

Bio-Indicator SIMICON ST/DA for steam sterilization

Product information

Field of application: SIMICON ST/DA is a biological indicator, which is designed for the validation and routine monitoring of steam sterilization processes.

Features: SIMICON ST/DA indicators contain populations of *Geobacillus stearothermophilus*.

Conformity: Biological indicator in compliance with ISO 11138-3 for steam sterilization at 121 °C / 134 °C.

Specification:

- Organism: Geobacillus stearothermophilus*
- Mean population (cfu): $\geq 10^5$*
- Carrier material: filter paper*
- Primary packaging: paper / foil*
- Shelf life: 24 months from the date of manufacturing*

- $D_{121\text{ °C}}$ -value: > 1,5 min*
- z-value: > 6 °C*
- Survival time: $[D\text{-value} \times (\log\text{ cfu} - 2)]$*
- Kill time: $[D\text{-value} \times (\log\text{ cfu} + 4)]$*

Storage: At + 18 °C to + 25 °C and rel. humidity from 35 % to 70 %. Protect from light and sterilants.

Disposal: After sterilization

Packing unit: 50, 100, 500 pcs

Order no.: BI-ST-1001-E

Example of use:

1. To monitor steam sterilization processes the biological indicators (strip with *Geobac. stearothermophilus*) need to be placed in the most difficult to sterilize goods (e.g.: pack of linen towels, container) or in standardized process challenge devices (PCD) in compliance with ISO 17665. Each program in use must be controlled separately.
2. For tests using a PCD, take spore-strips out of the primary packaging and place them into the PCDs. Wrap the PCDs in the usual sterilization packaging. Number the wrapped PCDs or biological indicators. Distribute biological indicators or PCDs in locations representative of a typical load. Use one biological indicator as a reference indicator (growth control). It must not be sterilized.
3. Place PCDs or biological indicators in the most difficult to sterilize area of the chamber. Start the program.
WHO-recommendation: 121 °C - 20 min or 134 °C - 5 min
4. After sterilization, aseptically transfer the processed spore strips and the reference indicator into 7 - 10 ml sterile TSB-Broth.
5. Incubate the spore strips for 7 days at 56 °C \pm 2 K.
6. Observe all tubes daily for specific and typical growth of the test strain.
7. Record results. Results are valid only if the reference indicator shows growth.
8. If typical growth of the test strain is observed, the test procedure needs to be repeated.
9. If typical growth is observed again, the sterilizer must be examined for malfunction.