Steam Control GST E6 SS (BA coupons)

Biological indicators of steam sterilization processes with spores of *Geobacillus stearothermophilus* (ATCC 7953) inoculated on stainless steel coupons.

DESCRIPTION

Steam Control GST E6 SS are used for regular control of steam sterilization cycles and validation of sterilizers. These biological indicators use a stainless steel BA finish support (coupon) previously inoculated with *Geobacillus stearothermophilus* (ATCC 7953) spores and enclosed in a steam permeable envelope.

The coupons are produced under strictly controlled conditions in order to satisfy the requirements indicated in the current editions of USP and EP and in accordance with ISO 11138, EN 866 and ISO 17665:2024. standards.

COMPOSITION

The coupons are inoculated with spores of *Geobacillus stearothermophilus* (ATCC 7953) in a predefined concentration: E6 = 1-5 x 10^6 CFU/coupon.

A certificate of analysis is included in the package providing the following data:

- Lot number
- Expiration date
- Species
- Certified population
- D-value (121°C)
- Z-value
- Survival time
- Kill time
- F_{BIO} value

PRINCIPLE

The spore containing coupons are exposed to the sterilization cycle and then incubated in a culture medium to promote germination (either Liofilchem® Steri Test Medium or Tryptic Soy Broth can be used for spores germination).
Sterilization is achieved if no spores survive: there will be any growth after incubation with no change of the medium. If the sterilization process is not performed correctly, spores will grow during the incubation period and cause turbidity of the medium or even a colour change if Steri Test Medium is used.

TECHNIQUE

1. Allow the coupons to reach room temperature before use. Coupons are exposed to steam, during sterilization, inside their original envelope or aseptically removed from their envelope and hanged utilizing the special hole.
2. Put the coupons, with or without the envelopes, inside the autoclave or plant steam treated with SIP, in the points considered the most difficult to sterilize by steam.
3. Follow the operative instructions indicated by the sterilizer manufacturer for the sterilization process. **NOTE**: when coupons are moved without envelope, it is essential to operate in asepsis to avoid accidental contaminations that could invalidate the results.
4. At the end of sterilization cycle, remove the coupons and deliver them with the unexposed control (positive control) from the same batch to the laboratory for culturing. In optimal conditions all culture procedures have to be performed under a laminar flow cabinet following aseptic methods.
5. Cut the envelope with a cold sterile scissors and by means of a cold sterile tweezers carefully transfer the coupon to a tube of Steri Test Medium or Tryptic Soy Broth (TSB). Gently shake the tube to ensure the coupon is completely dipped in the medium.
6. Incubate the tubes containing the coupons at 55-60°C (131-140°F) for at least 7 days.

INTERPRETATION OF RESULTS

Geobacillus stearothermophilus (ATCC 7953) spores are killed off if the sterilization cycle is efficient: no changes in the medium after the incubation period. If the sterilization cycle is not performed correctly, spores partially survive: the Steri Test Medium changes from violet/clear to yellow/turbid after incubation; in TSB spores survival is indicated by turbidity only. The medium inoculated with the unexposed coupon (positive control) should demonstrate microbial growth after incubation. If not, the test must be repeated after investigating the causes of such result.

EVALUATION TABLE		
MEDIUM CHARACTERISTICS	**SPORE**	**STERILIZATION**
Violet (Steri Test Medium) / Clear	Killed off	Successful
Yellow (Steri Test Medium) / Turbid	Vital	Unsuccessful

STORAGE

Store at 2-8°C: in these conditions the product maintains its validity until the expiry date indicated on the label. NOTE: The product may be held at room temperature (25°C) for up to 72 hours prior to use without any impact to the performance.

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is designed for professional use only and must be used by properly trained operators.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to the national and local regulations in force.

REFERENCES

1. United States Pharmacopoeia current edition.
2. Deutsches Arzneibuch current edition.
3. European Pharmacopoeia current edition.
4. ISO 11138 and EN 866 current edition.
5. ISO 17665:2024

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PRODUCT SPECIFICATIONS

NAME
Steam Control GST E6 SS (BA coupons)

PRESENTATION
Coupons inoculated with a predefined concentration of spores: *G. stearothermophilus* ATCC 7953

STORAGE
2-8°C

PACKAGING

Ref.	Content	Packaging
91091	50 coupons	Coupons individually packed

TECHNICAL PROPERTIES
Primary packaging: Steam-permeable envelope
Spore carrier: AISI 316L stainless steel BA finish coupon (approximately 20 x 7 mm)
Species: *Geobacillus stearothermophilus* ATCC 7953
Mean Population Recovery: $1x10^6$-$5x10^6$ spores per coupon
Purity: Bacterial contaminates less than 1 percent of the labeled population; this is the detection limit using the pour plate method with an aliquot that yields at least 100 colony forming units (CFU)
Resistance data: D-value, Z-value, F_{BIO} value, survival time and kill time

USE
Steam Control GST E6 SS (BA coupons) are biological indicators used for regular control of steam sterilization cycles and validation of sterilizers

TECHNIQUE
Refer to technical sheet of the product

APPEARANCE
Coupons are grey in colour

SHELFLIFE
1 year

QUALITY CONTROL
1. Control of general characteristics, label and print
2. Purity: <1% contamination. No moulds
3. Heat shocked population: 1-5 x 10^6 Spores/coupons
4. $D_{121°C}$: 1.5-4.5 minutes
5. Z-value: ≥ 6°C
6. F_{BIO} value: ≥ 12 minutes

TABLE OF SYMBOLS

Manufacturer	Contains sufficient for <n> tests	Temperature limitation
REF Catalogue number	Fragile, handle with care	Caution, consult accompanying documents
Use by	LOT Batch code	Do not reuse

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