

Biological indicator SIMICON EO for ethylene oxide gas sterilization

Product information

Field of application: SIMICON EO is a biological indicator, which is designed for the validation and the routine monitoring of ethylene oxide gas sterilization processes.

Features: SIMICON EO indicators contain populations of *Bacillus atrophaeus*.

Conformity: Biological indicator SIMICON EO in compliance with the requirements of ISO 11138-2.

Specifications:
*Organism: **Bacillus atrophaeus***
Mean population (CFU): $\geq 10^6$
*Carrier material: **filter paper***
*Primary packaging: **paper / foil***
*Shelf life: **24 months from the date of manufacturing***

Resistance characteristics 600 mg EO/l:
D-value (54 °C): $\geq 2,0$ min
Survival time: $[D\text{-value} \times (\log \text{ of bacterial count} - 2)]$
Kill time: $[D\text{-value} \times (\log \text{ of bacterial count} + 4)]$

Storage: Store at a temperature between + 18 °C and + 25 °C and a relative humidity between 35 % and 70 %. Protect from solar radiation and sterilants.

Disposal: After use, dispose with domestic waste

Packing unit: 50, 100, 500 pcs.

Order No:
50 Pieces: BI-EO-3101-50
100 Pieces: BI-EO-3101-100
500 Pieces: BI-EO-3101-500

Example of use:

1. For the monitoring of the performance of ethylene oxide gas sterilization processes place the biological indicator (strip with *Bac. atrophaeus*) either into a most difficult to sterilize medical device or into a process challenge device (PCD), according to DIN EN 1422, which represents a hollowware.
2. Each sterilization program must be tested and assessed separately.
3. For the monitoring with a PCD, take the indicator strip out of the primary packaging and place 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 typical sterilization load. One indicator is meant to be a growth and transport control. Do not sterilize the control indicator.
4. Arrange the indicators in the whole sterilization load and start the sterilization process.
(e.g.: 54 °C - 120 min with 600 EO/l)
5. When the program is finished transfer the sterilized indicator strips and the growth control indicator into tubes with 7 - 10 ml TSB-broth. It is important to work aseptically when transferring the indicator strips.
6. Incubate the spore strips for 7 days at a temperature of 33 °C \pm 3 K.
7. Daily check all tubes for growth and especially for growth of the test organism.
8. Note down the results. The results are only valid if the growth control shows typical growth.