

# DIRECTIONS FOR USE

for all GKE Steri-Record® Stearo-Ampoules

**STEAM**

Art.-No.*	Product Code	Population per ampoule	Content [ml]	Diameter/ Height [mm]	Quantity/Box	Result of the sterilization process	
						sterile	unsterile
						Colour change of ampoule after sterilization and incubation	
225-550	B-S-AMP-10-5	10 <sup>5</sup> CFU	1.5	11 / 45	50	Purple (no colour change)	Yellow-green
225-650	B-S-AMP-10-6	10 <sup>6</sup> CFU					
235-510	B-S-MAMP-10-5	10 <sup>5</sup> CFU	0.2	5 / 25	100		
235-610	B-S-MAMP-10-6	10 <sup>6</sup> CFU					

(\*) To all article numbers a 3-digit alpha code is added. The additional letter code refers to the language and/or customized version. It is only added on the outside label, the inside of the pack is identical to the article numbers on the above table.

## Application

The GKE Steri-Record® Stearo Ampoules can be used for sterilization monitoring of liquids in glass bottles, solid materials or waste. All thermal processes such as steam sterilization, liquid sterilization, microwaves or mixtures of those, except dry heat sterilization, can be monitored from 110 - 134°C with corresponding sterilization times.

The F<sub>Bio</sub>-value of the ampoule should be adapted to the F<sub>0</sub>-value of the sterilization process.

## Product Description

The two different Stearo-Ampoules (see table) contain liquid growth medium with a pH indicator and different populations of *Geobacillus stearothermophilus* spores. The larger ampoule (1.5 ml) is designed to sink to the bottom in water. The smaller mini ampoules (0.2 ml) float in the water so that approx. 1 mm of the glass dome still looks out of the liquid level which is not relevant because the heat is transferred quickly in the small volume.

After finishing the sterilization process, the glass ampoules are incubated. If not all spores were inactivated during the sterilization process, the germs replicate and produce acids. The resulting drop of the pH value results in a color change of the liquid from purple to yellow-green.

## Performance characteristics

The Stearo-Ampoules are produced according to EN ISO 11138-1 + 3 standards and the current European and United States Pharmacopoeia (EP+USP). Population and D-value are measured and certified for each batch and documented in the enclosed certificate. The continuous quality is guaranteed by the GKE quality management system according to EN ISO 13485.

GKE has optimized its growth medium so that no color change occurs of the growth medium alone, so that "negative controls" are not necessary when GKE Steri-Record® Stearo Ampoules are used (for more details see Technical Information No. 155).

## Incubator

GKE offers a special incubator for the ampoules where it is possible to monitor the colour change without taking out the ampoules. The corresponding aluminium block shall be selected to fit the ampoules in the correct hole diameter. Please see our incubator data sheet or ask for a quotation.

## Handling information

Place at least 2 ampoules depending on the chamber volume of the sterilizer in an area which is considered to be most difficult to heat up: directly in liquid bottles or inside of waste packs partially filled with water, the ampoules can be connected with a string and submerged in water. Afterwards they can be easily removed at the end of the process.

It is recommended to conduct a vitality test with one ampoule of each package to ensure that during transport and storage the vitality of the batch is secured.

Run the sterilization process.

Make sure to apply a support pressure in your process during the cooling phase until the liquid temperature in the ampoule falls below 100°C to prevent explosion.

**Attention:** During too fast decompression inside the sterilizer, the pressure inside the ampoule can exceed 1-2 atmospheres depending on the temperature. This may lead to a burst of the ampoule. Injuries may occur due to glass slivers and hot liquid.

After sterilization incubate the ampoule at 55-60 °C according to EN ISO 11138-1. Check the color of the ampoules daily. If there is no color change from purple to yellow/green after 7 days, all *Geobacillus stearothermophilus* spores were killed and the sterilization process was successful. Based on the GKE performance test results, a reduced incubation period of 48 hours is sufficient for GKE Stearo-Ampoules. The test report is available on request. If the purple pH-indicator has changed to yellow/green growth is detected. In this case the sterilization process was not successful and must be repeated.

Record the results. A documentation template is available for download: <https://www.gke.eu/en/documentation-system-video.html>

## Storage and Disposal

1. Store at 2 - 8°C in the refrigerator.
2. During transport and storage it's very important never to exceed temperatures above 25°C even not for short periods. If temperatures during transport or storage rise above 25 - 30°C, the spores begin to grow and the color of the media changes from purple to yellow green. In this case the ampoules cannot be used anymore and should be disposed.
3. Sterilized vials may be disposed with normal waste.

760-112 EN V10 07/2022