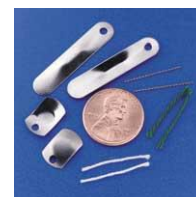


# Hygiene Monitoring

## Biological Indicators for Monitoring Sterilization Processes

### Product Information



**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</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 Combinded (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 Combinded (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 Combinded (dual) spore strips for monitoring steam, dry heat or ethylene oxide sterilization processes	7386	30 envelopes with 5 spore strips each
<b>Also available:</b> <b>BAG-BioStrip</b> G.stearothermophilus 10 <sup>3</sup> – 10 <sup>7</sup> <b>BAG-BioStrip</b> B.atrophaeus 10 <sup>4</sup> - 10 <sup>8</sup> <b>BAG-BioStrip</b> Bacillus pumilus 10 <sup>4</sup> - 10 <sup>8</sup> <b>SporeDiscs HPV</b> (stainless steel discs for H <sub>2</sub> O <sub>2</sub> sterilization) <b>Spore Suspensions</b>	on request	100 each

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:
  - G. stearothermophilus** – STEAM: at 55 – 60°C
  - B. atrophaeus** – EO / DRY: at 30 – 35°C
  - B. pumilus** – IRRAD: at 30 – 35°C
3. Check tubes every day during incubation. Final evaluation after 7 days:
  - Turbidity** = growth = **NOT sterile**
  - No turbidity** = no growth = **sterile**Control strip has to show growth.
4. Documentation of all results. Sterilize all bacteria cultures showing growth.

**Storage:** Dry at room temperature (10 – 38°C)

**Expiry:** 2 years from date of manufacture

05/08

# 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

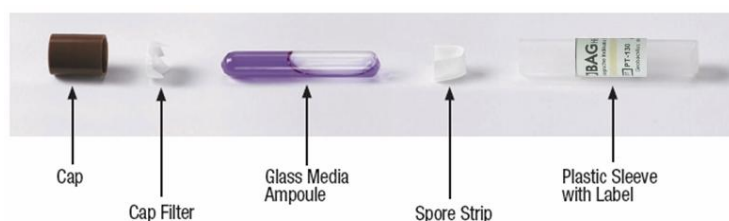
BAG-BioCheck are composed of a polypropylene vial containing a bacterial spore strip and an ampoule containing growth media. BAG-BioCheck STEAM contains spores from *Geobacillus stearothermophilus*, BAG-BioCheck EO contains spores from *Bacillus atrophaeus*.



	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>NEW 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)	7490	30

24-hour readout for BAG-BioCheck **STEAM** and H<sub>2</sub>O<sub>2</sub>

48-hour readout for BAG-BioCheck **EO**



## 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 strip 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 strips 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 – 35°C	for 48 hours
8. Begin monitoring after approx. 12 hours.

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

Final negative results (no growth) can be made after 24 hours of incubation for STEAM / H<sub>2</sub>O<sub>2</sub> 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<sub>STEAM</sub> / D<sub>EO</sub> / D<sub>H<sub>2</sub>O<sub>2</sub></sub>), Z-value
- Lot no., manufacturing date, expiry date

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

**Storage:** Dry at room temperature (10 – 38°C)  
**Expiry:** 2 years from date of manufacture

04/09

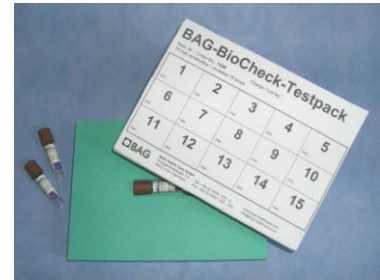
# BAG-BioCheck-Kit

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

Order-Nr.: 7499

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  
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 ( $D_{\text{STEAM}}$ ), 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 (10 – 38°C)  
**Expiry:** 2 years from date of manufacture

02/09

# Incubator

## Dry bath incubator for BAG-BioCheck Ampoules

**Order-No.:** 74751 (35°C)  
74752 (57°C)

**Packaging unit:** 1



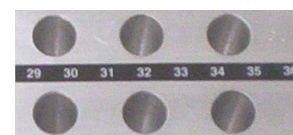
### Product features

Dry bath incubator with removable 14-well rack for incubating BAG-BioCheck STEAM with spores from *Geobacillus stearothermophilus* at 55-60°C or BAG-BioCheck EO with spores from *Bacillus atrophaeus* at 30-35°C. Temperature is preset, no adjustment necessary.

Additional racks for BAG-BioCheck (14-well), BAG-ProSpore 1 ml (18-well) or BAG ProSpore 4 ml (12-well) are available. Incubators for 120V voltage are also available.

### Instructions for Use

1. Connect incubator to any standard 220V grounded outlet. Signal lamps will light.
2. Heating: Incubation temperature of 57°C or 35°C is set automatically, red warming lamp indicates heating. Current temperature is indicated by illumination of the background of the temperature indicator strip.
3. Incubate BAG-BioCheck STEAM, Order-No. 7482 or 7483 at 55-60°C;  
Incubate BAG-BioCheck EO, Order-No. 7484 at 30-35°C.
4. Incubation time is 24 / 48 hours (see product information for BAG-BioCheck).
5. After use switch off incubator (disconnect from outlet) and allow rack to cool down



02/09

# BAG-ProSpore

## Control and Validation of Steam Sterilization Processes



### Specifications

BAG-ProSpore is designed for control and validation of steam sterilization processes at 121°C with liquids. BAG-ProSpore 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. BAG-ProSpore has received 510K notification for sale to healthcare facilities with a 48 hour incubation period. 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. 5 cm, diameter 1 cm (1.5 cm for the 4ml-ampoule). Filling size is 1 ml and 4 ml respectively. The ampoule may be placed in small vessels or automated ampoule filling systems.

Available populations:  $1 \times 10^4$ ,  $1 \times 10^5$  or  $1 \times 10^6$ .

### Product Survey

	Order-No.	Packaging unit
<b>BAG-ProSpore - 1 ml</b> <i>Geobacillus stearothermophilus</i> $10^4$	7536	50 ampoules
<b>BAG-ProSpore - 1 ml</b> <i>Geobacillus stearothermophilus</i> $10^5$	7534	50 ampoules
<b>BAG-ProSpore - 1 ml</b> <i>Geobacillus stearothermophilus</i> $10^6$	7535	50 ampoules
<b>BAG-ProSpore/4 - 4 ml</b> <i>Geobacillus stearothermophilus</i> $10^4$	75364	50 ampoules
<b>BAG-ProSpore/4 - 4 ml</b> <i>Geobacillus stearothermophilus</i> $10^5$	75344	50 ampoules
<b>BAG-ProSpore/4 - 4 ml</b> <i>Geobacillus stearothermophilus</i> $10^6$	75354	50 ampoules

**Storage:** 2 – 8°C

**Expiry:** 18 months from manufacture

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

07/07

# 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. BAG-ProAMP has received 510K notification for sale to healthcare facilities with a 48 hour incubation period. 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 may be placed in small vessels or automated ampoule filling systems. Available populations:  $1 \times 10^5$  or  $1 \times 10^6$ .

### Product Survey

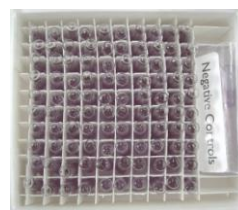
	Order-No.	Packaging unit
<b>BAG-ProAMP</b> <i>Geobacillus stearothermophilus</i> $10^5$	7487	100 ampoules
<b>BAG-ProAMP</b> <i>Geobacillus stearothermophilus</i> $10^6$	7488	100 ampoules

**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



05/08

# Spore Suspensions

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

Product Survey	Order-No.	ATCC
G. stearothermophilus 10 <sup>5</sup>	7363	7953
G. stearothermophilus 10 <sup>6</sup>	7364	"
G. stearothermophilus 10 <sup>7</sup>	7352	"
B. atrophaeus 10 <sup>5</sup>	7365	9372
B. atrophaeus 10 <sup>6</sup>	7366	"
B. atrophaeus 10 <sup>7</sup>	7369	"
B. atrophaeus 10 <sup>8</sup>	7361	"
B. pumilus 10 <sup>5</sup>	7381	27142
B. pumilus 10 <sup>6</sup>	7382	"
B. pumilus 10 <sup>7</sup>	7383	"
B. pumilus 10 <sup>8</sup>	7362	"

## Additional populations and species on request

G. stearothermophilus	ATCC 12980; ATCC 10149
B. thuringiensis	ATCC 29730
B. subtilis "6633"	ATCC 6633
B. subtilis "5230"	ATCC 35021 / 5230
B. megaterium	ATCC 8245
B. cereus	ATCC 11778
B. coagulans	ATCC 51232



**Storage:** 2 – 8°C  
**Expiry:** 12 months from manufacture  
**Delivery time:** approx. 4 weeks

05/08