

Biological indicator FA for Formaldehyde gas sterilization

Product information

Field of application:	FA is a biological indicator designed for the validation and routine monitoring of low temperature Formaldehyde gas sterilization processes, according to DIN EN ISO 14180.
Features:	FA indicators contain populations of <i>Geobacillus stearothermophilus</i> .
Conformity:	Biological indicator FA in compliance with the requirements of ISO 11138-5.
Specifications:	<p><i>Organism: Geobacillus stearothermophilus</i> <i>Mean population: $\geq 10^5$</i> <i>Carrier material: filter paper</i> <i>Primary packaging: paper/foil</i> <i>Shelf life: 24 months from the date of manufacturing</i></p> <p><i>Resistance characteristics 1 mol FA/l:</i> <i>D-value (60 °C): > 6 min</i> <i>Survival time: [D-value x (log of bacterial count - 2)]</i> <i>Kill time: [D-value x (log of bacterial count + 4)]</i></p>
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 of with domestic waste.
Packing unit:	50, 100 pcs.
Order No:	BI-FA-4401-50 BI-FA-4401-100

Example of use:

1. For monitoring the performance of Formaldehyde gas sterilization processes put the biological indicator FA in a standardized process challenge device (PCD), according to DIN EN 867-5.
2. Take the indicator strip out of the primary packaging and put it into a PCD. Place the PCD in a common sterilization pouch, seal it and number it.
Position it in a representative spot of a usual sterilization load. Use one indicator for verifying the growth performance after transport and shipping. Do not sterilize this control indicator!
3. Start the sterilization program.
4. When the program is finished, transfer the indicator strip from the PCD and the growth control indicator into tubes with 7 - 10 ml TSB-broth.
It is important to work aseptically when transferring the indicator strip.
5. Incubate the spore strip for 7 days at a temperature of 56 °C ± 2 °C.
6. Daily check all tubes for growth, especially for growth of the test organism.
7. Note down the results. The results are only valid if the growth control shows typical growth.