SBI-100 Qty: 100 Vials

Organism: *Geobacillus stearothermophilus*
ATCC No. 7953

Self-Contained BI for **Steam** Sterilization

Self-contained biological indicators are inoculated with viable Geobacillus stearothermophilus bacterial spores and are intended for monitoring the efficacy of saturated steam sterilization processes operating at 121°C and 132°C gravity displacement, 132°C flash gravity displacement and 121°C – 134°C prevacuum cycles. Self-contained biological indicators are also appropriate for use in monitoring the efficacy of saturated steam prevacuum sterilization processes operating at 135°C for 3 minutes exposure time.

Due to varying sterilizer come-up times, it is recommended to extend the cycle time from 3 minutes to 4 minutes in order to achieve consistent kill when testing the gravity steam process at 270°F (132°C) in Flash Cycles.

Biological indicators (BIs) meet quality specifications and suggested performance parameters published in the current USP and AAMI/ISO 11138 for steam gravity and dynamic-air-removal sterilization processes. Culture media is tryptic soy broth validated for growth promotion capabilities per USP guidelines. Media growth promotion has been validated for extended steam cycles operating at 132°C for 20 minutes exposure time.

Monitoring Frequency

Per AAMI standards, Steam sterilizers should be biologically tested at least weekly, preferably daily and every load that contains an implant.

Instructions for Use

1. Record the sterilizer number, load number and processing date on the BI label.
2. Place one or more BIs inside an instrument tray, rigid container, peel pouch or process challenge device, e.g. AAMI challenge pack, whichever is representative of the load being processed.
3. Test the most challenging area in the sterilizer as indicated in the sterilizer's instruction manual (i.e. the bottom shelf near the door, over the drain of a large sterilizer or in the middle shelf of a small sterilizer).
4. Process the load according to the sterilizer manufacturer's instructions.
5. Remove the BI and confirm the chemical indicator printed on the label has turned **brown.**
   Caution: After processing, the BI is hot and under pressure. Always allow to cool for ten (10) minutes before crushing. Failure to do so could cause the glass ampule inside the BI vial to burst which may result in injury. For this reason, safety glasses should be worn when handling and crushing a processed BI.

Activation and Incubation

1. Activate the processed BI within 8 hours after processing by gently crushing the inner glass media tube using a vial crusher.
2. Incubate at 55 – 60°C for **24 hours** checking for spore growth (visual color change from purple to yellow) at regular intervals (i.e. 3, 5 and 8 hours). Growth of surviving spores has been documented in as little as 2 1/2 hours.

Test Results

1. Record negative (no growth) results after full incubation in a Sterilizer Record Notebook. No color change in the purple media indicates proper sterilization.
2. Any positive (growth indicated by purple to yellow color change) result, should be reported immediately to a Supervisor and the sterilizer taken out of service until resolved.
3. The stability of positive growth as indicated by a yellow color change has been tested up to 48 hours.

Use of Controls

1. As a control, an unprocessed BI (from the same lot) should be gently crushed using a vial crusher and incubated each day the sterilizer is tested.

CERTIFICATION

Lot No. 9034
Exp. Date: 08/2025

Disposal: Autoclave at 121°C for 30 minutes or longer.

Purity: No evidence of contamination using standard plate count techniques.

Population[1]: 2.7 x 10^5 | **Steam z value:** 15.3°C

Performance Characteristics:

PROCESS	TEMPERATURE	D-VALUE	SURVIVES (+)[4]	KILLED (-)[4]
Steam (Saturated)	250°F (121.1 ± 0.5°C)	1.9 [2]	6.5 minutes	17.9 minutes
Steam (Saturated)	270°F (132.2 ± 0.5°C)	0.36 [3]	1.24 minutes	3.40 minutes
Steam (Saturated)	273.2°F (134 ± 0.5°C)	0.27 [3]	0.93 minutes	2.55 minutes
Steam (Saturated)	275°F (135 ± 0.5°C)	0.23 [3]	0.79 minutes	2.17 minutes

[1]After a preliminary heat treatment of 95-100°C for 15 min.
[2]Determined at the time of manufacture using fraction negative procedures (e.g. Stumbo Murphy Cochran) in an AAMI/ISO compliant test vessel. The D-value is reproducible only under the exact conditions under which it was determined. Users may not necessarily obtain the same results. The manufacturers D-value cannot be duplicated in a healthcare facility.
[3]Empirically derived data.
[4]Calculated using USP, AAMI and ISO survival and kill time formulas.

Storage: Store at controlled room temperature as defined by USP. Reference the USP for the complete definition.
Protect from light, chemicals and sterilants (e.g. Ethylene oxide), excessive heat and moisture. Optimal humidity range for long term storage is 20 to 70%. Do not desiccate.

INFORMER MED sp. z o.o. • ul. Winogrady 118, 61-626 Poznań • Poland, tel. +48 61 664 38 10 • www.informermed.eu

Rev 01/2018 PN 7224

SBI-100 Qty: 100 Vials

Organism: *Geobacillus stearothermophilus*
ATCC No. 7953

Self-Contained BI pro parní sterilizaci

SCBI jsou sestaveny s bakteriálním osídlením Geobacillus stearothermophilus a jsou určeny k monitorování účinnosti sterilizačních procesů ve vlhkém teple/páře při teplotách 121°C - 132°C, 132°C a 121%C - 134°C, 135°C, podle typu sterilizátoru.

Návod k použití:

1. Zaznamenejte údaje o sterilizátoru, vsázce a datu na etiketu na ampulce.
2. Jeden nebo více ampulek (dle národní legislativy) rozmístěte do instrumentačních sít, kontejnerů nebo je zabalte stejně, jako jsou zabaleny nástroje ve vsázce. Další umístěte do zátěžového tělíska.
3. Nezapomeňte přitom na místa, která výrobce označil jako nejhůře dostupná (například blízko dveří nebo blízko odtoku).
4. Spusťte sterilizační cyklus jako obvykle.
5. Po ukončení cyklu vyjměte ampulky, zkontrolujte procesový test, jeho barva se změní na tmavě hnědou.

POZOR: po ukončení cyklu jsou ampulky pod tlakem a horké. Nechejte je vychladnout nejméně 10 min.

Pokud postup nedodržíte, mohl by být výsledek negativně ovlivněn.

Aktivace a inkubace:

1. Co nejdříve ampulku aktivujte rozmáčknutím vnitřní skleněné nádobky s kultivační půdou přes vnější plastovou ampulku. Použijte speciální drtič.
2. Inkubujte při teplotě 55°C - 60 °C po dobu 24 hodin, průběžně výsledek kontrolujte v pravidelných intervalech 3,5 - 8 hod.) Růst spor musí být zazanemanáván.

Výsledek:

1. Negativní výsledek znamená, že se původní fialová barva v ampulce ani po 24 hodinách nezmění. Sterilizace proběhla efektivně a vsázka může být považována za sterilní
2. Jakákoliv změna barvy z fialové na žlutou musí být ihned zaznamenána a výsledek konzultován s odpověd-ným pracovníkem. Sterilizátor musí být následně důkladně prověřen přivolaným technikem.
3. Za pozitivní výsledek považujte i zakalení kultivační půdy, konečný výsledek získáte po 48-hodinové kultivaci.

Kontrolní test 1. Pro kontrolu životaschopnosti použité kultury inkubujte společně s vysterilizovanými ampulkami i jednu, která procesem sterilizace neprošla. Před inkubací ampulku opatrně aktivujte rozmáčknutím.

Výsledek kontrolujte a pokud se barva po inkubaci nezmění, je třeba příslušnou várku biologických indikátorů ověřit, aby nebyla kontrola falesně negativní.

CERTIFICATION

Lot No. 9034
Exp. Date: 08/2025

Disposal: Autoclave at 121°C for 30 minutes or longer.

Purity: No evidence of contamination using standard plate count techniques.

Population[1]: 2.7 x 10^5 | **Steam z value:** 15.3°C

Performance Characteristics:

PROCESS	TEMPERATURE	D-VALUE	SURVIVES (+)[4]	KILLED (-)[4]
Steam (Saturated)	250°F (121.1 ± 0.5°C)	1.9 [2]	6.5 minutes	17.9 minutes
Steam (Saturated)	270°F (132.2 ± 0.5°C)	0.36 [3]	1.24 minutes	3.40 minutes
Steam (Saturated)	273.2°F (134 ± 0.5°C)	0.27 [3]	0.93 minutes	2.55 minutes
Steam (Saturated)	275°F (135 ± 0.5°C)	0.23 [3]	0.79 minutes	2.17 minutes

[1]After a preliminary heat treatment of 95-100°C for 15 min.
[2]Determined at the time of manufacture using fraction negative procedures (e.g. Stumbo Murphy Cochran) in an AAMI/ISO compliant test vessel. The D-value is reproducible only under the exact conditions under which it was determined. Users may not necessarily obtain the same results. The manufacturers D-value cannot be duplicated in a healthcare facility.
[3]Empirically derived data.
[4]Calculated using USP, AAMI and ISO survival and kill time formulas.

Storage: Store at controlled room temperature as defined by USP. Reference the USP for the complete definition.
Protect from light, chemicals and sterilants (e.g. Ethylene oxide), excessive heat and moisture. Optimal humidity range for long term storage is 20 to 70%. Do not desiccate.

INFORMER MED sp. z o.o. • ul. Winogrady 118, 61-626 Poznań • Poland, tel. +48 61 664 38 10 • www.informermed.eu

Rev 01/2018 PN 7224