

BAG-ProSpore

Monitoring and Validation of Sterilization processes

Product description

BAG-ProSpore is a closed unit which is used to monitor and/or validate steam Sterilization processes (121°C) when sterilizing liquids. Handling is simple and does not require special laboratory equipment for evaluation. The ampoules contain spores of *Geobacillus stearothermophilus* which are aggraded in a special culture medium.

The suspensions, consisting of spores and culture medium, are contained in thin-walled glass ampoules made from a material which is used in the pharmaceutical industry.

The ampoules are approx. 5 cm long and available with a fill volume of 1 ml spore Solution. Their diameter is approx. 1 cm respectively. The small size of the BAG-ProSpore permits placement in small Containers with low amounts of liquids. The ampoules can also be used in production lanes and filling machines. Spore populations of $> 1 \times 10^4$, $> 1 \times 10^5$ and $> 1 \times 10^6$ are available in the existing concept.

Use

BAG-ProSpore is stored in the refrigerator at 2 - 8°C until used. After removing the required number of ampoules from the refrigerator, they should reach room temperature before use. ProSpore ampoules with *Geobacillus stearothermophilus* spores show a blue-violet colour prior to use, due to the pH indicator which is contained in the culture medium. Lengthened Sterilization cycles at 121°C may alter the ingredients of the culture medium and therefore also the blue-violet colour of BAG-ProSpore. In this event, it may become more difficult to assess the ampoules in terms of killing or growth of spores after incubation. BAG-ProSpore are inserted into the Containers being sterilized prior to autoclaving (if applicable, fasten to a thread for liquid quantities > 20 ml) or sterilized side by side with the product. 121°C are specified as the temperature for the Sterilization cycle. Ensure a comparable warming behavior between the product being sterilized and BAG-ProSpore. Differences may occur due to the viscosity of different products.

The number of bio-indicators to be used depends on the capacity of the Sterilization Chamber. The Bio-indicators are generally arrayed on various levels from top to bottom and front to back. Bio-indicators are also placed at the centre of the load. In autoclaves > 250 l, it is recommended to distribute at least 10 Bio-indicators in the load.

Incubation conditions and evaluation

The incubation temperature is 55 - 60°C. Since BAG-ProSpore is a closed system, incubation can take place in a water bath or an incubator commonly used for bacteriology. An unsterilized BAG-ProSpore ampoule is incubated together with the sterilized BAG-

ProSpore ampoules as a positive growth control. The appropriate incubation time is 48 hours. An initial Visual check is made with BAG-ProSpore before placing it in the incubator; another Visual check can be done after 18 hours.

When incubating in a Container, incubation times vary due to the differing sizes and liquid amounts as well as the initial temperature; this must be taken into account accordingly. The culture medium changes colour from blue-violet to yellow if there is spore growth. A yellow colouration means "test positive"; that is, not sterile. In excessively long Sterilization cycles - e.g. Sterilization overnight - the optical indicator (colour blue-violet) may pale, so that the medium appears light grey or brownish. This discolouration of the indicator does not influence the growth behavior of spores which were not killed. When there is growth of *Geobacillus stearothermophilus*, sterilized ampoules discolour to yellow, similarly to the positive growth control.

Certificates stating the spore population, D parameter, Z parameter and F_0 parameter or Killing Time (time at which all spores are killed) are included with every batch.

	Order No.	Sales
	unit	
BAG-ProSpore - 1 ml* <i>Geobacillus stearothermophilus</i> 10 ⁴	7536	100 Ampullen
BAG-ProSpore - 1 ml inkl. Neg-Kontrollen <i>Geobacillus stearothermophilus</i> 10 ⁵	7534	50 Ampullen
BAG-ProSpore - 1 ml inkl. Neg-Kontrollen <i>Geobacillus stearothermophilus</i> 10 ⁶	7535	50 Ampullen

Storage: In the refrigerator at 2 - 8°C

Shelf life: 18 months from the date of manufacture

Disposal: Autoclave BAG-ProSpore with yellow colouration (positive) prior to disposal

*not stocked - delivery time approx. 4 weeks

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