

# Biological indicator SIMICON FA for formaldehyde gas sterilization

## Product information

**Field of application:** SIMICON FA is a biological indicator, which is designed for the validation and the routine monitoring of low temperature steam formaldehyde sterilization processes, according to DIN EN ISO 14180.

**Features:** SIMICON FA indicators contain populations of *Geobacillus stearothermophilus*.

**Conformity:** Biological indicator SIMICON FA in compliance with the requirements of ISO 11138-5.

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

*Resistance characteristics 1 mol FAI:*  
*D-value (60 °C): > 6 min*  
*Survival time: [D-value x (log of bacterial count - 2)]*  
*Kill time: [D-value x (log of bacterial count + 4)]*

**Storage:** Store at + 4 °C to + 25 °C and a relative humidity of 35 % to 70 %. Protect from solar radiation and sterilants.

**Disposal:** After use dispose with domestic waste

**Packing unit:** 50, 100, 500 pcs.

**Order No:** BI-FA-4401-E

### Example of use:

1. For the monitoring of the performance of formaldehyde gas sterilization processes put the biological indicators SIMICON FA in the standardized process challenge device (PCD), according to DIN EN 867-5.
2. For the monitoring with PCD, take the indicator strip out of the primary packaging and put it into the PCD. Put the PCD in a common sterilization pouch, seal it, number it and place it at a representative spot of a usual sterilization load. One indicator is meant to be a growth and transport control. Do not sterilize the control indicator.
3. Start the sterilization program.
4. When the program is finished transfer the indicator strips, which are in the PCD and the growth control indicator in tubes with 7 - 10 ml TSB-broth. It is important to work aseptically when transferring the indicator strips.
5. Incubate the spore strips for 7 days at a temperature of 56 °C  $\pm$  2 K.
6. Daily check all tubes for growth and especially check for specific growth of the test organism.
7. Note down the results. The results are only valid if the growth control shows typical growth.