearothermophilus 10<sup>6</sup>, ATCC 7953 Ref.: 7441 PU: 100



## Specifications:

**Crosstex Glass Fiber SporeDiscs** are glass fiber discs inoculated with spores. Packaging material is Tyvek<sup>®</sup>/Mylar. Additionally spore discs with various custom made populations are available.

## Instructions for Use:

8. Place **Crosstex Glass Fiber SporeDiscs** into the sterilization chamber at various locations as one would with normal spore strip use. The spore discs/strips should not be removed from their primary packaging (Tyvek pouch). Depending on chamber size at least 10 discs should be used per cycle.
9. Take one disc as positive-control and do not sterilize it.
10. Run the sterilization cycle as normal.
11. Remove the **Crosstex Glass Fiber SporeDiscs** from the sterilization load and aseptically (use of laminar flow hood or similar equipment) remove spore disc from pouch and transfer into a sterile tube of growth media.
12. Incubate processed spore discs + one control for 7 days at 55-60°C.
13. Check and record results daily for Growth/No Growth. Final evaluation after 7 days:  
**Turbidity** = growth = **NOT sterile**  
**No turbidity** = no growth = **sterile**
14. Control disc has to show growth. If needed identify spores.
15. Documentation of all results. Sterilize all bacteria cultures showing growth.

**Storage:** 2 - 8° C

Every Crosstex Glass Fiber SporeDisc packaging unit contains an IFU and a Certificate of Analysis including

- Population and strain
- Resistance data: D-value
- Lot no., manufacturing date, expiry date

BAG biological indicators are manufactured according to ISO 11138.

ATCC is registered trademark of American Type Culture Collection

ctx\_sporedisc\_01\_eng  
Country of origin: USA, manufactured by Crosstex

# Crosstex SporeWires

Inoculated SporeWires for Monitoring VH<sub>2</sub>O.Sterilization Processes



## Specifications:

**Crosstex SporeWires** are braided steel wires inoculated with spores.

## Instructions for Use:

1. Place **Crosstex SporeWires** into the sterilization chamber at various locations as one would with normal spore strip use. Depending on chamber size at least 10 discs should be used per cycle.
2. Take one disc as positive-control and do not sterilize it.
3. Run the sterilization cycle as normal.
4. Remove the **Crosstex SporeWires** from the sterilization load and aseptically (use of laminar flow hood or similar equipment) remove spore disc from pouch and transfer into a sterile tube of growth media.
5. Incubate processed spore discs + one control for 7 days at 55-60°C.
6. Check and record results daily for Growth/No Growth. Final evaluation after 7 days:  
**Turbidity** = growth = **NOT sterile**  
**No turbidity** = no growth = **sterile**
7. Control disc has to show growth. If needed identify spores.
8. Documentation of all results. Sterilize all bacteria cultures showing growth.

**Storage:** Dry at room temperature (15 – 27° C)

Every **Crosstex SporeWires** packaging unit contains an IFU and a Certificate of Analysis including

- Population and strain
- Resistance data: D-value
- Lot no., manufacturing date, expiry date

BAG biological indicators are manufactured according to ISO 11138.

ATCC is registered trademark of American Type Culture Collection

<b>Crosstex Glass Fiber SporeDiscs for:</b>	<b>Lot.:</b>	<b>PU:</b>
<b>H<sub>2</sub>O<sub>2</sub>-Sterilization</b> G. stearothermophilus, 10 <sup>6</sup> , ATCC 7953	7441	100

ctx\_sporewrs\_01\_eng  
Country of origin: USA, manufactured by Crosstex

# ProLine PCD Steam



Indicatorsystem with integrated sporedisc for the monitoring and the validation of tubes during the Steam- & EO-Sterilization

**Order-No.:** 7438

**Packing-Unit:** 15

## Product-description

The sterilization of long tubes is often very difficult to proof because the critical point is the middle of it. The biological indicator (BI) “**ProLine PCD Steam**” could be used to solve this problem. The BI is equipped with a paper disc inoculated with spores of *G.stearothermophilus* or *B. atrophaeus*. The minimal amount of CFU in one PCD is about  $1,0 \times 10^6$ .

In the middle of the ProLine-System there is a filter-paper-disc in a glassine-wrapping, which allows the EO and the steam to go through it.

## Information for use:

The **ProLine PCD** is a single-use-system which allows you to monitor the sterilization of tubes with diameters of 3,175 mm up to 15,875 mm. This system could be furthermore used for the validation of medical tubes concerning their sterility.

For such a validation you have to use a representative tube which simulates the real tubes.

- Cut the tube in two pieces
- Place the **ProLine PCD** between the two tube-ends
- Put the whole Tube-ProLine-System into a sterilization-box and close it as normal
- Run the sterilization-cycle as normal
- After the end of the sterilization remove the **ProLine PCD** from the box
- Remove the tubes and transfer the **ProLine PCD** to a sterile area
- Break up the **ProLine** and remove the disc aseptically
- Transfer the disc aseptically to CSP-Boullion
- Growth at 55-60°C

Every **ProLine PCD Steam** packaging unit contains an IFU and a Certificate of Analysis including

- Population and strain
- Resistance data: D-value
- Lot no., manufacturing date, expiry date

BAG biological indicators are manufactured according to ISO 11138.

**Storage:** Dry at room temperature

ProL\_01/eng

Country of origin: USA, manufactured by Mesa

# BAG-BioCheck

Self-Contained Biological Indicators incl. Growth Media for Monitoring Sterilization Processes with STEAM, EO-Gas or H<sub>2</sub>O<sub>2</sub>

**EASY to use – CLEAR results – FAST 24-/48- hour readout**

## Product features

BAG-BioCheck are composed of a polypropylene vial containing a bacterial spore disc and an ampoule containing growth media. BAG-BioCheck STEAM and BAG-BioCheck H<sub>2</sub>O<sub>2</sub> contain spores from *Geobacillus stearothermophilus*, BAG-BioCheck EO contains spores from *Bacillus atrophaeus*.



	Order-No.	Packaging unit
<b>BAG-BioCheck STEAM:</b>		
<i>G. stearothermophilus</i> , 10 <sup>5</sup>	7482	100
<i>G. stearothermophilus</i> , 10 <sup>6</sup>	7483	100
<b>BAG-BioCheck EO:</b>		
<i>B. atrophaeus</i> , 10 <sup>6</sup>	7484	100
<b>BAG-BioCheck H<sub>2</sub>O<sub>2</sub>:</b>		
<i>Geobacillus stearothermophilus</i> 10 <sup>6</sup> (use with pre-vacuum cycles, e.g. Sterrad <sup>®</sup> , only)	74901	25

## Instructions for Use

1. Place at least 5 BAG-BioCheck vials or required number of vials depending on the size of the sterilizer chamber and/or depending on regional requirements or load in the sterilizer.
2. Position vials according to individual specifications in the sterilizer chamber. Keep one spore disc as control (growth control) out of the sterilizer.
3. Run sterilization cycle.
4. After sterilization handle units with care and allow vials to cool down at least 10 minutes.
5. Crush the media ampoule by squeezing sides of the plastic vial. Check that the media has been released from the ampoule and the spore disc is in contact with the released media.
6. Place processed vials and one growth control in dry bath incubator (order-no. 74752) or appropriate incubation unit.
7. Incubate vials according the species' requirements

<b>G. stearothermophilus</b>	– STEAM / H <sub>2</sub> O <sub>2</sub> :	at 55 – 60°C	for 24 hours
<b>B. atrophaeus</b>	– EO:	at 30 – 39°C	for 48 hours
8. Begin monitoring after approx. 12 hours.

Colour change towards yellow and/or Turbidity	= growth	= <b>NOT sterile</b>
Colour change and no turbidity	= no growth	= <b>sterile</b>

Final negative results (no growth) can be made after 24 hours of incubation for STEAM and after 48 hours for EO.
9. Documentation of all results. Sterilize all bacteria cultures showing growth.

Every BAG-BioCheck packaging unit contains an IFU and a Certificate of Analysis including

- Population and strain
- Resistance data: D-value ( $D_{\text{STEAM}} / D_{\text{EO}} / D_{\text{H}_2\text{O}_2}$ ), Z-value
- Lot no., manufacturing date, expiry date

BAG biological indicators are manufactured and tested according to ISO 11138.

**Storage:** At room temperature (15 – 27 °C), 30-70% RH  
**Expiry:** 2 years from date of manufacture

BioC\_02\_eng



# BAG-BioCheck-Kit

Biological Test Pack with Self-Contained Biological Indicator  
BAG-BioCheck for Monitoring Steam Sterilization Processes.  
Economic Solution with reusable Test Pack.

**Order-Nr.:** 7499/ 74991    **Packaging unit:** 1 Kit (15 Tests)

## Contents:

15 ampoules BAG-BioCheck STEAM  
with *G. stearothermophilus* 10<sup>6</sup>  
1 control ampoule BAG-BioCheck STEAM (Order-No 7499)  
3 control ampoules BAG-BioCheck STEAM (Order-No 74991)  
with *G. stearothermophilus* 10<sup>6</sup>

1 high-grade paper test pack, reusable 15 times,  
15 documentation sheets



## Product features

BAG-BioCheck-Kit is used as biological challenge test pack / biological load control for verification of biological kill in steam sterilization processes in pre-vacuum sterilizers. The paper test pack is reusable 15 times. Use with small CCS holder (Order-No. 74651). Incubation time for BI (biological indicator) is 24 hours. Small CCS holder can be used for BAG-BioCheck Kit and reusable Bowie & Dick test systems BAG-AutoCheck-Kit / BAG-AutoCheck-Kit II respectively.

## Instructions for Use

1. Open **BAG-BioCheck-Kit** and remove control ampoule. Mark as control BI. Control BI has to show growth (turbidity and/or color change towards yellow) after incubation (see below). If the control unit does not show growth, the test has to be considered as invalid.
2. Place BAG-BioCheck ampoule in the center of the reusable test pack (between white and green paper sheets). Record date on the cover sheet of the test pack (fields 1-15). Insert test pack into BAG-CCS stainless steel holder (Order-No. 74651) and close spring lock.
3. Place test system on the bottom of the loaded chamber (horizontal position). Run sterilization cycle (e.g. 5 minutes at 134°C).
4. Remove test system from chamber after cycle. Open spring lock, remove BAG-BioCheck ampoule from test pack. Handle units with care and allow vials to cool down at least 10 minutes.

*CAUTION: Metal holder may be hot!*

5. Crush the media ampoule by squeezing sides of the plastic vial. Check that the media has been released from the ampoule and the spore strips is in contact with the released media.
6. Place processed vials / growth control in dry bath incubator (Order-No. 74752) or appropriate incubation unit.
7. Incubate vials according the species' requirements:  
BAG-BioCheck STEAM *G. stearothermophilus*: at 55 – 60°C for 24 hours
8. Evaluate ampoules after incubation:

Color change towards yellow and/or turbidity	= growth	= <b>NOT sterile</b>
No color change and no turbidity	= no growth	= <b>sterile</b>

Final negative results (no growth) can be made after 24 hours of incubation.

9. Documentation of all results. Sterilize all bacteria cultures showing growth.  
Dry paper test pack prior next use.

Every BAG-BioCheck-Kit packaging unit contains a Certificate of Analysis including

- Population and strain for BAG-BioCheck STEAM
- Resistance data: D-value ( $D_{STEAM}$ ), z-value
- Lot no., manufacturing date, expiry date

BAG biological indicators are manufactured according to EN 866 and ISO 11138.

**Storage:** Dry at room temperature (15 – 27°C)

BioCheckKit\_01\_EN

# Incubator

Dry bath incubator for BAG-BioCheck Ampoules

Order-No.: 7475 (adjustable to 37°C, 57°C or 60°C)

Packaging unit: 1

## Product features

Dry bath incubator with 14 wells for incubating BAG-BioCheck STEAM with spores from *Geobacillus stearothermophilus* at 55-60°C and BAG-BioCheck EO with spores from *Bacillus atrophaeus* at 30-35°C. Different temperatures (37°C, 57°C, 60°C) are preselected and can be changed according to the species tested.



## Instructions for Use

The incubator is designed for continuous operation and does not have a power switch. The incubator will power on when it is plugged into a power source.

1. Plug the power supply into a power source.
2. The incubator will automatically power on and perform a self-test. Upon completion, the installed firmware revision will be displayed on the LED screen for two seconds.
3. The incubator will begin its warm-up phase. During this time the configured temperature set point will fade in and out on the LED screen.
4. The incubator is ready to use when the configured set point is no longer fading in and out, and the LED screen displays the current operating temperature of the incubator

Note: It may take approximately 15 minutes for the incubator to warm up to operating temperature.

## Temperature Selection

1. With the incubator powered on, simultaneously press and hold the two small buttons on the rear of the incubator for ~2 seconds until the currently selected temperature set point blinks on the LED display.
2. Release the buttons, then press either button repeatedly to toggle between the available temperature set points (37°C, 57°C, or 60°C).
3. When the desired temperature set point is blinking on the display, press and hold both buttons for ~2 seconds.
4. The configured set point will fade in and out on the LED screen until the incubator has reached temperature, upon which the actual temperature of the incubator will be displayed.

## Safety precautions

- Handle with care. The surface of the incubator may become hot to the touch
- Maximum relative humidity 80% for temperatures up to 31°C decreasing linearly to 50% relative humidity at 35°C

09/2013

# Steril AMP II “5230”



## Control and Validation of Steam Sterilization Processes

### Specifications

**Steril AMP II “5230”** is designed for control and validation of steam sterilization processes at 118-135°C with liquids. **Steril AMP II “5230”** is a hermetically sealed, type I borosilicate glass ampoule. The ampoule is filled with a modified Soybean Casein Digest Broth containing bromocresol purple acid indicator. Each ampoule also contains a population of *Bacillus subtilis* spores. Growth is evident by either turbidity and/or a color change from a purple to or toward yellow. Expiration is 18 months from the date of manufacture.

The dimensions of the ampoules are: length approx. 26.5 mm, diameter 6.5 mm. The ampoule (fill volume approx 0.35 ml) may be placed in small vessels or automated ampoule filling systems. Available populations:  $1 \times 10^5$  or  $1 \times 10^6$ . *Bacillus subtilis* '5230' is available for 105-115°C steam sterilization processes.

### Steril AMP II “5230”

*Bacillus subtilis*,  $10^6$  (105-115°C)

### Order-No.

7489

### Packaging unit

100 ampoules

**Standards:** ISO 11138-1, ISO 11138-3

**Storage:** 2 – 8°C

**Disposal:** Autoclave BAG-ProAMP ampoules with turbidity or color change to yellow

sterilAMP\_02\_eng  
country of origin: USA, manufactured by Mesa

# BAG-ProSpore

## Monitoring and Validation of Sterilization processes



### Product description

BAG-ProSpore is a closed unit which is used to monitor and/or validate steam Sterilization processes (121°C) when sterilizing liquids. Handling is simple and does not require special laboratory equipment for evaluation. The ampoules contain spores of *Geobacillus stearothermophilus* which are aggraded in a special culture medium.

The suspensions, consisting of spores and culture medium, are contained in thin-walled glass ampoules made from a material which is used in the pharmaceutical industry.

The ampoules are approx. 5 cm long and available with a fill volume of 1 ml spore solution.

Their diameter is approx. 1 cm respectively. The small size of the BAG-ProSpore permits placement in small containers with low amounts of liquids.

The ampoules can also be used in production lanes and filling machines.

Spore populations of  $>1 \times 10^4$ ,  $>1 \times 10^5$  and  $>1 \times 10^6$  are available in the existing concept. BAG-ProSpore has received 510K notification.

### Use

BAG-ProSpore is stored in the refrigerator at 2 - 8°C unit used. After removing the required number of ampoules from the refrigerator, they should reach room temperature before use.

ProSpore ampoules with *Geobacillus stearothermophilus* spores show a blue-violet colour prior to use, due to the pH indicator which is contained in the culture medium. Lengthened Sterilization cycles at 121°C may alter the ingredients of the culture medium and therefore also the blue-violet colour of BAG-ProSpore. In this event, it may become more difficult to assess the ampoules in terms of killing or growth of spores after incubation. BAG-ProSpore are inserted in the containers being sterilized prior to autoclaving (if applicable, fasten to a thread for liquid quantities > 20 ml) or sterilized side by side with the product. 121°C are specified as the temperature for the sterilization cycle. Ensure comparable warming behaviour between the product being sterilized and BAG-ProSpore. Differences may occur due to the viscosity of different products.

The number of bio-indicators to be used depends on the capacity of the Sterilization Chamber. The bio-indicators are generally arrayed on various levels from top to bottom and front to back. Bio-indicators are also placed at the centre of the load. In autoclaves > 250 l, it is recommended to distribute at least 10 Bio-indicators in the load.

### Incubation conditions and evaluation

The incubation temperature is 55 – 60°C. Since BAG-ProSpore is a closed system, Incubation can take place in a water bath or an incubator commonly used for bacteriology. An unsterilized BAG-ProSpore ampoule is incubated together with the sterilized BAG-ProSpore ampoules as a positive growth control.

The appropriate incubation time is 48 hours. An initial Visual check is made with BAG-ProSpore before placing it in the incubator; another Visual check can be done after 18 hours.

When incubating in a Container, incubation times vary due to the differing sizes and liquid amounts as well as the initial temperature; this must be taken into account accordingly. The culture medium changes colour from blue-violet to yellow if there is spore growth. A yellow colouration means “test positive”; that is, not sterile. In excessively long Sterilization cycles– e.g. Sterilization overnight – the optical indicator (colour blue-violet) may pale, so the medium appears light grey or brownish. The discolouration of the indicator does not influence the growth behaviour of spores which were not killed. When there is growth of *Geobacillus stearothermophilus*, sterilized ampoules discolour to yellow, similarly to the positive growth control.

Certificates stating the spore population, D parameter , Z parameter and  $F_0$  parameter or Killing Time (time at which all spores are killed) are included with every batch.

	Order-No.	Packaging unit
<b>BAG-ProSpore - 1 ml*</b> <i>Geobacillus stearothermophilus</i> 10 <sup>4</sup>	7536	100 ampoules
<b>BAG-ProSpore - 1 ml incl. neg. controls</b> <i>Geobacillus stearothermophilus</i> 10 <sup>5</sup>	7534	50 ampoules
<b>BAG-ProSpore - 1 ml incl. neg. controls</b> <i>Geobacillus stearothermophilus</i> 10 <sup>6</sup>	7535	50 ampoules

**Storage:** In the refrigerator at 2 – 8°C

**Disposal:** Autoclave BAG-ProSpore with yellow colouration (positive) prior to disposal

\* not stocked – delivery tome approx. 4 weeks.

BAG\_ProSpore\_01\_en

# BAG-ProAMP



## Control and Validation of Steam Sterilization Processes

### Specifications

BAG-ProAMP is designed for control and validation of steam sterilization processes at 118-135°C with liquids. BAG-ProAMP is a hermetically sealed, type I borosilicate glass ampoule. The ampoule is filled with a modified Soybean Casein Digest Broth containing bromocresol purple acid indicator. Each ampoule also contains a population of *G. stearothermophilus* spores. Growth is evident by either turbidity and/or a color change from a purple to or toward yellow. Expiration is 18 months from the date of manufacture.

The dimensions of the ampoules are: length approx. 26.5 mm, diameter 6.5 mm. The ampoule (fill volume approx 0.35 ml) may be placed in small vessels or automated ampoule filling systems. Available populations:  $1 \times 10^5$  or  $1 \times 10^6$ . *Bacillus subtilis* '5230' is available for 105-115°C steam sterilization processes.

BAG-ProAMP	Order-No.	Packaging unit
Geobacillus stearothermophilus, $10^5$	7487	100 ampoules
Geobacillus stearothermophilus, $10^6$	7488	100 ampoules
Geobacillus stearothermophilus, $10^6$	74884	25 ampoules

**Standards:** ISO 11138-1, ISO 11138-3

**Storage:** 2 – 8°C

**Expiry:** 18 months from manufacture

**Disposal:** Autoclave BAG-ProAMP ampoules with turbidity or color change to yellow

ProAmp\_03\_en



## BAG-DriAMP for Dry Heat

Biological Indicator for Monitoring Dry Heat Sterilization Processes at High Temperatures, incl. Media Ampoules with 72-Hour-Read-Out

**Order-No.** 75370  
**Packaging unit** 50 spore ampoules + 50 media tubes

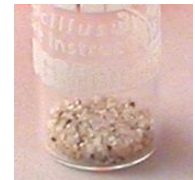
**BETTER with 72  
hour-read-out**



### Specifications

BAG-DriAMP for dry heat is a hermetically sealed ampoule (4.9 x 1.1 cm) containing silica sand inoculated with *Bacillus atrophaeus* spores  $>10^6$ . This application enables monitoring longer dry heat sterilization processes and cycles with higher temperatures (180-240°C) respectively, while regular paper spore strips might lose integrity. BAG-DriAMP provides a greater challenge to dry heat cycles as resistance data (D-value) exceed specifications in ISO 11138.

Every packaging unit includes 50 ampoules with inoculated silica sand and 50 tubes containing a special growth medium providing a reduced incubation time with a final read-out after 72 hours. Just crack the ampoule at the designated point and transfer the silica sand into a media tube.



### Incubation and evaluation

Incubation temperature is 36-38°C. The silica sand has to be aseptically transferred into the included media ampoules. A not sterilized sample has to be incubated as positive growth control. The recommended read-out-time is 72 hours. If needed check and record results daily for growth/no growth. A color change to yellow indicates growth = not sterile.

Accompanying certificates include data for D-value, z-value, nominal population, survival and killing time in dry heat sterilization processes.

**Storage:** dry, 15-27°C  
**Disposal:** sterilize all ampoules showing growth (yellow color)

06/12



# Spore Suspensions

- > Spore Suspensions in 40% Ethanol or deionized water
- > Concentration per 0.1 ml, 10 ml per vial
- > Certificate with species, population and D-value

Product Survey	Order-No.	ATCC
G. stearothermophilus 10 <sup>4</sup>	7367	7953
G. stearothermophilus 10 <sup>5</sup>	7363	"
G. stearothermophilus 10 <sup>6</sup>	7364	"
G. stearothermophilus 10 <sup>7</sup>	7352	"
B. atrophaeus 10 <sup>4</sup>	7372	9372
B. atrophaeus 10 <sup>5</sup>	7365	"
B. atrophaeus 10 <sup>6</sup>	7366	"
B. atrophaeus 10 <sup>7</sup>	7369	"
B. atrophaeus 10 <sup>8</sup>	7361	"
B. subtilis "6633" 10 <sup>4</sup>	7368	6633
B. subtilis "6633" 10 <sup>6</sup>	7371	"
B. subtilis "6633" 10 <sup>7</sup>	7370	"
B. subtilis "6633" 10 <sup>8</sup>	73705	"
B. pumilus 10 <sup>4</sup>	7380	27142
B. pumilus 10 <sup>5</sup>	7381	"
B. pumilus 10 <sup>6</sup>	7382	"
B. pumilus 10 <sup>7</sup>	7383	"
B. pumilus 10 <sup>8</sup>	7362	"
B. pumilus 10 <sup>9</sup>	73621	"
B. subtilis "5230" 10 <sup>4</sup>	73591	35021
B. subtilis "5230" 10 <sup>5</sup>	73592	"
B. subtilis "5230" 10 <sup>6</sup>	73593	"
B. subtilis "5230" 10 <sup>7</sup>	75394	"

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*Additional populations and species available:*

G. stearothermophilus	ATCC 12980; ATCC 10149
B. thuringiensis	ATCC 29730
B. megaterium	ATCC 8245
B. cereus	ATCC 11778
B. smithii	ATCC 51232



**Storage:** 2 – 8°C  
**Delivery time:** approx. 4 weeks